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THE INFLUENCE OF FEMORAL HEAD DIAMETER TO THE OUTCOME AFTER TOTAL HIP REPLACEMENT

Kaunas 2007
Doctoral dissertation was prepared at Kaunas University of Medicine during the period 2002–2007. Dissertation is defended extramurally.

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ABBREVIATIONS

CoCr – Cobalt Chromium
CRR – cumulative revision rates
FR - femoral neck fractures
LT- Lithuania
OA - osteoarthritis
PE - polyethylene
RA - rheumatoid arthritis
SE – Sweden
THA – total hip arthroplasty
UCLA - University of California Los Angeles
UHMWPE – ultrahigh molecular weight polyethylene
US – Ultrasound
1. INTRODUCTION

The cemented total hip arthroplasty (THA) was introduced in 1961 worldwide [1]. Since then total joint replacement has become widely recognized as one of the most cost-effective intervention in medicine. The effects of THA in terms of reduction of pain and improvement of function and health related quality of life is well documented in literature [2, 3]. Worldwide is more than 1.000.000 patients treated with a hip replacement annually [4]. Since 1991 THA was started as a routine surgical procedure in Lithuania. Now, approximately 2500 hip replacements are performed annually. The results have improved over time, as reflected by relative decrease of clinical failures requiring reoperation. This decrease is associated with improved quality of the implant and development of surgical technique. Survival rates of 90 to 95% after 10 years and 80 to 90% after 20 years are reported especially among elderly patients [5, 6]. In younger patients the results are inferior [7, 5].

Aseptic loosening is the major complication and causes more than 85% of the revisions in hips in Lithuania [8]. The etiology of aseptic loosening is multifactorial, involving both mechanical and biological processes. Socket and stem micromotion and polyethylene wear are important factors that influence the long term durability of THA’s [9-12]. The expected annual wear of polyethylene (PE) cups is approximately 0.1mm [13, 14]. This means that billions of submicron-sized wear particles are released into the hip joint [13-15]. These particles induce inflammatory process in the THA hip and have been recognized as a major reason for osteolysis and subsequent failure of the prosthetic hip[13-15]. It has been recognized that besides other factors femoral head size significantly influences wear. Larger diameter femoral head is associated with increased volumetric wear in metal-PE THA [16, 17]. You would expect that the differences eventually would show up in different cumulative revision rates (CRR) for different head sizes. However few reports in the literature analyzed survival rates in THA with different diameter femoral heads and did not find a significant difference when followed up to 12 years [18-19]. It is still unknown if a longer-term follow-up would reveal differences in CRR depending on head size. Our aim was to analyze cumulative revision rates in THA in order to investigate if a follow-up up to 21 years would reveal differences in CRR depending on head size.

PE particles induced inflammatory process results prosthetic hip effusion and surrounding soft tissues inflammatory reaction [20, 21]. How the diameter of the femoral head and associated volumetric polyethylene wear would affect hip joint effusion after THA is still unknown. We measured polyethylene wear and sonographic “capsular distance” in THA hips with 28 and 32 mm femoral heads.

How surgical implantation technique and experience in THA surgery would affect outcome has achieved increased attention in the literature recently. That surgical THA experience matters
has been reported by Marston et al. who analyzed the differences in revision rates between experienced and trainee surgeons and found it significant [19]. It has been stated that the risk of aseptic loosening is affected by the quality of the initial fixation [22]. It can be argued that surgical technique and surgeon’s experience affect the quality of the initial fixation and thus also the outcome. We analyzed the cumulative revision rate after the introduction of the ScanHip THA in Lithuania, without previous experience in THA, compared with that of the introduction of the same implant in Sweden, which had long experience with this type of surgery

1.1 Aim of the study

To analyze if a femoral head size, volumetric polyethylene wear and surgical technique affects outcome after total hip replacement.

1.2 Tasks of the study

1. To analyze cumulative revision rates in total hip arthroplasty with 22 and 32mm femoral heads performed in Lund University Hospital and followed from 9-21 years.
2. To compare cumulative revision rates after total hip replacement in performed in Klaipeda in 1991-2001 to that in Lund in 1983-1993 and both followed for a 14 years to analyze outcome depended on surgical technique and experience in such type of the surgery.
3. To analyze polyethylene wear depended on femoral head size and correlate with patient’s activity level, body mass index, and age and cup inclination angle.
4. To analyze hip joint effusion/synovitis i.e. “capsular distance” depended on femoral head size.

1.3 Actuality and originality of the study

To our knowledge there are no reports in the literature analyzing outcome after THA depended on femoral head size then followed up to 21 years. The longest follow-up reported then comparing cumulative revision rates with 2 different diameter femoral heads was up to 12 years and did not show any difference in CRR depended on head size [18, 19]. Analyzing if longer follow up with 2 different diameter femoral heads will reveal any changes in cumulative revision rates is of interest.

