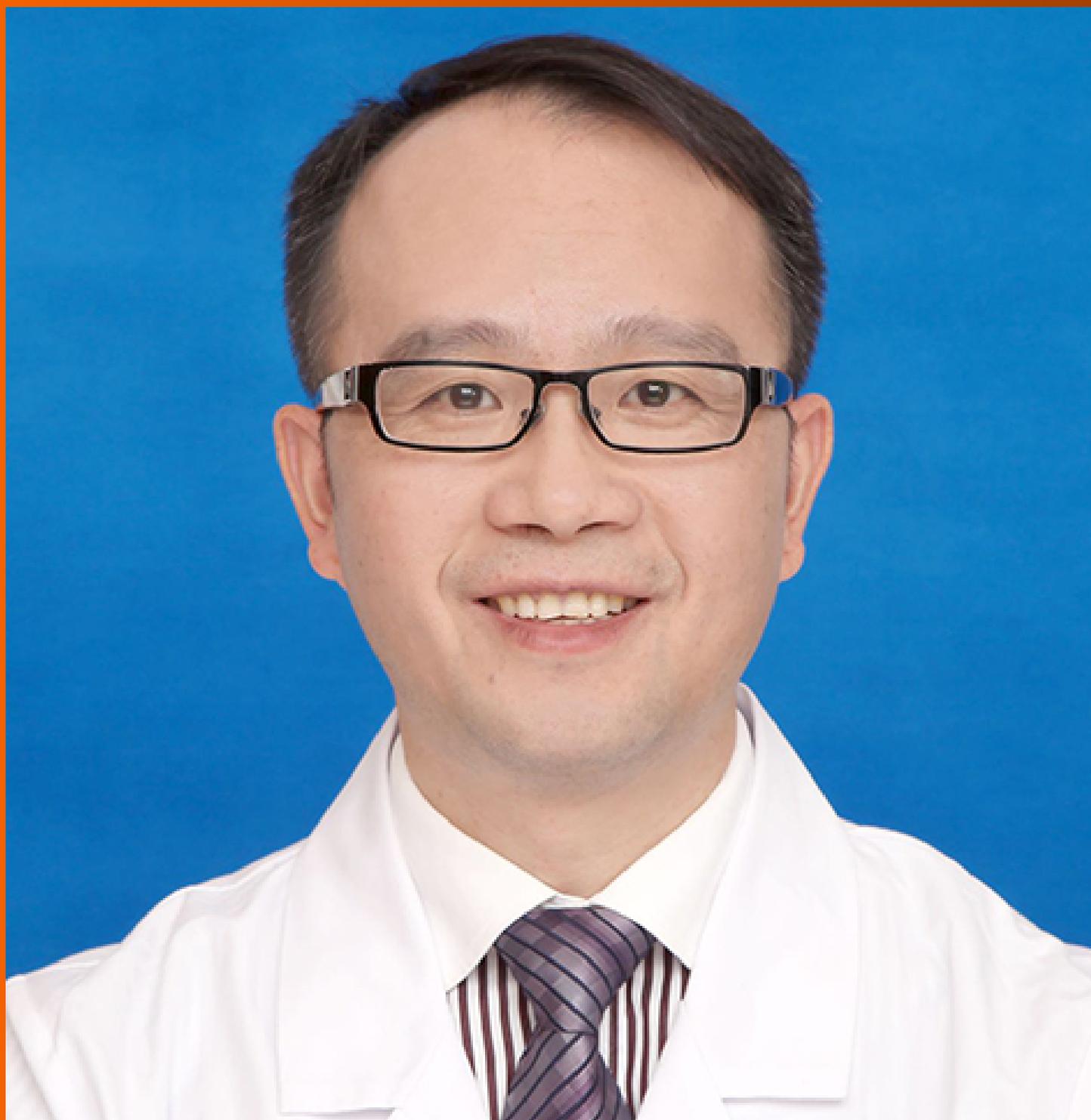


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Prospective Study

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 M M J Kerkhoffs, Daniël Haverkamp

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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

To determine the 5-year survival of the Optimys hip stem.

