Subsidence is a Predictor for Stem Revision due to loosening or osteolysis
247 primary cemented stems with rough surface followed for 2-17 years with Radiostereometric Analysis

Master thesis in Medicine

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Abstract

The cemented Spectron EF stem, frequently used in Sweden between 1990 and 2010, underwent minor design changes in 1994 and was renamed Spectron EF Primary and smaller sizes were introduced. The length of the stem, previously 15 cm for all sizes, was reduced by steps for each reduction in size. According to data from the Swedish Hip Arthroplasty Register, these design changes were associated with a 3-4 times increased risk of revision due to loosening or osteolysis after 6 years. From 1995 to 2005 the Spectron EF Primary stem was used in several radiostereometric (RSA) studies to evaluate new types of cement and polyethylene. This study uses data from several of studies and aims to evaluate if stem subsidence measured with RSA could be used to predict later revision due to loosening or osteolysis. Ethical approval was received from the regional ethics review board in Gothenburg.

Patients and Methods

In total 279 hips operated with a Spectron EF Primary stem between 1996 and 2005 were identified. All had previously been included in RSA studies. The stems were supplied with small titanium towers press-fitted into the stem at the shoulder, at the collar and at the tip of the stem, each containing tantalum beads. For measuring purposes, the femoral head center was also included in the stem segment. RSA examinations were performed within one week after operation and further studies were scheduled after 6 months, 1 year, 2, 5, 7, 10, 13, 15 and 17 years. Conventional radiographic examinations were performed at each follow-up occasion past the 6-month follow-up. The inclusion criteria were existing migration data up to at least 2 years. This resulted in 247 hips (161 females, 86 males) available for further analysis. Median age at operation was 62 years (range 29-80) and median follow-up time was 13.9 years (range 2.6-18.2). Case records and the Swedish Hip Arthroplasty Register database were used to obtain information about revision procedures. At the last follow-up 27 stem had

been revised due to mechanical failures related to stem loosening with or without osteolysis. Another 5 were classified as radiographic failures.

Results

The 10-year stem survival was 93.8 percent (95% CI 89.7% - 96.3%), slightly below 95 percent which would be considered good for cemented stems. 15-year survival decreased to 86.3 percent (95% CI 81.3% – 91.3%). Wilcoxon signed-rank tests show that the stems are continually subsiding even after 12-13 years at a significant rate ($p < 0.0005$). Each mm of subsidence at 2 years increases the risk of later loosening 5.7 times ($p < 0.001$). Subsidence exceeding the risk-value 0.15mm at two years increased the risk of later loosening 5.2 times ($p < 0.001$). Small stem size (size 1) increased the risk of later failure 7.8 times compared to stem size 2. For stem sizes 3 or bigger the risk decreased compared to size 2 (HR 0.06, 95% CI 0.004 – 0.80). High offset increased the risk of later loosening 3.2 times (95 % CI 1.5-7.0). Male gender was associated with increased risk of later loosening (HR 6.5 95% CI 3.0 -16).

Discussion and Conclusion

The reason why seemingly minor design changes of the Spectron stem resulted in substantially higher revision rates due to loosening and osteolysis is not clear but the introduction of smaller sizes seem to explain some of it. According to our study a rather minor increase of the stem subsidence and rotation into retroversion within 2 years increased the risk of revision. Poorer results with the smaller sizes associated with accelerating subsidence past 2 years suggest that debonding of the stem from the cement mantle due to repetitive load occurring more easily after the design changes were made. Thus, it seems probable that a major drawback with the altered design was reduction of the load bearing surface area of the stem facing the cement mantle. Our study indicates that RSA is of value in predicting failure of a cemented stem with rough surface.

Introduction

Symptomatic osteoarthritis of the hip is a common problem. Though the incidence varies in different populations, osteoarthritis of major joints is a. A conventional total hip replacement includes removal of the femoral head and the surface layer of the acetabulum. A stem supplied with a modular head that articulates against a prosthetic cup is fastened into the acetabulum. This gives the opportunity to treat serious cases and provide pain relief as well as dramatic improvements in health and quality of life (Bruyere et al., 2012) for patients who otherwise would become disabled for their remaining life.

Although total hip replacement surgery is normally successful, 5-10% require revision within a 10-year period (NewZeeland, 2009; SwedishRegistry, 2009). Revision surgery is more extensive than the primary surgery and has a higher risk for per- and postoperative complications (Rohrl, Nivbrant, Snorrason, Karrholm, & Nilsson, 2006) and often more costs. When a new implant is introduced on the market, it is therefore imperative that these can be evaluated reliably.

During the period 1995-2010, a modified version of the so-called Spectron EF stem (femoral stem of a total hip prosthetic) was frequently used in Sweden and during most of these years more than 1000 operations were performed. Several studies were conducted using RSA technology showing a good fixation up to 2 years after surgery.

RSA is an abbreviation of radiostereometric analysis, a radiographic technique that allows measurement of prosthesis fixation over time with an accuracy of about 0.1 mm. These measurements during the early stages after surgery have been shown to have significant value since early migration, even at magnitude of a few tenth of a millimeter during the first two years increases the risk of future loosening of the stem (Karrholm, Borssen, Lowenhielm, & Snorrason, 1994).

The original Spectron stem had a straight, tapered collared design with a matte surface (RA-value between 0.5 and 1 µm). It was later replaced with the Spectron EF stem which was similar in shape but had the proximal one-third roughened through sand-blasting. In 1995 the EF primary system was introduced which was similar in design but came in varying (particularly smaller) sizes and had a revision alternative with a longer stem.