To our knowledge there is no reports on the literature analyzing cumulative revision rates then comparing two different countries with different experience in prosthetic surgery when the same
type of implant used in both countries from the introduction. Precise monitoring after the introduction of a new type of surgery is important because such registration and follow-up allow for early identification of problems. It also allows comparing outcome results with other more centers. Thus, we believe our findings will stimulate to analyze our failures and improve outcome after THA in the future.

There are no reports in the literature analyzing prosthetic hip joint effusion when comparing two different diameter femoral heads in THA hips with no radiographic signs of loosening. The theory that increased joint effusion may play a role in development of aseptic loosening as a route for wear debris transportation has gained increased attention in the literature recently [23]. The relation between polyethylene particles, increased effusion and its role in development of aseptic loosening in THA hip is unknown.

### 1.4 Actuality and practical value of the study

After we summarize our finding practical recommendation regarding size of the femoral head will be provided to orthopedic surgeons working in THA. The knowledge about affect of the femoral head size and associated volumetric wear on hip joint effusion will provide us better understanding of wear debris transportation process in THA hip. It is always hard to determine if the surgical technique and experience outcome after THA. However our study showed that continuous learning and use of modern surgical techniques will benefit outcome after THA.
2. LITERATURE OVERVIEW

2.1 Polyethylene particles and osteolysis

Polyethylene particles appearing as a result of prosthetic hip metal on PE articulation are the most investigated particles and several authors have discussed their role in the aseptic loosening process. Howie et al. [24] presented an animal study in which polyethylene particles alone could cause bone resorption in the absence of motion and infection. Later studies did not confirm these results [25, 26] these results.

As a result of metal femoral head and polyethylene cup articulation appeared PE particles are phagocytosed by macrophages that act two major ways in the bone remodeling process. First they release cytokines involved in bone remodeling such as Prostaglandin E2, Interleukin 1 alfa and beta, Interleukin 6 and Tumor necrosis factor alfa. These cytokines modulate osteoblast and osteoclast activity, which in turn increases the osteolysis [25, 27]. Secondly macrophages may differentiate into osteoclasts after stimulation of PE-particles [28]. Several animal studies have addressed the question of whether PE-particles alone are responsible for bone resorption around implants.

Dowd et al. [29] found significant correlation between PE wear and osteolysis in human study. When investigating Charnley arthroplasties, Sochart [30] found that wear linear wear rates below 0.1 mm a year resulted in more than 90% survival of the implant whereas annual wear greater than 0.2 mm resulted in failure of all implants within 25 years. These two studies imply that wear rate and thus PE particles may play a role in aseptic loosening process. However how polyethylene wear debris influences the prosthetic joint it is still poorly understood. It is hard to assume that polyethylene particles are the main cause of osteolysis and subsequent aseptic implant loosening. Other factors with a more direct link to mechanical load must be involved. One such factor, the increased static and dynamic fluid pressure in the prosthetic hip joint, has been suggested [23, 31]

2.2 Survival and diameter of the femoral head

Since the early days of THA the choice of the proper diameter of the femoral head in metal on PE articulation has been debated with respect to its effect on wear.

The volume of wear debris depends on the size of the femoral head. The larger the head, the greater the sliding distance, and thus also the amount of wear debris generated [16, 32]. An increase of 1mm in head radius increases the rate of volumetric wear by 5.1 mm$^3$ per year [33]. In a study that included a subset of patients in our material, Kesteris et al. [32] measured polyethylene wear
and found that 32mm was associated with 3 times increased volumetric and linear wear as compared with 22mm femoral head.

The most widely accepted theory explaining aseptic loosening of THA is that of polyethylene particles induced osteolysis [9-11]. Thus you would expect that the differences eventually would show up in different cumulative revision rates for different head sizes. However, when following 1,660 patients for 2-12 years, Kesteris et al. 1998 did not find a significant difference between 22 and 32 mm heads. Similarly, Marston et al. (1996) followed 413 THA patients for 5 to 10 years and did not find that survival was affected by head size (log-rank test \( p=0.77 \)).

Our aim was to investigate if a longer-term follow-up would reveal differences in CRR depending on head size.

### 2.3 Prosthetic loosening

Failure of prosthetic hip joints is most frequently due to loosening of their components. Many new materials have been designed, new biomaterials developed and surgical technique improved. These changes have gradually led to considerable improvements and longevity of prosthetic hips [5]. Nevertheless, loosening remains the main problem in prosthetic hip surgery. Aseptic loosening of the cup and the stem is defined on the plain radiographs of prosthetic hip i.e. migration of the component and cement and complete 100 per cent radiolucent zone around the cement mantle or in stem-cement interface, (Figure 1) [34].

