Improving functional outcome and outcome measures in total knee arthroplasty

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THESIS SUMMARY

The aim of this thesis was to assess several innovations aimed at improving functional outcome and functional outcome measures in total knee arthroplasty (TKA). In Part 1, the effects of a fast-track protocol and of changes in bearing design of the prosthesis were evaluated for their effect on functional outcome in TKA patients by performing prospective randomised trials and a comprehensive literature review. In Part 2, a questionnaire designed for more active patients was validated in Dutch, and instrumented gait analyses using trunk-based accelerometry in both clinical and domestic settings were studied for their possible added value in evaluating functional outcome of TKA patients.

PART 1 Improving functional outcome

Fast-track

The introduction in hospitals of fast-track protocols for TKA patients has led to quicker mobilisation and discharge from hospital, whilst reducing pain and use of analgesics and without an increase in complications or readmissions. While patients staying in hospital for less than a week after their operation would be the exception rather than the rule up to the 1990s, fast-track protocols reduced length of stay (LOS) to as short as three to five days in the first decade of this millennium. After this, several new protocols were developed to further reduce LOS and help patients rehabilitate more quickly. Studies evaluating these protocols most often focused on clinical outcome on the medium- to long-term follow-up, with patients having their first follow-up measurements done two to six weeks after the surgery. This feels contradictory to the measures often incorporated in fast-track protocols, which are aimed at reducing pain and facilitating start of rehabilitation in the first hours and days after surgery. Therefore, in Chapter 2, we used a randomised clinical trial (RCT) to assess our own fast-track protocol aimed at discharge two days after TKA surgery, with a special emphasis on the first seven days. We included both clinical and functional outcome parameters. Fifty patients were randomly allocated to two groups, and followed up to five years after their operation. Patients with the fast-track protocol had significantly lower VAS scores for pain directly after and in the first and second hour after the surgery compared to the regular protocol. VAS scores for knee pain at rest were significantly lower in this group throughout the first week. Significantly better scores were also seen on several functional tests in the first week in the fast-track protocol group, but

only a few significant differences were found at 2, 6, 12 weeks and 1, 2, and 5 years after surgery. This indicates that discharge from hospital two days after TKA is achievable in most patients, and that the most important gains of a fast-track protocol are achieved in the first seven days without adverse effects on the long term. Research into fast-track protocols should therefore focus more on this early time period.

Implant design

Several proposed limitations of fixed bearing TKA (FB-TKA) in replicating three dimensional natural knee motion led to the development of mobile bearing TKA (MB-TKA) in the 1980s. Because of the mobility of the poly-ethylene (PE) insert, MB-TKA was hypothesized to have several important advantages over FB-TKA: less wear of the PE insert, less signs of loosening of the prosthesis, a higher survival rate of the prosthesis, and improved clinical outcome. A large number of studies comparing MB-TKA and FB-TKA have been performed, analysing different factors of both types of prostheses. Reviews and meta-analyses on this subject have so far been unable to determine differences between the bearing types. However, these reviews and meta-analyses often used the same limited number of randomised controlled trials. These types of reviews omit important studies with a lower level of evidence, even though these could possibly provide added insight as to which type of bearing would be preferential. We therefore decided to perform a comprehensive literature review of all relevant studies comparing MB-TKA and FB-TKA, as reported in Chapter 3. After including and analysing 127 articles (9 meta-analyses, 3 systematic reviews, 48 RCT's, 44 comparative studies, 10 reviews and 13 studies that examined patients who received bilateral TKA (one MB-TKA and one FB-TKA)), we concluded that there were still only a few articles that reported only minor differences between the two types of bearing. Preference for any bearing type should therefore be decided on other factors, e.g. surgeons' experience with certain implants.

There have been developments in the design of PE inserts of both MB-TKA and FB-TKA prostheses over the last years, with manufacturers and researchers hoping that these new designs would improve outcome in patients. In Chapter 4, we examined four different types of inserts, two mobile bearing (rotating and rotating/translating) and two fixed bearing (normal dish and deep dish). The study included analysis of survival, quality of life (QoL), clinical, and functional outcome parameters. Out of 237 patients included in two different hospitals, 146 completed the whole five-year protocol. No differences were found when looking at functional and QoL parameters. A small significant difference between the two types of

mobile bearing inserts over time was found in Knee Society Scores, which was thought to have no clinical relevance. Survival of MB-TKA was worse compared to FB-TKA (94.7% and 99.2% respectively) after five years. Time to revision for any reason was in favour of FB-TKA. This difference was not found when looking at the specific inserts within groups, although there were indications that the mobile bearing rotating/translating insert performed the least well out of the four inserts studied. We concluded that when using this specific type of TKA prosthesis, choosing FB-TKA over MB-TKA would be advisable.