METHODS

This was a prospective multicenter cohort study of 500 patients conducted in two hospitals in the Netherlands. 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. The secondary outcome measurements included patient-reported outcome measures (PROMs). Kaplan-Meier analysis was used to calculate the 5-year survival rate. 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 1st 2 years after surgery. Analyses were modeled separately for the 1st and 2nd years to calculate the yearly change in PROMs during both follow-up periods with accompanying 95% CIs.

RESULTS

The mean age of the total 500 patients was 62.3 years (standard deviation: 10.6) and 202 were male (40%). At a median follow-up of 5.5 years (interquartile range: 4.5-6.7), 7 patients were deceased and 6 revisions were registered, for infection ($n = 3$), subsidence ($n = 2$) and malposition ($n = 1$). This resulted in an overall 5-year survival of 98.8% (95%CI: 97.3-99.5). If infection was left out as reason for revision, a stem survival of 99.4% (95%CI: 98.1-99.8) was seen. Baseline questionnaires were completed by 471 patients (94%), 317 patients (63%) completed the 1-year follow-up questionnaires and 233 patients (47%) completed the 2-year follow-up. Both outcome measures significantly improved across all domains in the 1st year after the operation ($P < 0.03$ for all domains). In the 2nd year after surgery, no significant changes were observed in any domain in comparison to the 1-year follow-up.

CONCLUSION

The Optimys stem has a 5-year survival of 98.8%. Patient-reported outcome measures increased significantly in the 1st postoperative year with stabilization at the 2-year follow-up.

Key Words: Total hip arthroplasty; Femoral stem; Short stem; Optimys; Survival; 5-year survival; Revision; PROMs

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Core Tip: The Optimys hip stem showed an excellent 5-year survival of 98.9%, and when excluding infections this was 99.4%. This is in line with the earlier results of the Roentgen Stereophotogrammetric analysis study completed by our group, and we expect it to be in line with the National Institute for Health and Care Excellence criteria on total hip arthroplasty for the 10-year follow-up. This study showed that in a large, varied patient population there is similar survival as other cohorts with short femoral stems.

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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 been introduced to the market and has 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 radiostereometric analysis study of the Optimys hip stem showed excellent results in the stabilization of the Optimys short stem at 2 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 Orthopaedic Data Evaluation Panel (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 outcomes 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 post-traumatic coxarthrosis. Patients were excluded in cases of revision surgery, an American Society of Anesthesiologists 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 LROI. Prior to the operation, at 6 wk, 3 months, 6 months, 1 year, and 2 years post-surgery, 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 THA was left to the surgeon's preference (anterior, anterolateral, or straight lateral). The day of the surgery or 1 d postoperative, patients were mobilized using two crutches and were allowed full weight bearing (Figure 1).

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 2 years post-surgery)[13-16].

Statistical analysis

IBM SPSS Statistics 26 (IBM Corp., Armonk, NY, United States) 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 were presented as the median and interquartile range. Categorical 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 1st 2 years after surgery. Analyses were modeled separately for the 1st and 2nd 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 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 body mass index was 26.5 kg/m² (SD: 4.1) (Table 1).

Survival

At a median follow-up of 5.5 years (interquartile range: 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. In 1 patient, the debridement, antibiotics, and implant retention 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 1st year after the operation (*P* < 0.03 for all domains). In the 2nd year after surgery, no significant changes were observed in any domain in comparison to the 1-year follow-up (Table 3 and Figure 3). Although

Table 1 Demographic characteristics, n = 500

Characteristic	Value
Male sex ¹	202 (40)
Age	62.3 (10.5)
Right side ¹	286 (57.0)
Height in cm	173.2 (9.2)
Weight in kg	79.9 (15.8)
BMI in kg/m ²	26.5 (4.1)

¹n (%) or mean (standard deviation). BMI: Body mass index.