![Figure 1. Aseptic loosening of the prosthesis](image)
Clinically aseptic loosening of the prosthesis is accompanied with mild or severe pain, walking disability.

2.4 Assessment of long term results

Survival analysis, using Kaplan-Meier’s or Life table method has been adapted to calculate revision and survival rates of prosthetic joints, and it is now widely used for reporting long-term results of THA. National registers of THA in Sweden and Norway have proven to be effective instruments in assessing long-term results [5, 35]. Since large patient cohorts are studied, the results of small differences in implant design, methods of fixation and surgical techniques can be detected. The knowledge of confidence intervals and of definitions of end-points used is important for the correct interpretation of the results [36]. The Cox regression model is used to adjust survival results to other variables i.e. age, gender, implant features, surgical technique differences.

Other ways of obtaining long term results are retrospective or prospective studies, including both clinical and radiological analysis. The main advantage of such studies is that it permits collection and analysis of more detailed and precise information than nation-wide survival studies. The disadvantages are that such studies usually include only smaller groups of patients and are limited to one department.

2.5 The end – point definition

Although commonly used, the terms success and failure are difficult to define in the context of surgical intervention, where the primary objectives of the treatment can vary. Thus, postoperative results for a given patient might be called a success, while for another it would be a failure. Even seemingly obvious failures (pain, loosening, instability, wear) may be low grade and not easily distinguished from normal postoperative condition. Thus, depending on definition of failure and the interval of follow-up, it can be difficult to decide if and when the end-point has been reached. The reason why revision arthroplasty has become the most widely accepted end-point is that unlike pain, radiological signs of loosening and range of motion or health scores it can be hardly disputed if and when revision occurred.

In spite of being easy to define, using revision as an end-point is not without problems, as not all patients need to offered surgery or can sustain surgery due to health conditions. Further, even when revision is used as the end-point indicating failure, there is a variation in the literature regarding if all or only specific revisions should be used as the end point. Some authors do not include revisions for infection in results [37-39], claiming that they are not related to durability of the implant. Similarly, revisions for other than plain mechanical reasons (e.g. dislocation of the hip prosthesis) are sometimes excluded from survival analysis [5].
2.6 Evaluation of linear wear

Linear wear can be measured in two ways: indirectly, by measuring the penetration depth of the femoral head on radiographs or directly on the cups extracted during revision surgery. Indirect measurements can be done in two different ways, i.e. manual and computer assisted. When you measure wear in manual way on plain radiographs ruler, caliper and concentric ring templates is needed. The first on-film measuring method was described by Charnley and Cupic [40]. It is a uni-radiographic method in which linear wear is defined as half of the difference between the shortest and greatest distance from the center of the femoral head to the contrast ring of the cup. This method, shown to be incorrect when the two distances were not collinear [41], but subsequently it was improved by Hall et al. [42]. They analyzed retrieved cups and measured the direction of the wear and wear angle and proposed to define linear wear as the difference between the measured radius of the cup and the shortest distance from the center of the femoral head to the back surface of the cup. Wear was calculated with the formula: \( w = r-a \). Where “\( w \)” is linear wear, “\( r \)” the radius of the cup measured on the radiograph and “\( a \)” is the shortest distance from the center of the femoral head to the back surface of the cup (Figure 2).

![Figure 2. Measurements of linear PE wear.](image)

To obtain more accurate measurements of the linear wear, the duo-radiographic measuring method was introduced by Charnley and Halley and Griffith et al. [43, 44]. It was later modified by Livermore [16]. It consisted of the difference between the shortest distance from the center of the femoral head to the back surface of the cup and the midpoint of the cup to the back surface of the cup. Several studies have shown a good correlation between radiographically measured wear and true wear, measured directly on extracted cups [16, 45], although usually the radiographic measurements tend to underestimate the true wear [46]. A number of potential sources of error caused by the position of the cup and method of radiographic examination have been reported [46].
### 2.7 Methods of calculating volumetric wear

When particle-induced osteolysis is discussed, it is useful to use the volume of wear debris as a variable. The simplest calculation of the volume of wear is the circular cylinder approach by Charnley et al. [47], he used the formula for the volume of a cylinder: $v = \pi r^2 w$ in with “$v$” – volumetric wear, “$r$” is the radius of the femoral head and “$w$” is linear wear. The femoral head is assumed to bore a linear trace perpendicular to the entrance plane of the cup (Figure 3, curved dotted area).

