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WORD COUNT	2937	TIME SUBMITTED	25-DEC-2023 05:28PM
		PAPER ID	105727287

Name of Journal: *World Journal of Orthopedics*
Manuscript NO: 89465
Manuscript Type: ORIGINAL ARTICLE

Prospective Study

Mid-term survival of the Optimys short stem: a prospective case-series of 500 patients

Bryan Hamans, Sheryl de Waard, Sjoerd Kaarsemaker, Esther R. C. Janssen, Inger N Sierevelt, Gino MMJ Kerkhoffs, Daniël Haverkamp

Abstract

BACKGROUND

In recent years, there has been an increase in the number of total hip arthroplasty procedures in the younger patient population. This active group has higher expectations of their prosthesis in comparison to the older population, and there is a greater physical demand for the prosthesis. Short femoral stems were introduced to retain proximal bone stock and joint biomechanics and became more common to implant in this specific population. Currently, the long-term survival and functional outcomes of various short stems are still being investigated in different clinics.

AIM

The aim of this study was to determine the 5-year survival of the Optimys hip stem

METHODS

This is a prospective multicenter cohort study of 500 patients, conducted in two hospitals in the Netherlands. Patients scheduled for THA between January 2014 and December 2021 were asked to participate. All patients suffered from primary or secondary osteoarthritis, which included coxarthrosis, dysplastic coxarthrosis, rheumatoid arthritis, necrosis of the head of the femur or posttraumatic coxarthrosis.

Patients were excluded in cases of revision surgery, an American Society of Anesthesiologists (ASA) score >3, sepsis or malignant tumors. All patients received the Optimys short stem (Mathys Ltd, Bettlach, Switzerland).The primary outcome measure was survival of the hip stem, with revision as the endpoint. Revision was defined as a surgical procedure in which all or part of the previous implanted prosthesis was replaced. Reasons for revision were described. The secondary outcome measurements included patient-reported outcome measures (PROMs). Kaplan–Meier analysis was used to calculate the 5-year survival rate by censoring patients at death or at the end of the observation period before 5 years. Log-minus-log transformation was performed to calculate the 95% confidence interval (95%CI).mixed model analyses were performed to assess the course of the PROMs during the first two years after surgery. Analyses were modeled separately for the first and second years to calculate the yearly change in PROMs during both follow-up periods with accompanying 95%CIs.

RESULTS

A total of 500 consecutive patients were included in this study, of whom 202 (40%) were male. The mean age was 62.3 years (SD 10.6), and the mean BMI was 26.5 kg/m^2 (SD 4.1).

At a median follow-up of 5.5 years (IQR 4.5: 6.7), 7 patients were deceased with their prosthesis in situ, and 6 revisions were registered. Infection was the reason for revision in 3 patients, and they were initially treated with debridement, antibiotics and implant retention (DAIR). In 1 patient, the DAIR failed, and a two-stage revision was needed. Furthermore, 2 patients were revised due to subsidence of the stem (due to an undersized stem but with good fixation), and 1 patient was revised because of malposition of the stem. This resulted in an overall 5-year survival of 98.8% (95%CI 97.3; 99.5) in the study population (figure 2). If infection was left out as the reason for revision, a stem survival of 99.4% (95%CI 98.1; 99.8) was seen, with no cases of aseptic loosening.

Of the 500 included patients, 471 patients (94%) completed the baseline questionnaires, and 317 patients (63%) completed the 1-year follow-up questionnaires. At the 2-year follow-up, this number had decreased to 233 patients (47%) (table 2). The HOOS and SF-36 scores at all follow-up time points are presented in table 2. Both outcome measures significantly improved across all domains in the first year after the operation ($p<0.03$ for all domains). In the second year after surgery, no significant changes were observed in any domain in comparison to the 1-year follow-up (table 3; figure 3). Although sensitivity analysis showed smaller effects during the first year, the same comparable effect was observed during the 2-year follow-up (Supplemental table 1; supplemental table 2).