Long-term follow-up has shown that the Spectron EF stem suffers from a higher frequency of late loosening than its comparatively similar predecessor. The reason for this difference in terms of late stem loosening is not known. Our research group has since 1992 continuously followed about 300 hip replacement operations with the Spectron EF stem (and different types of cups) in various randomized studies approved by the regional ethics committee of Gothenburg. In all cases the migration of the stem has been measured with RSA. In this study data on all these stems were compiled into a database and information about any revision or presence of radiographic loosening were collected from case records, the Swedish Hip Arthroplasty Register and conventional radiographs.

Scientific importance

Being able to evaluate a prosthesis is of great clinical importance in order to be able to make well informed decisions about which prosthetic design should be used given different conditions. The database built during the project will also be of importance for future research. Though the material is unique, the results will to some extent be applicable to similar types of prosthesis.

Total hip replacement surgery

In total hip replacement surgery, the natural joint (head of femur) is completely removed and replaced by mechanical parts. The mechanical joint consists of two major parts; the cup and the stem.

Most patients who undergo THA suffer from hip osteoarthritis (degenerative arthritis). Other indications include rheumatoid arthritis, arthritis due to trauma and in some cases fractures caused by trauma or necrosis due to restricted blood flow in turn causing pain and loss of function. The resulting improvements in function and pain reduction is often dramatic.

A cup consisting of metal and/or plastic is fastened into the acetabular socket using cemented or non-cemented techniques. In order to accommodate the cup and keep it covered by the acetabular upper wall the acetabulum usually needs to be deepened. Both cemented and un-cemented techniques are used to varying degrees in different parts of the world with good results. Since this paper focuses on the stem we will not go into greater detail regarding the cup part of the prosthetic joint.

A femoral stem replaces the femoral part of the joint. The stem is fastened within the femoral marrow canal using cemented techniques, press-fit techniques or a combination of both. The Spectron EF Primary stem used in this study is cemented. Cemented hip replacement surgery was pioneered in the early 1960s by Sir John Charnley and though a lot of progress has been made, the basic design remains largely unchanged though the materials have been updated.

Anatomical considerations in hip replacement systems

The objective of a THR is to achieve a long lasting function of the hip joint which mimics the one of the natural joint. To a large extent, good design ties into the considerations that need to be made by every orthopedic surgeon during hip replacement surgery. A good femoral stem design will allow the surgeon to address these considerations individually. These considerations can roughly be categorized into femoral offset, leg length, femoral neck anteversion, canal size (stem size) and positioning.

Femoral offset

The femoral offset is the horizontal distance between the rotational center of the head and a line drawn down the vertical center of the femur and it is important to preserve it as closely as possible. A smaller offset leads to decreased tissue tension around the joint which increases the risk of dislocation. Reduced offset decreases the lever arm of the pelvic abductors and they need to increase their contraction force in order to preserve stability. This will in turn increase the reactive forces the joint and its components are subjected to, which may contribute to aseptic loosening. A larger offset on the other hand will cause strain on lateral tissue, for example the fascia lata, and may cause trochanteric bursitis. The Spectron EF Primary was available with two offsets corresponding to two lengths of the true neck of the stem. Another design strategy for controlling the offset independently to other variables is a modular femoral head with a female cone of varying depth. The depth of cone will determine the functional length of the neck. For most designs 3-4 head/neck lengths are available.

Even leg length

Uneven leg length is a comparatively common problem which sometimes causes discomfort to the patient in terms of limping and maybe also back and knee pain, even if these last two symptoms most frequently are caused by other reasons. The tension of surrounding structures and the leg length is tested during the operation by relocating the hip. The easiest way to control the leg length is the femoral insertion depth of the stem. A collarless stem may be inserted at a variable depth while a collared stem is limited by its collar.

Anteversion

Femoral anteversion is anatomically defined as the orientation (angle) of the femoral neck compared to the frontal plane traversing the posterior part of the femoral condyles. Depending on the angle at which the stem is inserted, the resulting anteversion can be controlled. Some stems, though not the Spectron EF Primary, have a built in anteversion (e.g. Lubinus SP).

It is difficult to define correct anteversion for a prosthetic hip. The goal is not necessarily to construct a copy of the original anteversion but rather constructing a well-balanced hip with an optimal range of movement. Different surgical techniques will mean different optimal anteversion and it is also affected by the angular insertion of the acetabular part of the prosthetic joint. A poorly chosen anteversion may lead to decreased range of movement, risk of dislocation and likely also aseptic loosening due to unfavorable load-bearing.

Femoral canal size

Proper matching of the stem to the width of the femoral canal is important. Problems may arise, especially when the canal is thin. If a thin stem is inserted, there is an increased risk of stem breakage and especially in the young and active patient. If a small and cemented stem is inserted the surface area facing the cement will decrease. This will increase the risk of debonding between the stem and the cement. If the stem is polished (Ra-value < 0.5 µm, the consequences of this debonding is probably small. If the stem is matte (Ra-value 0.5-1 µm), abrasive wear may occur, a problem that will be addressed in this thesis.

Too large a stem leaves too little space for the cement within the femoral canal and may lead to cement mantle defects which may decrease the longevity of the implant. However, the so-called French paradox states that equally good results can be achieved using an extremely thin layer of cement (Langlais, Kerboull, Sedel, & Ling, 2003).

General stem design

In order for the stem to work for an extended period of time it is important to avoid high peak pressures and micro motion. There are a few different design philosophies to achieve this but in the end it all comes down to distributing the load evenly over the cement mantle and the interfaces (stem/cement and cement bone).