![Figure 3. Volume calculation for wear perpendicular to the entrance plane](image)

This method would be adequate for a wear perpendicular to the entrance plane of the cup, but it has been shown that the direction of wear is primarily cranial and rather lateral than medial and pure circular cylindrical wear rarely occurs [42]. Therefore the wear volume is systematically overestimated with the Charnley’s [47] formula. With increasing interest in wear and wear related problems, there was the need for a formula that accounts for the direction of wear (Table 1).

**Table 1. Different formulas used for calculation of volumetric PE wear.**

<table>
<thead>
<tr>
<th>Formula</th>
<th>Formula</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Charnley et al. [47]</td>
<td>$V = \pi \cdot r^2 d$</td>
<td>Linear wear, femoral head perpendicular to entrance plane</td>
</tr>
<tr>
<td>2. Kabo et al. [48]</td>
<td>$V_{Kabo} = \pi \cdot r^2 d - r^2 \left[ d \cos^{-1} \left( \frac{d \tan (\beta)}{r} \right) - \sqrt{r^2 \tan (\beta) - d^2 + \frac{r^2}{\tan (\beta)}} \right]$</td>
<td>Linear wear, direction not perpendicular to entrance plane</td>
</tr>
<tr>
<td>3. Hall et al. [49]</td>
<td>$V = V_{Kabo} + \frac{2 rfd}{\cos \beta}$</td>
<td>Linear wear with direction correction</td>
</tr>
<tr>
<td>4. Kosak et al. [50]</td>
<td>$V_{Kosak} = \frac{r^3 d}{2} (\pi + \pi \sin \beta)$</td>
<td>Linear wear, direction not perpendicular to entrance plane</td>
</tr>
<tr>
<td>5. Hashimoto [51]</td>
<td>$V_{Hashimoto} = \frac{r^3 d}{2} (\pi + 2 \beta + \sin(2\beta))$</td>
<td>Linear wear with direction correction</td>
</tr>
<tr>
<td>6. Kadaba and Ramakrishnan (unpublished data)</td>
<td>$V = \frac{r^3 d}{2} \left( \pi + \pi \sin \beta + \frac{d}{r} \sin(2\beta) \right)$</td>
<td>Linear wear with direction correction</td>
</tr>
</tbody>
</table>
The formula of Kabo et al. [48] was the first directing that problem, it was frequently used without limitations. Hall et al. [49] noted that the formula of Kabo underestimated the true wear volume. But they accepted the (wrong) concept of Kabo et al. and added a (mathematically incorrect) correction term, accounting for a cylindrical bore in the entrance plane of some cups. Derbyshire [50] showed that Kabo et al. used a wrong geometrical concept of wear: Kabo et al. are only correct for $\beta = 0$ (Figure 4) which is never the true scenario.

Kosak et al. [51] developed a new formula (Table 1) for calculating wear volumes and found that their formula came closer to the fluid displacement measurements of retrieved cups as compared to calculations with the Kabo [48] formula. For our calculations we used Kadaba and Ramakrishnan formula as the most correct way of calculations of volumetric wear which take in to account the wear direction.

Direct measurements of extracted acetabular cups is practically the most accurate to determine the true penetration depth of the ultra high molecular weight polyethylene (UHMWPE) cups. The shadowgraph technique is one of the commonest methods [49]. A cast of socket bore is made, using a high definition silicone-based mass of methylmethacrylate. A profile of the cast is then measured in a shadowgraph apparatus, to obtain the linear wear value. The volumetric wear then can be calculated with an appropriate formula. Gravimetric analysis is another method for measuring wear volume directly on extracted cups [52]. The bore of the cup is filled with ethyl alcohol. The weight of the liquid is precisely measured and the value obtained is then transformed in to the volume.

None of these methods can determine how much of the measured deformity is due to creep of the polymer, and how much is due to wear. Isaac et al. [53] have shown that an average of 0.14mm of the total penetration depth during 10-year period can be ascribed to creep.

2.8 Diameter of the femoral head and wear parameters

The linear and volumetric wear differences in different diameter of femoral heads analyzed by number of authors are presented in (Table 2).
Table 2. Previously reported PE wear data with different diameters of femoral heads.