At the 2-year follow-up, 210 (42%) had completed the satisfaction score; 132 patients (63%) were very satisfied, 60 patients (29%) were satisfied, 9 patients (4%) were neutral, 7 patients (3%) were unsatisfied, and 2 patients (1%) were very unsatisfied with their hip prosthesis.

CONCLUSION

This study showed a 5-year survival rate of 98.8% for the Optimys stem. Functional outcome and quality of life increased significantly in the first year postoperative with stabilization at two-year.

INTRODUCTION

Osteoarthritis has become more prevalent in recent years due to a growing and aging population.[1] According to the Dutch Arthroplasty Registry (LROI), the yearly number of total hip arthroplasties (THA) has increased from approximately 23.000 to 31.500 between 2010 and 2021.[2] As the total number of THAs has increased over the years, the number of younger patients (<65 years) receiving THA has also increased to 20% of the total.[2] This younger group has a more active lifestyle, which results in a greater demand for hip prostheses. This makes them more susceptible to revision of their total hip, as

there is an increase in wear and/or loosening of the components due to increased forces.[3-7]

In recent decades, a short, curved stem as a femoral component in THA has come on the market and become more popular for implantation in this younger patient population. The philosophy behind short stems is bone-stock preservation in the proximal femur due to more proximal loading and restoration of the patient's specific anatomy.[7-10] With the introduction of new implants, it is important to monitor survival. The Optimys stem, manufactured by Mathys Ltd. Bettlach, is a meta-diaphyseal anchoring short stem and has been on the market since 2010. An earlier RSA study of the Optimys hip stem showed excellent results in the stabilization of the Optimys short stem at two years of follow-up.[11] At this time, to the best of the authors' knowledge, mid-term survival and functional outcomes have been described in only two studies, and the Optimys has an ODEP rating of 7A.[12]

Therefore, the aim of this study was to determine the mid-term survival of the Optimys hip stem in a large, varied patient population and to assess functional outcome and quality of life in this patient population.

MATERIALS AND METHODS

This study was a prospective multicenter cohort study conducted in two centers in the Netherlands, the Xpert clinics Orthopedie Amsterdam and VieCuri Medisch Centrum Venlo. This study was submitted and approved by the medical ethics research committee of Amsterdam UMC, location AMC Amsterdam (NL47055.048.13). Patients scheduled for THA between January 2014 and December 2021 were asked to participate. All patients suffered from primary or secondary osteoarthritis, which included coxarthrosis, dysplastic coxarthrosis, rheumatoid arthritis, necrosis of the head of the femur or posttraumatic coxarthrosis. Patients were excluded in cases of revision surgery, an American Society of Anesthesiologists (ASA) score >3, sepsis or malignant

tumors. After confirmation of participation, all patients gave informed consent before they were included in this study.

Patients returned for a clinical follow-up at 6 wk, 3 months and 1 year post surgery. Hereafter, revision status was verified using patient files and the Dutch National arthroplasty register (LROI). Prior to the operation, at 6 wk, 3 months, 6 months, 1 year, and 2 years postsurgery, patients were asked to fill out a questionnaire.

Surgery

All patients received the Optimys short stem (Mathys Ltd, Bettlach, Switzerland). The Optimys stem is a calcar-guided short stem with a curved design. It is made of Ti6Al4V (titanium-aluminum-vanadium), according to ISO 5832-3, with a titan plasma spray and calcium phosphate coating for better ingrowth of the stem into the bone. The approach during total hip arthroplasty was left to the surgeon's preference (anterior, anterolateral, or straight lateral).

The day of the surgery or one day postoperative, patients were mobilized using two crutches and were allowed full weight bearing.

Outcome measurements

The primary outcome measure was survival of the hip stem, with revision as the endpoint. Revision was defined as a surgical procedure in which all or part of the previous implanted prosthesis was replaced. Reasons for revision were described. The secondary outcome measurements included patient-reported outcome measures (PROMs), which consisted of the Hip Disability and Osteoarthritis Outcomes Score (HOOS), the 36-item Short Form (SF-36), and a 5-point Likert scale for satisfaction (at two years postsurgery).[13-16]

Statistical analysis

IBM SPSS Statistics 26 (IBM Corp., Armonk, NY) was used for the statistical analysis.