Stem philosophy

The largest difference in design philosophical is between the loaded-taper model and the composite beam (Scheerlinck & Casteleyn, 2006). In the loaded-tapered philosophy the interface between stem and cement is assumed to fill with fluid from the surrounding tissue and the stem is not bonded to the cement. By using a stem with a tapered shape it will wedge into the femoral cavity. When the stem is subjected to vertical force it will subside slightly into the femoral cavity and the load will be evenly distributed over the mantle through a liquid interface present between the stem and the cement-mantle. This type of stem-philosophy is sometimes referred to as using force closed fixation (from the German engineering term Kraftgeschlossen) (Huiskes, Verdonschot, & Nivbrant, 1998) since it relies on load-bearing to keep it stable. Theoretically, this form of construction would be allowed to shift and settle slightly post-operatively. A good example of a stem using this philosophy would be the polished Exeter stem.

In a composite beam philosophy, the goal is to bond the stem to the cement forming a single solid body; the stem is not allowed to subside. Making the stem/cement bond too rigid, for example by using stems pre-coated with PMMA (polymethylmethacrylate) or cement that fuse very tightly to the cement mantle, will result in increased tensile and shear stress in the cement/bone interface. On the other hand, a weak bond will lead to increased proximal cement strain. This is sometimes referred to as shape closed fixation (from the German engineering term Formgeschlossen), implying that stability is attained through matching geometry of stem and cement mantle.

Horizontal and cross sectional geometry

Curved stems that are formed to follow the curvature of the femur or symmetrical stems may be used in the solid beam stems. The load-bearing will be different and theoretically the curved stem would allow for a more centralized positioning and a more even cement layer while symmetrical stem designs allow for more standardized instruments during the operation. The cross-sectional diameter and shape may vary. Examples of cross-sectional geometry are oval and box-shaped with varying degrees of rounded corners.

In some cases, a proximal stem collar is used. By adding a collar, mechanically weak cancellous bone is removed and the load-bearing is moved closer to more stable cortical bone. It may also be a help at the insertion stage to make sure the stem is inserted to the correct level. It is difficult to assess how collars affect long term stability but the collar may certainly interfere with initial settling and is never used with tapered stem designs.

Different types of stem surfaces have been tried but generally, tapered stems favor polished surfaces and composite-beam stems favor rougher surfaces. Varying surfaces within the same stem have been tried, for example increased roughness around the proximal parts of the stem, where finite element analysis and clinical experience indicate increased focal loads. The stem surface will affect how well the stem bonds to the cement.

Stem head

The ball part of the femoral stem does not need to be the same size as the original femoral head in a total prosthetic but it does need to preserve the rotational center and match the acetabular prosthetic. Experience has shown that a larger head will increase frictional torque leading to increased strain on surrounding tissue and early loosening of the cup. A smaller head may lead to increased wear inside the cup and a greater risk of dislocation. This is not an aspect of design discussed further within this essay. The material of the head is metal or ceramic.

Stem materials

Materials used for the stem may vary and examples of materials used are steel, stainless steel, cobalt-chromium-molybdenum alloy, titanium or titanium alloy. For the cup various combinations of metal, ceramics for the cup casing and metal, ceramic or plastic for the lining are used.

Specific stem designs

Good clinical results have been published for both matte and polished stems and it is no longer obvious that polished or matte surfaces should be favored (Huiskes et al., 1998). However, it is important that the surface is suitable for the chosen stem design.

Evolution of the Charnley stem

The original Charnley stem technology was developed in association with the dental school at the University of Manchester, building on their experience of working with dental prosthetics (Briggs, 2013). Charley's idea was to use acrylic cement used in dental surgery to fasten the hip prosthetic to bone. The first Charnley stem had a flat back and was made of polished stainless steel. The first surgery was performed at Wrightington Hospital in England in November 1962 (Charnley, 1972). The initial stems suffered a few cases of fractures and in response Charnley modified the stem changing the surface finish to a harder low friction bead blasted Vaquasheen surface. Both the frontal profile and the cross-section were changed to more rounded designs in an attempt to alleviate focal stress. In 1971 the material was changed to 316 low carbon vacuum-melted stainless steel to improve corrosion resistance and fatigue properties.

An attempt to improve proximal loading was done when the stem-design was changed from the flat-backed to the so-called cobra-flanged design. This also meant a switch from a tapered design to a composite beam design. The scope of the biomechanical differences in these two design philosophies may not have been appreciated at the time but have later been extensively investigated (Shah & Porter, 2005).

Other design changes were the introduction of the 40 mm femoral offset in 1982, decreased neck-length from 12.5 mm to 10 mm in 1984 and improvement of the head/neck ratio to decrease the risk of impingement. Since the 80s a lot of design-changes have been suggested and tested. Not all have been successful and to some extent, the stem evolution since the 90s has been retrograde.

Experiences with the matte Exeter-stem

The Exeter stem was originally a collar-less polished (Ra = 0.02 µm) steel stem with a distal centralizer (Howie, Middleton, & Costi, 1998). The stem was straight and tapered in the frontal plane and although it curved out medially towards the neck, the anterior and posterior surfaces of the stem were practically parallel. In 1998 a study was conducted using a modified matte (Ra-value = 1.0 µm) version of the stem, comparing it to the original polished one. After a minimum follow-up time of nine years, four matte stems of 20 had been lost to aseptic loosening. The 20 polished stems were found to have subsided slightly within the cement mantle but they did not loosen. The conclusion was that the matte surface was not well suited for the tapered Exeter design.

The Spectron EF stem

The stems used in this material are all Spectron stems. The Spectron EF is a cemented stem system that has been in used in THA since 1982. The original Spectron stem was straight and tapered with a proximal stem collar and had a matte surface (Ra-value = 0.8). The cross-section was trapezoidal with vertical cement groves.

It was later replaced by the Spectron EF stem which had a roughened surface (Ra = 5 µm) around the stem where it left the proximal femur. The reasoning for this design change was that this part of the stem would be subject to very large rotational forces, particularly when standing up or sitting down, and by improving the bonding between cement and stem the risk of stem loosening in this area would be decreased.