PART 2 Improving functional outcome measures

Patient Reported Outcome Measures

The most commonly used way of assessing clinical outcome of TKA is by asking patients to complete questionnaires, known as patient reported outcome measures (PROMs). This is an easy method to gather data on patient satisfaction, experienced pain, and QoL. Most of these questionnaires have been used for several decades. However, recent analyses of the clinimetric properties of PROMs showed that there are often ceiling effects when assessing TKA patients. This could be partly due to the recent developments in TKA patient populations, with patients being younger when undergoing TKA and remaining active up to an older age. To allow researchers to discriminate between active and very active patients, the High Activity Arthroplasty Score (HAAS) was developed by Talbot et al., and has already been validated in both English and French. Chapter 5 contains our cross-cultural translation and validation of the HAAS into Dutch. One hundred and eight patients (51 after total hip artroplasty and 57 after TKA) completed the HAAS and several other PROMs. The Dutch version of the HAAS showed a good internal consistency and had significant positive correlations with almost all other PROMs that were used. Importantly, the HAAS did not show a floor or ceiling effect.

Gait analysis

Accelerometers and other inertial measurement units (IMUs) have been successfully used for years in the field of human movement sciences for the analysis of movement tasks, most notably gait, and the effects of several diseases on gait. Currently, these devices are increasingly used in the field of orthopaedic surgery. This is mainly due to the decreased size and improved availability of accelerometers. To determine whether accelerometers could be used in the

analysis of TKA patients, we used trunk-based accelerometers to analyse the quality of 65 patients' gait before and one year after unilateral TKA in Chapter 6. These accelerometers measure acceleration in three dimensions: anterior-posterior (AP), mediolateral (ML), and vertical (VT). Gait measurements consisted of patients walking 50 meters twice during their outpatient clinic visit. Patients were also asked to complete several PROMs together with the gait measurements. A principal axis factor analysis was done on the gait quality parameters, to determine which parameters were most representative for gait quality. Three gait quality factors were identified: 'AP/VT gait quality', with stride regularity-VT as the highest loading parameter with a loading of -0.883; 'ML gait quality', with stride regularity-ML with a factor loading of 0.784; and 'Symmetry', with harmonic ratio-AP as parameter with a loading value of 0.787. All PROMs were grouped in a separate factor from the gait quality parameters, implying that instrumented gait quality parameters measure different aspects of functional outcome than PROMs. Correlations between the values of the gait parameters of each factor and the highest loading parameter in the PROMs factor (the Oxford Knee Score (OKS)) between both time points were calculated, which showed only weak to moderate associations. This confirmed the notion that PROMs and instrumented gait quality measurements evaluate different aspects of functional outcome after TKA, and that therefore accelerometer measurements could be of added value in the functional evaluation of TKA patients.

To expand on the knowledge gathered in Chapter 6, we wanted to see which results accelerometer analysis of TKA patients would yield when performed in the domestic setting rather than in the clinical setting of the outpatient clinic. Therefore, in Chapter 7, 38 patients wore an accelerometer for a whole week both before and three months after their knee was replaced. Again, patients were asked to also complete PROMs at the same time as their gait analysis. At both time points, data were collected on gait quality, gait behavior (in the form of both quantity of gait and walking speed), and on patients' perception of their own walking abilities. Using the same parameters that had the highest loading for the gait quality factors in the previous chapter, no significant improvement in either gait quality parameters or gait behavior after three months were found. Additionally, no significant improvement was seen in dynamic reliability and stability gait quality parameters. In contrast to this, both patients' perceived walking abilities and their PROMs scores did improve significantly. This discrepancy shows that patients' own perception of their walking abilities does not necessarily represent their actual daily function and activities. To measure what level of functional outcome patients are achieving at home, it appears accelerometers

are needed besides PROMs. Measuring functional outcome after TKA with accelerometers in a daily life setting could therefore provide supplementary information for orthopaedic surgeons and other caretakers, and could possibly be used for improving rehabilitation strategies for patients on an individual level.

GENERAL DISCUSSION

PART 1 Improving functional outcome

The challenges in reporting outcome of total knee arthroplasty

In this thesis, I used several different approaches to improve functional outcome and measurement of functional outcome of undergoing total knee arthroplasty (TKA). Assessment of outcome after TKA is challenging and includes different aspects like satisfaction, pain relief, and function. Unfortunately, in literature the definition and use of these terms varies significantly. Especially the term "function" has been used to describe everything from scores on function-related questionnaires, easy tasks as being able to stand up or perform walking tasks (e.g. the Timed Up & Go test), the range of motion (ROM) of flexion and extension of the knee, to sophisticated analyses of gait patterns using complex instrumentation and algorithms. Another complicating factor in trying to improve functional outcome and functional outcome measures after TKA is that a large number of different factors are directly or indirectly associated with outcome. The preoperative expectations of patients, pain relief, and improvement in knee ROM are the factors most often reported in literature as being associated with TKA outcome.[1] However, these factors often influence each other as well. We know for example that more intense pain during flexion and extension before surgery is predictive of higher pain scores after surgery.[2] Also, Jain et al. found that attention for increasing preoperative patient expectations can improve scores on patient related outcome measures (PROMs), but does not increase postoperative satisfaction rates.[3] These findings show that when researching functional outcome after TKA attention should be given to both preoperative and postoperative measurements since both time points could provide opportunities for improvement. Another factor associated with functional outcome after TKA is patient satisfaction. Dissatisfaction after TKA has proven to be an especially persistent and multifactorial problem, which is influenced by other factors besides function as varying as the nation in which people live[4], to the kindness of hospital staff and the quality of hospital food.[5] Improving functional outcome after TKA