In the case of a normal distribution, all continuous outcomes were reported as the means and standard deviation (SD). In the case of a skewed distribution, the outcomes are presented as the median and interquartile range (IQR). Categorial outcomes are presented as frequencies with accompanying percentages. Kaplan– Meier analysis was used to calculate the 5-year survival rate by censoring patients at death or at the end of the observation period before 5 years. Log-minus-log transformation was performed to calculate the 95% confidence interval (95%CI).

Second, mixed model analyses were performed to assess the course of the PROMs during the first two years after surgery. Analyses were modeled separately for the first and second years to calculate the yearly change in PROMs during both follow-up periods with accompanying 95%CIs. A p value of < 0.05 was considered statistically significant for all analyses. As PROM analyses were secondary, no correction for multiple testing was performed. Due to considerable loss of patients filling out PROMs during follow-up, a sensitivity analysis was performed according to a last observation carried forward (LOCF) protocol to avoid overestimation of the effect.

RESULTS

Patient characteristics

A total of 500 consecutive patients were included in this study, of whom 202 (40%) were male. The mean age was 62.3 years (SD 10.6), and the mean BMI was 26.5 kg/m^2 (SD 4.1) (table 1).

Survival

At a median follow-up of 5.5 years (IQR 4.5: 6.7), 7 patients were deceased with their prosthesis in situ, and 6 revisions were registered. Infection was the reason for revision in 3 patients, and they were initially treated with debridement, antibiotics and implant retention (DAIR). In 1 patient, the DAIR failed, and a two-stage revision was needed. Furthermore, 2 patients were revised due to subsidence of the stem (due to an undersized stem but with good fixation), and 1 patient was revised because of

malposition of the stem. This resulted in an overall 5-year survival of 98.8% (95%CI 97.3; 99.5) in the study population (figure 2). If infection was left out as the reason for revision, a stem survival of 99.4% (95%CI 98.1; 99.8) was seen, with no cases of aseptic loosening.

PROMs

Of the 500 included patients, 471 patients (94%) completed the baseline questionnaires, and 317 patients (63%) completed the 1-year follow-up questionnaires. At the 2-year follow-up, this number had decreased to 233 patients (47%) (table 2). The HOOS and SF-36 scores at all follow-up time points are presented in table 2. Both outcome measures significantly improved across all domains in the first year after the operation ($p<0.03$ for all domains). In the second year after surgery, no significant changes were observed in any domain in comparison to the 1-year follow-up (table 3; figure 3). Although sensitivity analysis showed smaller effects during the first year, the same comparable effect was observed during the 2-year follow-up (Supplemental table 1; supplemental table 2).

At the 2-year follow-up, 210 (42%) had completed the satisfaction score; 132 patients (63%) were very satisfied, 60 patients (29%) were satisfied, 9 patients (4%) were neutral, 7 patients (3%) were unsatisfied, and 2 patients (1%) were very unsatisfied with their hip prosthesis.

DISCUSSION

This study, which included 500 patients, showed a high survival rate of 98.8% at the 5-year follow-up mark with 6 revisions. The reasons for overall revision were an infection (0.6%) in 3 cases, subsidence of the stem (0.4%) in 2 cases and malposition of the stem (0.2%) in one case. During the revision surgery in the two cases with subsidence, it was noted that the femoral stem had good fixation in the femur, confirming that the stem was undersized during the primary placement and was now settled with bone growth around the stem for fixation. If infection as a reason for revision was left out, a survival

of 99.4% of the Optimys stem was seen. No aseptic loosening was observed in this cohort.

Furthermore, a significant increase in the PROMs at the first year of follow-up was observed. The HOOS scores increased by 34.8 to 43.3 points, and the SF-36 scores increased by 2.4 to 54.5 points across all subscales. After the first year, no significant changes in either score were observed. Almost all patients (91.4%) were very satisfied or satisfied with their total hip arthroplasty.