In 1995 the so-called EF Primary was introduced. Like the Spectron EF, the proximal one-third of the stem was roughened through grit-blasting it. The EF primary system was made in varying sizes with longer revision alternatives (not represented in this material).

Hypothesis

Can measurement of early stem migration predict future clinical stem loosening and need for revision for patients with the Spectron EF Primary stem? If so - how long should the patient be monitored to ensure not missing following complications?

Material and Methods

All studies were conducted on patients having undergone total hip replacement (stem and cup). In order to track the prosthesis movement and wear they were followed up with regular checks. The checks were performed using X-ray with RSA technology as well as conventional X-ray. Data from several studies that used the same techniques have been collected and cross-referenced with case records and the Swedish Hip Arthroplasty Register. Thereafter the data has been deidentified to protect the integrity of the patients. Statistical evaluation was performed using Cox' proportional hazard method which is a type of regression analysis that allows for taking into account the time factor when observation times vary (Breslow, 1979).

The data used consisted of two parts, the RSA data and conventional x-ray examinations. This study, as such, will not incur additional clinical inspections or monitoring in addition to those already planned in the respective sub-studies. Here follows a brief description of the two methods.

RSA

RSA (RadioStereometric Analysis or Roentgen Stereophotogrammetric Analysis) was introduced in 1974 (Selvik, 1989) and has been widely used and accepted. Though there exists several parallel implementations of RSA and an attempt to create general guidelines was presented in 2005 (Valstar et al., 2005). RSA can be used to accurately measure the movement of two bodies or points relative to each other.

Markers

During the operation, spherical tantalum markers with a diameter of 0.5, 0.8 or 1.0 mm are inserted to obtain distinct landmarks. Today, mainly markers with a diameter of 0.8 and 1.0 mm are used for measurements in the human hip region. Tantalum is a radio-dense material which makes it easy to detect on radiographs. Larger diameters will yield larger x-ray projections and higher precision provided that measurements are based on digitized image processing.

In geometry, it is enough to use three well-defined and non-collinear (should not form a line and not be too close) points to describe the orientation of a rigid three-dimensional object. When using x-ray technology there is always a risk of markers being obscured by metal in prosthetics or other markers. Also, there is always a risk of loosening of individual markers, especially if not properly implanted. Hence, it is recommended to use 6-9 well-scattered markers. Other objects that are identifiable in x-ray projections may also be used as markers, for example the femoral head of the hip stem. There have been attempts made to match a virtual projection of a three-dimensional object to the radiographic projection of the prosthetic (Kaptein, Valstar, Stoel, Rozing, & Reiber, 2003; Valstar, de Jong, Vrooman, Rozing, & Reiber, 2001). The measurements in this study are however based on marker based techniques.

Examination

During the examination, two x-ray tubes are focused on the joint. Under the x-ray table a calibration cage is placed containing markers and two roentgen cassettes or digital screens (side-by-side or placed orthogonally). The calibration cage used in this study is uniplanar. By using the dual projections and the known positions of markers within in the calibration cage, the positions of the roentgen foci and of the tantalum markers can be determined in a three-dimensional coordinate system. When making follow-up measurements it is preferable that the same setup is used and that the position of the patient is about the same as during previous examinations to facilitate marker identification.

Consecutive RSA measurements require that the marked structures (in this case bone and stem) can be treated as rigid bodies (this study will not go into greater detail regarding the validity of this assumption). This in turn would imply that the markers should maintain their position relative to each other over time. Initially the markers are measured and named according to which segment body they belong to (femur or stem). Based on the rigid body assumption the markers should maintain their position relative to each other within each structure. By letting the markers describe a polytope (thee-dimensional polygon) and applying a transformation matrix to accurately rotate and position the new measurement to align with the reference measurement, a mathematical best-guess can be made that gives the minimum total deviation from the original polytope. If individual markers are missing (obscured) or have migrated this best-guess becomes unpredictable and markers may be misinterpreted. This can sometimes be handled by omitting markers.

Computation of stem motions

When the markers have been correctly identified and screened for looseness they can be used to compute the relative position of the rigid bodies pairwise. In this form of study, the bone tissue (femur) should be considered the reference and stem motions relative the bone is measured. When compared to previous measurements on the same patient this method will make it possible to gauge whether there has been a change in positioning and orientation of the rigid bodies relative to each other. The change in position are described as translations and rotations. Translations are the shift in relative position of the computed geometrical center of the rigid body defined by the markers (x lateral-medial, y distal-proximal, z posterior-anterior) and rotation is the change of rotation in the two bodies relative to each other. In short, the rotation is described by three angles each describing rotation around one axis in the same three-dimensional coordinate system as the translations.

Precision and accuracy

The precision (smallest detectable change of position) and accuracy (measuring error) of RSA measurements may vary with implementation. To assess the precision and accuracy of an implementation you would need to compare it to a method of significantly better resolution. Testing of precision or repeatability is performed by use of so called double examinations of the same patient. When performed within a small time frame, repeated measurements should show no change and thus changes detected can be attributed to imperfect measuring. Accuracy is typically 0.25 mm (precision 0.05 mm 95% CI) for translations and 0.7 degrees (precision 0.5 degrees 95% CI) for rotations for measurements comparable to the ones in this study (Onsten, Carlsson, & Besjakov, 1998). This is around ten times the precision of conventional radiology (Malchau, Karrholm, Wang, & Herberts, 1995).

Radiographic evaluation

In order to systemize the radiographic evaluation of loosening of stems the widely accepted Gruen zones (regions) were used. These zones were described by Gruen for frontal views (zone 1-7) (Gruen, McNeice, & Amstutz, 1979). Later, a corresponding system for the lateral view (zone 8-14) has been adopted.