Table 2 Hip Disability and Osteoarthritis Outcome Score and 36-item short form survey baseline and follow-up scores

Outcome	Baseline, n = 471	6 wk, n = 388	3 months, n = 371	6 months, n = 355	1 yr, n = 317	2 yr, n = 233
HOOS						
Symptoms	42.1 (18.1)	71.6 (18.2)	76.3 (17.9)	81.1 (17.7)	85.9 (16.2)	85.9 (16.7)
Pain	42.5 (16.5)	77.4 (16.7)	83.7 (16.6)	87.1 (15.8)	89.6 (15.0)	90.2 (14.7)
ADL	42.6 (17.5)	74.7 (17.8)	81.0 (17.8)	85.4 (16.1)	88.6 (16.4)	89.5 (15.4)
Sports and recreation	24.3 (19.6)	51.9 (26.8)	65.6 (25.1)	71.2 (24.9)	77.1 (24.2)	77.0 (24.9)
Quality of life	25.9 (15.7)	54.6 (20.4)	66.9 (22.3)	72.8 (21.8)	78.4 (21.6)	80.0 (21.0)
SF 36						
Physical functioning	35.6 (18.6)	57.8 (22.8)	69.6 (22.4)	74.5 (22.4)	78.7 (22.4)	81.8 (19.8)
Role physical	23.3 (35.7)	29.5 (36.0)	57.5 (42.5)	71.0 (40.4)	81.0 (34.9)	80.8 (34.4)
Bodily pain	35.7 (17.2)	55.9 (22.1)	70.7 (22.1)	75.9 (21.2)	80.6 (22.4)	80.8 (22.8)
Social functioning	61.0 (26.0)	68.1 (26.0)	79.9 (23.8)	85.0 (21.0)	88.5 (19.3)	87.7 (20.4)
Mental health	73.4 (17.8)	80.2 (16.2)	82.0 (16.3)	81.8 (15.7)	83.1 (15.0)	83.0 (14.3)
Role emotional	63.3 (43.7)	67.5 (41.5)	77.2 (38.2)	84.1 (33.6)	89.6 (27.0)	90.0 (27.2)
Vitality	57.3 (19.9)	66.0 (18.4)	69.5 (18.4)	70.8 (18.2)	72.9 (17.4)	73.9 (16.7)
General health perceptions	66.6 (18.5)	73.5 (17.9)	72.4 (19.0)	70.4 (19.7)	72.0 (19.9)	73.4 (18.5)

Data are mean (standard deviation). ADL: Activities of daily living; HOOS: Hip Disability and Osteoarthritis Outcome Score, SF-36: 36-item Short Form Survey.

sensitivity analysis showed smaller effects during the 1st year, the same comparable effect was observed during the 2-year follow-up (Supplementary Tables 1 and 2).

At the 2-year follow-up, 210 (42%) had completed the satisfaction score with results as follows: 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 three cases, subsidence of the stem (0.4%) in two 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.

Table 3 Yearly change in the patient-reported outcome measures (β) during the 1st and 2nd postoperative years

Outcome measure	1 st yr		2 nd yr	
	β (95%CI) ¹	P value	β (95%CI) ¹	P value
HOOS				
Symptoms	34.8 (31.9, 37.6)	< 0.001	0.7 (-0.9, 2.3)	0.38
Pain	36.8 (34.0, 39.7)	< 0.001	0.3 (-1.0, 1.6)	0.63
ADL	36.2 (33.3, 39.1)	< 0.001	0.9 (-0.6, 2.5)	0.24
Sports and recreation	43.3 (39.7, 46.9)	< 0.001	-0.1 (-2.6, 2.4)	0.93
Quality of life	41.8 (38.7, 45.0)	< 0.001	1.5 (-0.7, 3.8)	0.18
SF-36				
Physical functioning	34.5 (31.4, 37.7)	< 0.001	0.8 (-1.7, 3.4)	0.56
Role physical	54.4 (49.0, 59.7)	< 0.001	-1.2 (-6.2, 3.8)	0.64
Bodily pain	36.5 (33.4, 39.6)	< 0.001	-0.4 (-3.3, 2.6)	0.80
Social functioning	22.8 (19.5, 26.0)	< 0.001	-0.9 (-3.5, 1.7)	0.49
Mental health	6.1 (4.1, 8.1)	< 0.001	-0.7 (-2.4, 1.1)	0.45
Role emotional	23.3 (18.1, 28.5)	< 0.001	0.0 (-4.4, 4.5)	1.00
Vitality	10.8 (8.5, 13.1)	< 0.001	-0.6 (-2.6, 1.4)	0.56
General health perceptions	2.4 (0.3, 4.6)	0.03	0.1 (-1.7, 1.8)	0.95

¹Mixed model analysis. ADL: Activities in daily living; CI: Confidence interval; HOOS: Hip Disability and Osteoarthritis Outcome Score; SF-36: 36-item short form survey.