The National Institute for Health and Care Excellence (NICE) criteria state that total hip replacements for patients with arthritis have revision rates or projected revision rates of 5% or less after 10 years of follow-up.[17] With a revision rate of almost 99% at the 5-year follow-up, our study results are expected to be in line with these NICE criteria.

In 2022, Kutzner *et al*[18] published a study on the mid-term results of the Optimys hip stem for 782 patients at 6 years of follow-up. It showed a survival rate of 98.4%, with 26 revisions in total (including infection and acetabular cupmalposition), of which 14 were stem revisions. This is comparable to our study with a survival rate of 98.8% and 6 overall revisions, of which 4 were stem revisions in a population of 500 patients.

Furthermore, both studies had comparable baseline characteristics of the patients. Kutzner *et al* used the Harris Hip Score (HHS) as a functional outcome measure. The HHS is used to evaluate the function of the hip before and after surgery for a range of different disabilities.[19] The outcome showed a large increase in the first six months before flattening out. At the 2-year follow-up, their HHS reached a mean of 98.2, meaning that most patients showed an excellent functional outcome after 2 years. This is similar to our study, which indicates consistent excellent survival and functional results among the two different clinics.

Studies on comparable short stems, such as the Nanos and Fitmore stems, are in line with our results. The NANOS stem, produced by Smith and Nephew, is also a calcar-

guided short stem and has an ODEP rating of 7A. A study by Ettinger *et al*[20] presented mid-term results in 65 patients receiving a NANOS short stem at 5 years of follow-up. In this study, the patient population had similar demographics compared to our study population. At the 5-year follow-up, only two infections were registered. As there were no revisions of the stem itself, a survival of 100% was observed. For functional outcomes, this study also used the HHS. The HHS increased from 47.3 before surgery to 97.6 at the final 5-year follow-up.

Another widely used short stem is the Fitmore Hip stem, produced by Zimmer Biomet. It has an ODEP rating of 10A. A study by Thalmann *et al*[21] presented clinical results in 96 patients at 5 years of follow-up. At the 5-year follow-up, only one revision was seen, resulting in a survival of 99%. The mean HHS increased from 59.3 before the surgery to 93.8 at 5 years of follow-up.

A systematic review by Oldenrijk *et al*[22] compared the revision rate of 19 different short stems across 49 studies. These short stems were divided into three groups: collum, partial collum and trochanter sparing. In this study, the Optimys stem was classified as a partial collum stem. This group contained 8 stem types across 24 studies in 2357 patients. Follow-up ranged from 0.5 to 11.2 years, with a mean follow-up of 4.0 years and a mean survival rate of 99.3%. Our results for the Optimys stem are in line with these results. The results can also be compared with the trochanter-sparing group, which contained 8 stem types across 20 studies in 3628 patients. Follow-up ranged from 0.3-12.0 years, with a mean of 3.4 years and a mean survival of 99.2%. Our results are also in range compared to this group of short stems.

The study, however, still used the old NICE benchmark of revision rates of 10% of less at 10 years of follow-up, while the current benchmark as mentioned earlier is 5% or less at 10 years of follow-up.

This study had a few limitations. First, the use of the LROI registry is limited in information about the reason for revision. As such, the reason for revision for

malposition was not clear, and further information could not be obtained, as the data were anonymous. Second, the number of patients who completed the PROM questionnaire was small. This can especially be seen at the 2-year follow-up. This could lead to a bias of the presented results, as the response rate of patients can depend on the results of their prosthesis. However, as the functional outcome scores in our study did not differ between the one- and two-year follow-ups and a sensitivity analysis showed similar results, it is assumed that not only the patients with lasting complaints of their hip filled out the two-year follow-up questionnaires.

A strong point in this study was the large prospective cohort. A total of 500 patients were followed for a median follow-up of 5.5 years.

Although this study shows a good survival rate at the 5-year follow-up, further research on the Optimys short hip stem is still necessary to include the long-term survival of this hip stem. This cohort will be followed for the long-term survival data.

CONCLUSION

This study showed a 5-year survival rate of 98.8% for the Optimys hip stem in a population of 500 patients. Functional outcome and quality of life increased significantly in the first year after implantation with subsequent stabilization at the two-year follow-up.

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