The evaluation required a database to be constructed consisting of the latest pictures available of the stem as well as the earliest postoperative pictures available. For each stem, an AP pelvic view, an AP hip view and cross-table lateral view were gathered. The total database for this study consisted of more than 2000 images. Each image was divided into Gruen regions. Regions (zones) 1-7 are numbered from later-proximal (region 1) surrounding the stem ending up medial-proximal with region 7. Thus, region 1 starts where the stem meets the femur and contains the greater trochanter. Region 7 contains the proximal half of the lesser trochanter.

The division is performed by drawing a line through the lesser trochanter perpendicular to the lateral side of the stem. A second line roughly parallel to the first is drawn at the very tip of the stem. Zone 4 is distal from this line. A third line is drawn between equidistantly from the first two lines forming the last four Gruen zones. A similar division is made for the lateral view and the zones are numbered 8 to 14 where 8 is anterior and 14 is posterior.

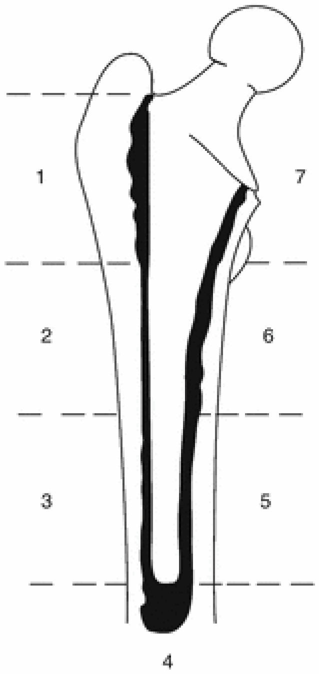

Figure 1 Gruen zones in a coronary view. Sectioning into Gruen zones is used in order to systemize the radiographic analysis. Parallel lines are drawn across the trochanter minor and at the tip of the stem. A third line is drawn half-way between the first two. The resulting zones are numbered laterally to medially from 1-7. Analogously, seven zones named 8-14 are created for the lateral view.

Each zone is scored for loosening between stem and cement (yes/no). Loosening between cement and bone and judged on a scale from 0-3 (0 = none, 1 < 50%, 2 > 50%, 3= 100%) and a total percentage is calculated for the view (0-100%). For each view the largest osteolysis (if any) was measured and recorded.

Radiologically loose

The final definition of radiographic failure was osteolyses larger than 4x10mm in Gruen regions 2-6 or a complete radiolucent line between the cement and the bone (Harris, McCarthy, & O'Neill, 1982).

Figure 2. This is an example of a PA hip projection image of a hip arthroplasty. The tantalum-pellets used for the RSA measurements are clearly visible in the bone as well as the press-fitted towers on the stem.

Ethics

All studies were conducted in patients undergoing hip replacement. To follow prosthesis movement and wear follow-up at regular intervals using stereoradiographs and conventional radiographs. After data matching with the patient registry the data was depersonalized. Even if this study, as such, not will incur additional clinical inspections or monitoring and even though ethical approvals has been obtained for each separate study included, an ethical approval for this combined evaluation was obtained from the regional ethical review board in Gothenburg (2016-01-27, nr 003-16). The original studies had consent from patients.

Patients and methods

The project is based on data from five completed/ongoing studies with the first starting in 1996. All patients underwent total hip surgery with a Spectron EF Primary stem. Data included observations up until November 30th 2015. The operations were conducted at Mölndal Hospital and Sahlgrenska Hospital. Data were collected according to the individual protocol for each study and complementary information was obtained from the case records. Data was deidentified by removing the identification number and each operation was assigned a serial number. The database was saved after the end of the project to be used in future research.

Inclusion criteria

The condition for inclusion was presence of RSA data at the 2 years follow up. Cases revised due to infection were excluded.

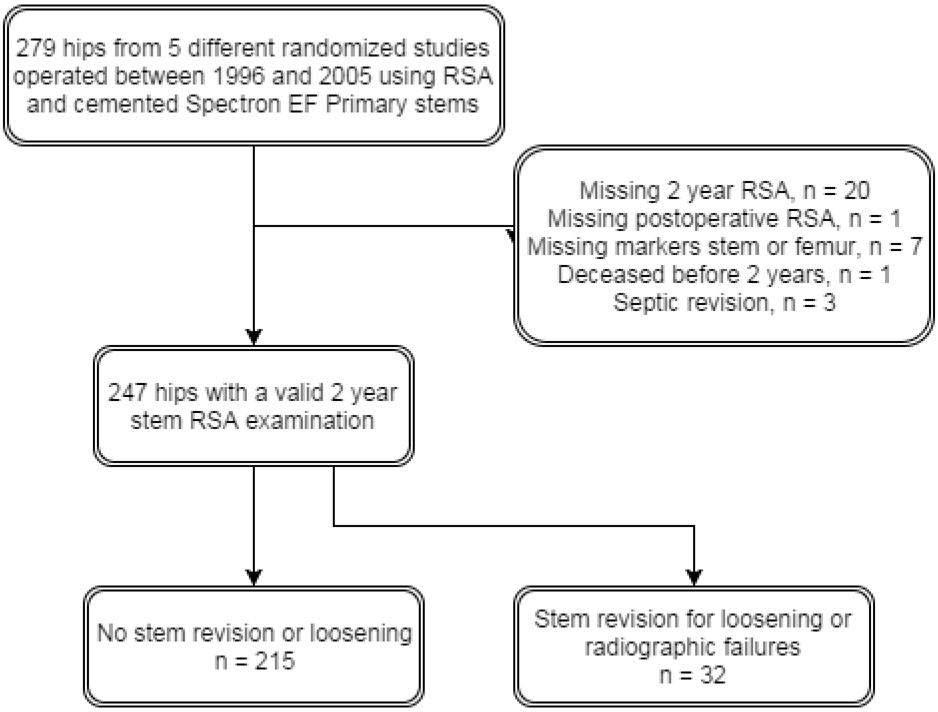

Figure 3 Flow chart showing the inclusion criteria for this study

Student's t-test and non-parametric tests showed no significant differences in regards to these variables between the group of excluded cases and the group of included cases.