<table>
<thead>
<tr>
<th>Author</th>
<th>Head size (mm)</th>
<th>Linear wear rate (mm/yr)</th>
<th>Volumetric wear rate (mm³/yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charnley and Cupic [40]</td>
<td>22</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>Charnley and Halley [43]</td>
<td>22</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td>Scheier and Sandel [54]</td>
<td>32</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Griffith et al. [44]</td>
<td>22</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>Wroblewski [45]</td>
<td>22</td>
<td>0.21</td>
<td></td>
</tr>
<tr>
<td>Livermore et al. [16]</td>
<td>22</td>
<td>0.13</td>
<td>47.50</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>0.10</td>
<td>84.10</td>
</tr>
<tr>
<td>Callaghan et al. [55]</td>
<td>22</td>
<td>0.12</td>
<td>48.36</td>
</tr>
<tr>
<td>Kesteris et al. [32]</td>
<td>22</td>
<td>0.15</td>
<td>57.00</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>0.18</td>
<td>148.00</td>
</tr>
<tr>
<td>Eggli et al. [17]</td>
<td>22</td>
<td>0.12</td>
<td>44.6</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>0.16</td>
<td>125.9</td>
</tr>
</tbody>
</table>

The wide range of measurements reported suggests that other factors besides diameter of the femoral head may affect linear and volumetric wear. These factors can be divided in three groups i.e. implant related, surgeon related and patient related. Implant related factors possibly affecting wear of the PE are PE quality and sterilization, PE thickness, metal type for femoral head and polishing quality. Surgeon related factors i.e. cup inclination, abduction angles, medialization of the cup, stem positioning might also be related with PE wear. Patients weight, age, activity level can be called as patient related factors affecting wear of the PE.

2.9 Implant related factors affecting wear

Several authors analyzed if metal type and polishing technique of the femoral head would affect PE wear. Saikko et al. [56] analyzed ultra-high molecular weight polyethylene acetabular cups of 5 different total hip systems were worn on a new 5-station hip joint simulator. The cups articulated against modular metallic (stainless steel, Ti-6Al-4V, Co-Cr-Mo). Ti-6Al-4V heads showed lowest wear rates as compared with stainless steel and Co-Cr-Mo). To determine how femoral head characteristics will affect wear in well functioning hip Sychterz et al. [57] analyzed 24 prosthetic femoral heads retrieved out of the autopsy from previously well functioning hips. The Gross examination revealed that CoCr femoral heads had scratches all over. However he found no correlation between metal roughness and PE wear.

Gamma irradiation with 25 to 40 kGy in an air environment has been the industry standard PE sterilization technique since 1968. Gamma irradiation breaks polymer chains, creating reactive free radicals sites. The oxygen reacts with residual free radicals, generated by the radiation [58, 59]. These changes reduce the fracture strength and the resistance to wear [60]. Since 1995 almost all manufactures have changed to alternative sterilization techniques either by substitution of radiation
with ethylene oxide or gas plasma sterilization or by gamma radiation in a reduced oxygen environment.

Polyethylene thickness remains a factor affecting wear. Oonishi et al. [61] analyzed 112 patients at least 6 years after THA; they measured polyethylene wear with respect to PE thickness. The average wear rate of cups 7 and 8mm thick was about twice that of cups 10 and 11mm thick. On the whole, the thicker the cup, the lower was the linear wear rate measured. The same results they reported when analyzing volumetric wear of the PE [61]. Bartel et al. [62] in his finite-element study reported that the polyethylene thickness of more than eight millimeters should be maintained when possible due to reduced surface damage with increased polyethylene thickness.

2.10 Surgeon related factors affecting wear

PE wear is directly related to surgical implantation technique of the prosthesis. Wroblewski et al. [63] followed 1092 patients after THA clinically and radiologically. PE wear was measured for all patients, two groups were formed one with high linear wear rate >0.2mm/year, second <0.02mm/year. This wide separation between low and high wear groups was chosen to clarify variables affecting the wear rate. Analysis revealed factors associated with surgical technique affecting wear; i.e. valgus position of the stem p=0.023. Contrary pressurizing of the cup (p=0.07) and medialization of the cup (p=0.07) were approaching significance when analyzing factors affecting lower wear.

There are different reports analyzing correlation between cup inclination angle and PE wear rates. Kennedy et al [64] investigated 75 total hip arthroplasties at a 4-year minimum follow-up and reported that lower cup inclination angle had less osteolysis, less asymmetric polyethylene wear, and less acetabular component migration. Results of the Hirakawa et al. [65] study also suggest that a lower abduction angle of 40º is associated with better long-term results and fewer complications compared with an abduction angle of 45º or greater.

Some authors reported the best position of the acetabulum mathematically or biomechanically. Murray and O'Conner [66] hypothesized that the wear direction faces toward the perpendicular line of the axis of rotation (normally superolateral). They also hypothesized that superomedial femoral head penetration was attributable to creep because the penetration was in the same direction as that of the normal joint contact force. In the Hirakawa et al. [65] study, a lower cup abduction angle was associated with superior and medial femoral head penetration. Hips with a medial wear direction had a lower rate of revision when compared with hips with a superior and lateral direction of wear. These results suggested that medialized penetration of the acetabular cup was mostly creep as hypothesized by Murray and O’Connor [66]. The superior and lateral head
penetration combined with a higher abduction angle seemed to cause true polyethylene wear. Different results were reported by Goosen et al. [67]; he investigated the rate of polyethylene wear of a cementless acetabular component and found no relationship between the inclination angle of the acetabular component or femoral head orientation and the rate of wear.