Figure 1 Optimys short stem (Mathys Ltd. Bettlach, Switzerland).

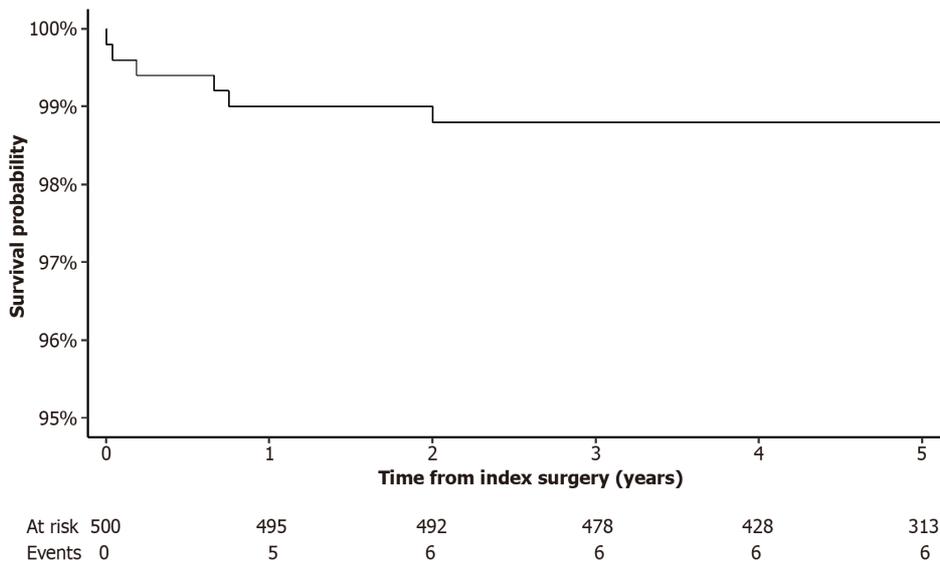


Figure 2 Kaplan-Meier survival curve illustrating 5-year survival, including all reasons for revision.