Inclusion of dual stems

In total 38 patients with bilateral operations were included. It could be argued that this would lead to skewed results, but exclusion of the second hip did not alter our main outcomes.

Case analysis

In total, there were 247 cases included. Until November 30th 2015, 27 of 247 stems had been revised. Another 5 were found to be radiographically loose but have not yet been revised.

Variable analysis

Important variables are presented in table form.

Table 1 Variable overview. This table was originally included in the paper "Early Subsidence Predicts Failure of a Shape-closed Cemented Femoral Stem. Radiostereometric Studies of 247 Hips".

	Non-failed stems N=215	Failed stems N=32	All included N=247
Age, years (*median, range*)	62 (29 - 80)	57.5 (34 - 75)	62 (29 - 80)
Sex (Male/female), (*numbers*)	69 / 146	17 / 15	86 / 161
Diagnosis (*numbers*)			
Primary osteoarthritis	164	25	189
Secondary osteoarthritis	40	6	46
Subcapital femoral neck fracture	11	1	12
Stem size (*numbers*)			
1	46	19	65
2	100	12	112
3+	67	1	68
Missing	2	0	2
Femoral offset (*numbers*)			
High	40	13	53
Normal	174	19	193
Missing	1	0	1

Demographic variables

It can be noted that the study contains a disproportionate amount of women. Diagnosis was included as reference information but is not used in the analysis.

Results

Cemented stems subside over time

At a glance it looks like the cemented Spectron stems subside over time. This seems especially clear for the group of failed stems.

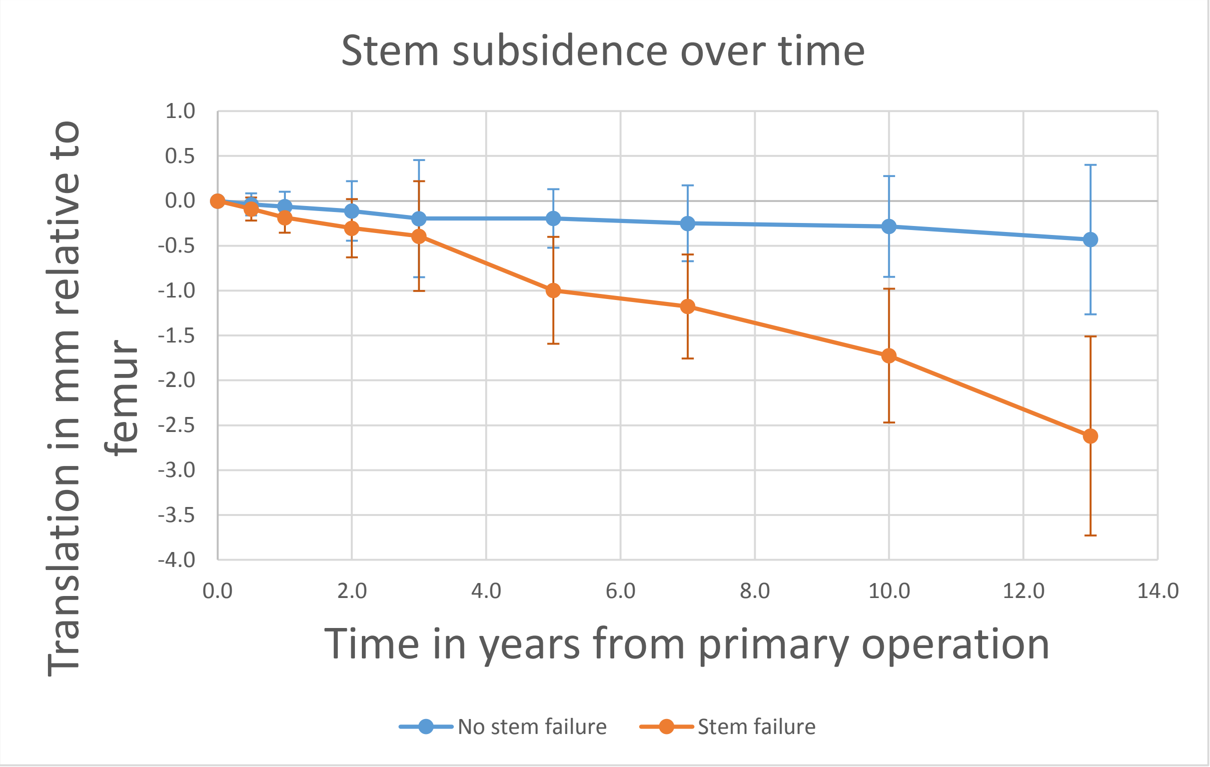

Figure 4 Stem subsidence over time. The graph shows the mean vertical movement over time of the stems relative to the femur with 95% confidence intervals. Data is grouped into failed stems and non-failed stems. The group of failed stems is smaller resulting in notably larger confidence intervals.

In order to prove this trend statistically we used a Wilcoxon signed-rank test, which is a paired difference test, to investigate the y-axis translation. The test compares the mean ranks of two groups of linked data. By systematically performing a pairwise comparison between each follow-up and the previous one we are able to judge whether there is a statistical trend.

Table 2 Wilcoxon signed ranks tests. In order to statistically confirm the movements shown in Figure 4 wilcoxon signed ranks tests were performed in order to show statistically significant mean movement between follow-ups. After year 12/13 the sample sizes become too small for analysis.