2.11 Patients related factors affecting wear

Patient related variables such as age, gender, body mass index, physical activity level may affect the PE wear rates. It would seem logical that increased body mass index would cause more wear. However, clinical studies have not supported this [32, 42]. McClung et al. [68] analyzed the relation between body mass index and physical activity level and found that higher body mass index patients had lower activity level. Thus may explain why there were no relation between body mass index and PE wear. Contrary the level of physical activity showed to have an effect on PE wear rates. Feller et al. [69] analyzed 109 hips in 79 patients showed that patient activity level was the most significant variable among patient factors affecting sliding distance. Patients were grouped in to 5 different categories of activity level, and the results were compared with PE wear data determined radiographically. Higher activity patients were associated with higher PE wear rates. Devane and Horne [70] has also analyzed the PE wear in respect to patients activity level. They found that patients who were more active had a greater rate of volumetric wear than patients who were sedentary (133 mm$^3$ versus 95 mm$^3$; $p < 0.05$). Kim et al. [71] in randomized controlled study analyzed PE wear differences between CoCr and Zirconia femoral heads and effect of gender and age on wear rates. He found that in both the cobaltchromium and the zirconia head group, there was a significant relationship between polyethylene wear and the age of the patient ($p = 0.028$) and male gender ($p = 0.042$). Patients age and activity level have a direct correlations as usually activity level decreases with increasing patients age. If we assume that PE wear particles are inducing osteolysis and subsequent implant failure, thus repots in Swedish Hip Register [5] that higher survival rates correlates with older patients age is in concordance with findings that higher patients physical activity associated with increased PE wear rates.

2.12 Synovitis of prosthetic hip and wear

Aseptic loosening in total hip arthroplasty is described as a polyethylene particle-induced complex inflammatory process that results in bone resorption [11]. Exactly how polyethylene wear debris influences the prosthetic joint is still poorly understood. Previous animal studies except one were not able to prove that PE particles can induce osteolytic process on their own [24, 25, 26]. It is
hard to assume that polyethylene particles only are the main cause of osteolysis. Other factors with a more direct link to mechanical load must be involved. One such factor, the increased static and dynamic fluid pressure in the prosthetic hip joint, has been suggested [23, 31]. Kesteris et al. analyzed 48 THA hips sonographically and radiographically. He demonstrated a correlation between radiographic wear and loosening of the polyethylene cups and sonographically measured distance between the anterior capsule and the prosthetic femoral neck, i.e distension of the capsule, in cemented THA [20]. Furthermore Robertsson et al. [21] showed that capsular distance, i.e. “capsular distension” as measured with US was significantly increased in loose THA as compared to THA without any clinical or radiological signs of loosening, and that it correlated with increased intracapsular pressure. All these findings suggest that increased intracapsular distance i.e. increased synovitis of prosthetic hip may play a role in implant loosening mechanism after THA.

Though a seldom-used method in the examination of THA, sonography has proven valuable in diagnosing synovitis and infection [72, 73]. Laurell et al. [74] demonstrated a high correlation between US measurements of the capsular distance and those from MRI scans, and also demonstrated a good intra- and interobserver agreement in US measurements of the capsular distance of the hip in children.

### 2.13 Surgical experience and outcome

That surgical THA experience affects outcome has been reported by Marston et al. [19] who analyzed the differences in revision rates between experienced and trainee surgeons and found statistical significance (p=0.005). Fender et al. [75] analyzed the results of the Charnley THA, and found that the 5-year risk of revision was affected by the number of THA performed by each consultant. Their results were inversely proportional to the number of operations performed. The 5 year risk of revisions was 4% for the surgeons performing ≥ 60 operations/year while surgeons performing < 30 operations had 16% risk of revision. Espehaug et al. [76] investigated associations between the survival of total hip replacements, type of hospital and annual number of THA per hospital. The study was based on 39,505 primary THRs reported to the Norwegian Arthroplasty Register from 45 local (n 20,756), 15 central (n 12,455) and 10 university hospitals (n 6,294) during 1988-1996. Their study showed that University hospitals with high number of THA per institution but low annual number of THA per surgeon were associated with higher CRR. These inferior results authors related to single surgeon experience due to small THA numbers per surgeon and possibly heavier cases operated in University hospital. Kesteris et al. [18] analyzed 1,660 arthroplasties performed by 58 surgeons, with the number of operation varying from 1 to 313 per surgeon. 16 were experience hip surgeons who performed 67% of the arthroplasties. In his series
surgeon’s experience had no beneficial effect on the revision rates contrary then on other previously described series [19, 75, 76]. This difference can probably be explained by even quality of educational and postgraduate training system in Sweden. To our knowledge there is no reports in the literature analyzing if the introduction of new type of surgery and implant would affect outcome when compared with experienced in such type of surgery country. The main interest is will the initial learning process will affect outcome after THA.