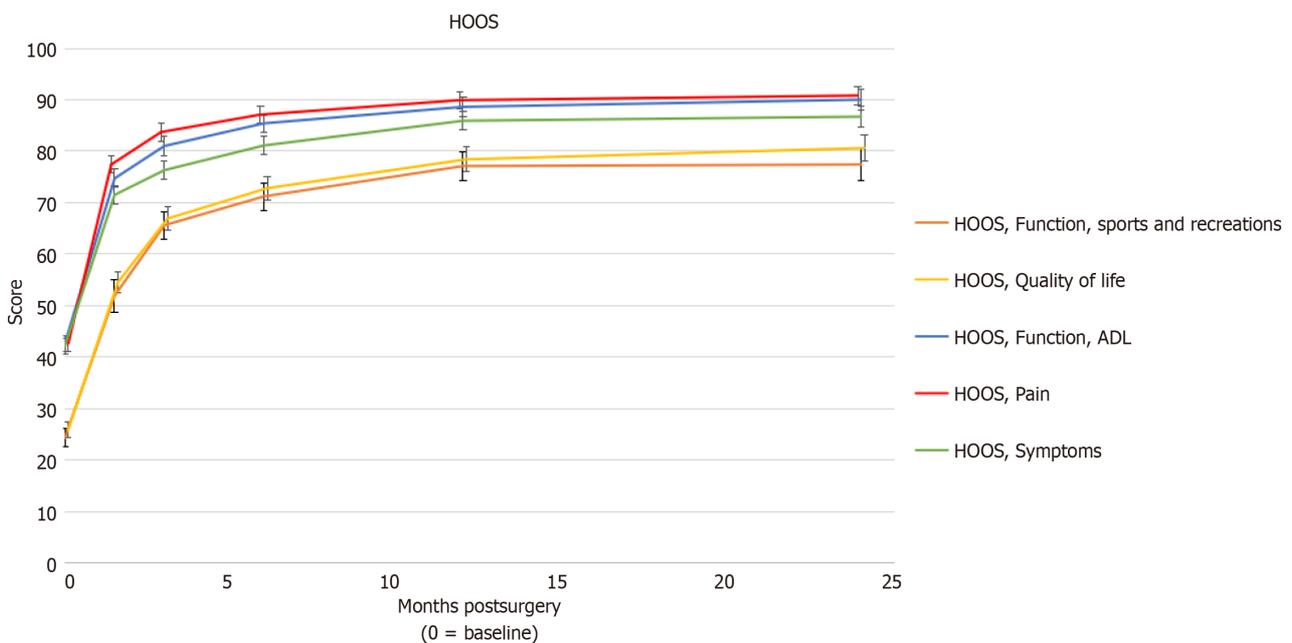


Figure 3 Follow-up graph of the Hip Disability and Osteoarthritis Outcomes Score scores from baseline to the 2-yr follow-up (means with 95% confidence interval). HOOS: Hip Disability and Osteoarthritis Outcome Score; ADL: Activities of daily living.

Furthermore, a significant increase in the PROMs at the 1st 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 1st year, no significant changes in either score were observed. Almost all patients (91.4%) were very satisfied or satisfied with their THA.

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 cup malposition), 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*[18] 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 6 months before flattening out. At the 2-year follow-up, the 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 indicated 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 van 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 eight stem types across 24 studies in 2357 patients. Follow-up ranged from 0.5 years 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 were in line with these results. The results can also be compared with the trochanter-sparing group, which contained eight 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 were also in range compared to this group of short stems. The study, however, still used the old NICE benchmark of revision rates of 10% or 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 has limited 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 1-year and 2-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 2-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 1st year after implantation with subsequent stabilization at the 2-year follow-up.

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ARTICLE HIGHLIGHTS

Research background

Short stems in total hip arthroplasty are becoming more popular in the 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. As with all new implants on the market, stepwise introduction is needed to avoid a high failure rate in patients. This study contributes to the knowledge of midterm survival data of the Optimys hip stem.

Research motivation

Short hip stems have advantages compared to the widely used conventional stems, especially in the younger and more active patient population. However, long-term survival of the conventional stems is high, so newly introduced implants must have at least a survival rate of 95% at the 10-year follow-up, according to the National Institute for Health and Care Excellence guidelines.

Research objectives

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 outcomes and quality of life in this patient population. This can show us if the hip

stem is an implant that can be commonly used in the daily practice of an orthopedic surgeon. The study can contribute to the fact that this hip stem is safe to implant in a large and varied patient population with an excellent survival rate.

Research methods

This was a prospective multicenter cohort study conducted in two hospitals in the Netherlands (Amsterdam and Venlo). This gave a large and varied patient population. 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. Kaplan-Meier was used for 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. The secondary outcome measurements included patient-reported outcome measures (PROMs), which consisted of the Hip Disability and Osteoarthritis Outcomes Score, the 36-item Short Form, and a 5-point Likert scale for satisfaction (at 2 years post-surgery). Mixed model analyses were performed to assess the course of the PROMs during the 1st 2 years after surgery. Analyses were modeled separately for the 1st and 2nd years to calculate the yearly change in PROMs during both follow-up periods with accompanying 95% confidence intervals. A *P* value of < 0.05 was considered statistically significant for all analyses.

Research results

The survival rate of the Optimys hip stem at the 5-year follow-up was 98.8% in a group of 500 patients if all revisions were included (*n* = 6). If infection was left out (*n* = 3), a survival of 99.4% was seen. The functional outcome and quality of life was significantly improved at the 1-year follow-up and subsequently stabilized at the 2-year follow-up.

Research conclusions

Short curved hip stems had a high survival rate at the 5-year follow-up, showing that it is a safe and viable stem for common use in total hip arthroplasty.

Research perspectives

Future research includes the long-term follow-up of the Optimys hip stem to determine the survival rate at the 10-year follow-up.

FOOTNOTES

Author contributions: Hamans B and Sierevelt IN analyzed the data; Hamans B, de Waard S, Kaarsemaker S, Janssen ERC, Sierevelt IN, Kerkhoffs GMMJ, and Haverkamp D prepared the manuscript; de Waard S, Kaarsemaker S, and Haverkamp D included patients; de Waard S, Kaarsemaker S, Janssen ERC, Sierevelt IN, and Haverkamp D collected data; Sierevelt IN and Haverkamp D designed the research study; All authors read and approved the final manuscript.

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