Failed stems			
	Year 5 and 7 N = 23	Year 7 and 10 N = 16	Year 10 and 12/13 N = 10
Significant signed difference	Yes	Yes	Yes
P-value	0.005	0.001	<0.0005
Non-failed stems			
	Year 5 and 7 N = 173	Year 7 and 10 N = 151	Year 10 and 12/13 N = 109
Significant signed difference	Yes	Yes	Yes
P-value	<0.0005	<0.0005	<0.0005

The tests show that there is a continuous subsidence of the stem between each follow up occasion up to 12 to 13 years after the operation in both groups.

Survival analysis

The 10-year stem survival was 93.8 percent (95 percent CI 89.7% - 96.3%) and the 15-year survival decreased to 86.3 percent (95 percent CI 81.3% – 91.3%). The corresponding survival rate using stem revision as endpoint was slightly higher at 88.0 percent (95 percent CI 83 – 92). A Kaplan-Meier survival curve with end-point stem failure for all 247 included cases with 82 hips remaining at 15 years is shown below.

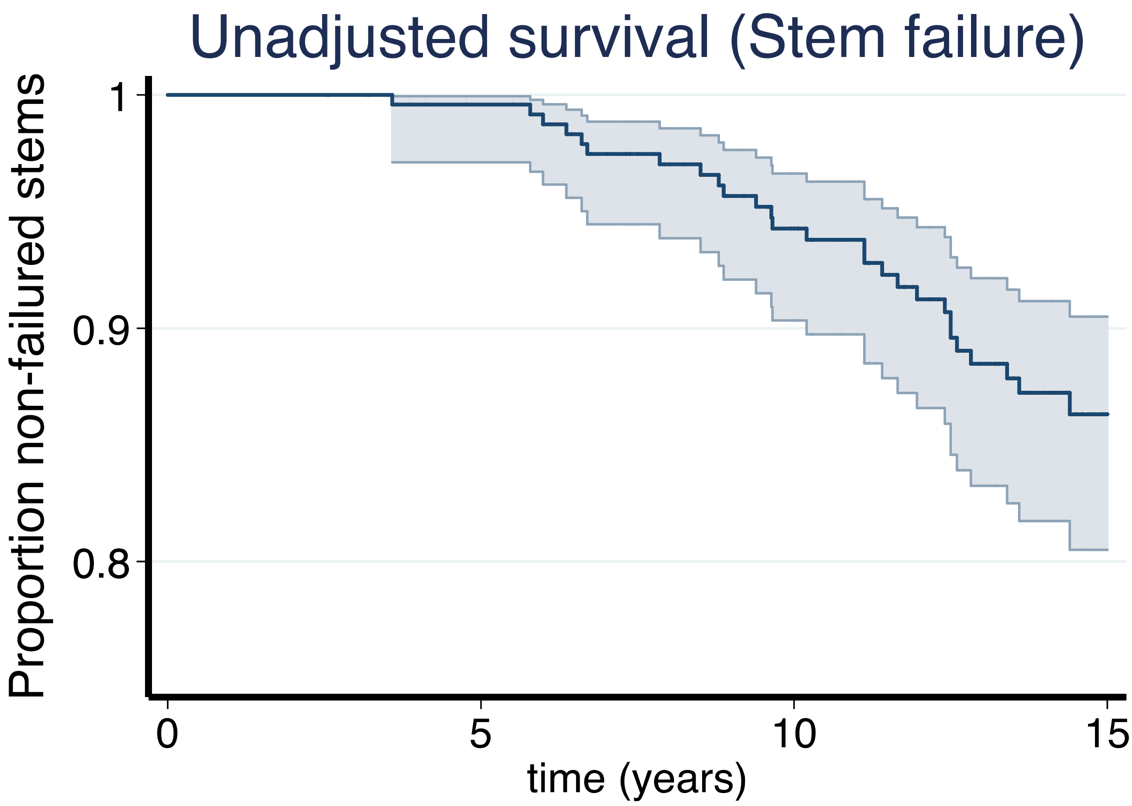

Figure 5 Kaplan/Mayer survival graph. Shows the proportion of non-failed stems over time with a 95% confidence interval.

Regression analysis

Previous knowledge indicates increased risk of loosening when stem subsidence exceeded 0.15 mm at 2 years (van der Voort et al., 2015). In the regression analysis we used subsidence at 2 years as a continuous variable. In an additional analysis we used it as a dichotomized variable (>0.15mm/≤0.15 mm).

Early micro motion increases the risk of later loosening

The analysis shows that each mm of subsidence at 2 years meant the risk of later loosening increased 5.7 times ($p < 0.001$). If the subsidence exceeded the risk-value of 0.15mm at two years, it increased the risk of later loosening 5.2 times ($p < 0.001$).

Stem size, off-set and gender are factors for later loosening

Small stem size (size 1) increased the risk of later failure 7.8 times (7.9 times when using the risk value) compared to stem size 2. For stem sizes 3 or bigger the risk decreased further compared to size 2 (Hazard ratio = 0.06 95 percent CI 0.004 – 0.80). We believe that this can be explained by the smaller load-bearing surface causing a larger focal pressure between stem and cement.

High offset increased the risk of later loosening by 3.2 times (95 percent CI 1.5-7.0). This may be caused by the higher off-set resulting in a longer lever causing increased strain.

Male gender was also associated with increased the risk of later loosening (male/female HR 6.5 95 percent CI 3.0 -16). One possible explanation is that some men have narrow femoral canals. In these cases, it would be natural to choose a smaller sized stem. It is possible that the explanation for the increased risk associated with male gender I due to a higher prevalence of smaller stems in this group.