2.14 Cement type and outcome

Bone cements are used for the fixation of artificial joints. The cements fill the free space between the prosthesis and the bone and constitute a very important zone. Owing to their optimal rigidity, the cements can evenly buffer the forces acting against the bone. The close connection between the cement and the bone as well as cement and the prosthesis leads to an optimal distribution of the stresses and interface strain energy. The transfer of the forces bone-to-implant and implant-to-bone is primary task of the bone cement. The ability to do so reliably for a long period of time is crucial for the long-term survival of the implant [77]. In the early phases of total hip replacement, surgery focus was on design of the femoral stem, and on bearing surfaces. There was less focus on different types of bone cement. Later, when aseptic loosening became a recognized problem and the term "bone cement disease" was introduced. The Swedish and Norwegian hip implant registers have shown that the type of cement is important for the performance of the hip implant and type of cement may in many ways be more important than the design of the prosthesis [5, 35]. Havelin et al.[78] analyzed survival rates after THA in 7922 patients operated with high, low viscosity bone cements and cold curing bone cement Boneloc. The prosthesis that had been implanted with high viscosity bone cement showed superior implant survival rates when compared with low viscosity (p<0.0001) and cold curing bone cement Boneloc (p<0.0001). The poor performance of low viscosity bone cements might in part be explained difficult handling characteristics of these cements [77]. However the differences between bone cement brands within high viscosity cement group must also be recognized. Espehaug et al. [79] have assessed the survival of 17,323 primary Charnley hip prostheses in patients with osteoarthritis based upon the type of cement used for the fixation of the implant. Three brands (CMW1-3, Palacos, Simplex) of high viscosity bone cement well known in worldwide marked were compared. A 10 year follow-up of the different cement brands used in Norway showed that the high viscosity cement CMW1 performed poorer than the other high viscosity cements Palacos and Simplex. A Charnley prosthesis implanted with CMW cement had a failure rate of 12% at 10 years, but only 5.9% when used with gentamicin-containing Palacos cement.
Systemic antibiotics are mixed in bone cements to prevent infection of the artificial joint. Gentamicin is usually used because it releases from bone cement over long period of time and is proven to be very effective in producing long-term high-level concentrations [80]. The concern of a biomechanically weaker bone cement due to added antibiotics does not have any clinical significance, at least not within 10 years [81]. Espehaug et al. [82] analyzed the 10,905 primary cemented total hip replacements, performed for osteoarthritis of the hip and reported to the Norwegian arthroplasty register between 1987 and 1995. The lowest rate of revision for infection was found among patients receiving antibiotic-containing cement plus systemic antibiotics (n = 5804). The revision rate for the 4586 patients receiving systemic antibiotics only was 4.3 times greater (95% CI 1.7 to 11.0, p = 0.001); in 239 with antibiotics in the bone cement only it was 6.3 times greater (CI 1.6 to 25.0, p = 0.003); and in the 276 who did not receive antibiotics it was by 11.5 times greater (CI 2.1 to 63.0, p = 0.002).

2.15 Modern cementing technique and outcome

Modern cementing technique aim is to improve the mechanical interlock between bone and cement in order to establish a durable interface. The use of distal plug, cement gun, pulsative lavage, vacuum mixing and cement pressurizing devices have been shown to significantly improve long-term results [83].

In first decade of cemented THA, cementing technique was poor. Irrigation of bone bed was limited and high viscosity bone cement was mixed and applied manually. The survival results from this decade were rather poor and soon became obvious that not only stem design but, in particular operative and cementing technique had to considered important factors influencing the outcome after THA [84, 85]. Since then the modern cementing technique started to develop (Table 3).