Discussion

We found that the stem survival in our material of Spectron EF Primary stems was about 5 percent lower than in the Swedish Hip Arthroplasty Register including all kinds of cemented stems (88 versus 94 percent using stem revision due to loosening as endpoint). This difference becomes more pronounced if you compare to the two most frequently used cemented stems in Sweden; the Lubinus SP 2 stem and the Exeter polished stem. Data in the Swedish hip register show a stem survival of 96.2% ± 0.3% for the Lubinus stem and 95.9% ± 0.3% for the polished Exeter stem after 15 years with stem revision due to loosening as endpoint.

These discrepancies can most probably be attributed to the inferior performance of the Spectron EF Primary stem. Another reason for this discrepancy could be that our cases were followed and monitored so closely, which probably contributed to an earlier decision about revision to avoid extensive bone loss.

A lot of the Spectron EF primaries poor performance seems to be linked to the smaller stem sizes and it is possible that a more liberal use of larger stem sizes would have given different and better results.

Since patients were followed continuously we could demonstrate that RSA technology can be used to predict clinical problems also for implants where the loosening process is initiated in terms of debonding of the stem from the cement mantle. Information is obtained about the mechanical loosening process at the micro level and whether this information can be used to predict loosening at an early stage. If not addressed in time, migration and loosening can lead to extensive bone destruction which makes a reoperation complicated and impairs outcome after surgery (Howie et al., 1998).

A well cemented stem should have a lifespan of at least 10 years for at least 95% of the patients (Breusch & Malchau, 2005). This means that it could take a long time to evaluate new designs. The risk value analysis after two years is important as it allows us to evaluate the quality of a new stem design already after two years based on micro movements (van der Voort et al., 2015). In the case of the Spectron EF primary this could have made a difference in how it was used.

The study is based on a uniquely large material with a long follow-up time. RSA is considered the golden standard within the field and can be used to detect even very small changes in position reliably (Valstar et al., 2005).

Possible weaknesses in the study is that it uses a combined material from several studies. There is always a risk of there being systematic differences between the materials, for example the different studies used different kinds of cement and mixing technique as well as involving different operators, sometimes using different techniques.

There is an obvious imbalance between participating men and women with more than twice the number of women. A totally random sample from the population of patients who have undergone THA would be expected to show a more even distribution but it is difficult to say how this may have affected the outcome.

The data collected and analyzed during the course of this thesis work can be used for further analysis. This essay focusing on translations along the y-axis but the data collected also includes other translational data as well as rotational. This was later done in a separate publication. The could also be possible to analyze the performance of different cement types as well as analyzing the impact of the operator.

Populärvetenskaplig sammanfattning

Höftleden består av lårbenets rundade huvud som kan vrida sig i en skål i höftbenet. Vid en total höftplastik ersätts patientens led med en konstgjord led. Ledhuvudet på lårbenet sågas av och den övre ihåliga rörformade delen av lårbenet gröps ur ytterligare för att få plats med protesstammen vars ena ände är en ny ledkula. Stammens nedre ände kilas ner i lårbenet och fästs. I denna uppsats sker infästningen med hjälp av cement. I höftbenet görs motsvarande för att skapa en ny ledskål som passar den nya ledkulan.

Samtliga patienter i denna studie är opererade med cementerade stammar vid namn Spectron EF Primary. Spectron EF stammar användes till totala höftplastiker i Sverige mellan 1990 och 2010. 1994 gjorde man förändringar i designen och införde bland annat mindre storlekar. Den omdesignade stammen fick namnet Spectron EF Primary. I samband med detta startades flera studier med radiostereometrisk (RSA beskrivs nedan) uppföljning för att utvärdera om förändringarna blivit lyckade. Denna uppsats använder sig av materialet från fem av dessa undersökningar som genomförts med samma teknik på patienter opererade på Mölndals sjukhus och Sahlgrenska sjukhuset mellan 1995 och 2005. Totalt ingick 279 patienter.

RSA kan användas för att se om protesstammen sitter fast eller rör sig och kan upptäcka även mycket små förflyttningar. Det fungerar så att man i samband med operationen opererar in små kulor som syns väl på röntgen i benvävnaden. Det sitter även kulor fast i stammen. Genom att ta röntgenbilder från två olika riktningar kan man sedan mäta kulornas position i förhållande till varandra mycket exakt och upptäcka även mycket små förflyttningar.

Alla patienter har undersökts dels direkt efter operation och dels efter 6 månader, 1 år, 2 år, 3 år, 5 år, 7 år, 10 år, 12 år (ibland 13 år), 15 år och 17 år. Undersökningarna pågår fortfarande enligt detta schema. Genom att ta reda på vilka patienter som fortfarande har kvar sina proteser i ursprungligt skick och genom att granska röntgenbilder har vi kunnat ta reda på vilka som har lossnat och vilka som fortfarande är i gott skick.

Vi har kunnat konstatera att cementerade stammar fortsätter att sjunka ner i lårbenet långsamt, fortfarande efter så mycket som 12 år och vi tror att de fortsätter sjunka även efter detta.

Vi ser att små storlekar på proteser löper större risk för senare lossning. Vi tror att detta kan bero på att en mindre protesstorlek gör att hela trycket fördelar sig på en mindre yta där stammen fäster i lårbenet. Även manligt kön ger en ökad risk för lossning och vi tror att detta kan bero på att män har trängre märghåla i lårbenet än kvinnor vilket kan ha gjort att man valt mindre storlekar för män, trots att män över lag är större och tyngre än kvinnor.

Det visar sig att proteser som börjar röra sig tidigt efter operation löper en högre risk att lossna senare. Vi tror därför att man skulle kunna utvärdera designförändringar så snart som efter ett eller två år med hjälp av RSA-teknik och inte behöva vänta på att de verkligen lossnar vilket annars är alternativet.

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