Table 3. Evolution of cementing techniques [83]

<table>
<thead>
<tr>
<th>First - generation</th>
<th>Second-Generation</th>
<th>Third - Generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited bone-bed preparation</td>
<td>Bone-bed preparation (irrigation/drying)</td>
<td>Thorough bone –bed preparation (pulsative lavage)</td>
</tr>
<tr>
<td>Unplugged femur</td>
<td>Distal cement restrictor (bone/plastic)</td>
<td>Improved distal cement restrictor</td>
</tr>
<tr>
<td>Stiff, doughy cement introduced by hand</td>
<td>Retrograde cement a application via cement gun</td>
<td>Retrograde cement application via cement gun</td>
</tr>
<tr>
<td>Digital pressurisation</td>
<td>Femoral and acetabular cement pressurization</td>
<td>Femoral pressuriser, acetabular pressuriser</td>
</tr>
<tr>
<td>Hand mixing of cement</td>
<td>Open atmosphere cement mixing by hand</td>
<td>Vacuum mixing/ stem centralizers/cement spacers</td>
</tr>
</tbody>
</table>

The aim of modern cementing technique is to improve the mechanical interlock between bone and cement in order to establish a durable interface. Acetabulum and stem pressurization and lavage
of cancellous bone have been identified the most significant factors with regards to improved cement interdigitation [84, 85]. Several clinical studies comparing patients before and after the introduction of modern cementing technique have confirmed their benefit of improved cement application techniques [86, 87]. The Swedish hip register has provided the most important evidence to support this relation. They analyzed the revision rate after THA and compared three periods of time, one with old cementing technique, second with early cementing technique and third with modern third-generation cementing technique used. Their finding was, that the use of distal plug, pulsative lavage, cement gun and proximal seal reduce the risk for revision by approximately 20% each [5].

2.16 Summary of literature overview

Summarizing this section we conclude that there are many studies in the literature analyzing outcome after THA. Most of the studies report that greater diameter metal femoral head when articulating with PE cup is associated with increased volumetric wear and osteolysis. When analyzing cumulative revision rates in THA with different diameter femoral heads it did not revealed significant difference when followed-up to 12 years.

The synovitis and it’s relation to wear of the PE has gained increased attention it the literature. The researches analyzed relations between intraarticular pressure, synovitis of prosthetic hip, wear and aseptic loosening after THA. Their findings that increased synovitis and increased intraarticular pressure was found in hips with aseptic loosening suggest that intraarticular fluid may play a role in development of aseptic loosening.

The role of surgical experience and surgical technique when analyzing outcome after THA has been debated. The results varied depended on country in which study was conducted.

In conclusion, sometimes 12 year follow-up after THA is not enough and extended follow-up is needed to reveal differences between implants. The correlation between femoral head diameter and synovitis in prosthetic hip must be analyzed. Surgical experience and surgical technique remains important issues for analysis when evaluating outcome after THA.
3. PATIENTS AND METHODS

We analyzed 1,720 Scan Hip Classic I THA implanted in 1,550 patients performed at Lund University Hospital, Sweden during 1983 to 1995. We compared cumulative revision rates in 22 and 32 mm diameter femoral heads with the same ScanHip femoral stem. The follow-up ranged from 9 to 21 years.

We analyzed 655 Scan Hip Classic I THA implanted in 582 patients at Klaipeda Hospital, Lithuania during 1991-2001 and compared cumulative revision rates to 932 Scan Hip Classic I THA implanted in 825 patients at Lund University Hospital, Sweden during 1983-1993. The patients were followed up to 14 years in both locations. ScanHip Classic I prosthesis was introduced in 1983 in Sweden and in 1991 in Lithuania. We analyzed the effect of experience on cumulative revision rates after THA. Lithuania had no previous experience in prosthetic surgery in 1991 contrary to Sweden, which had ample experience in total hip replacement, when this particular implant was introduced in both locations.

60 patients, a subset of survival study in Lithuania were randomly selected and called for review 10 years after THA. The effect of head size diameter on PE wear and synovitis was determined.

3.1 Survival study of THA with 32 and 22 mm femoral heads

3.1.1 Inclusion criteria

The patients admitted for elective total hip replacement surgery with three major diagnoses i.e. osteoarthritis (OA), femoral neck fractures (FR), rheumatoid arthritis (RA) in Lund University Hospital were included in the study. We included patients operated in 1983-1995 with the ScanHip Classic I femoral stem and ScanHip all polyethylene cup with was available in 22 and 32 mm diameter. The inclusion of patients was stopped in December 1995 because the use of particular implant was discontinued in Lund University Hospital. The choice of prosthetic head size was based only on the surgeon’s preferences at Lund University hospital since both heads were available in inclusion period.

3.1.2 Exclusion criteria

The THA patients operated on for other reason than osteoarthritis, femoral neck fracture and rheumatoid arthritis were excluded from survival analysis. All revisions performed for reasons other
than aseptic loosening were excluded from the analysis. Thus excluded 16 revisions for recurrent dislocation and 7 for infection in Lund University. 12 revisions were excluded from 32 mm group and 4 revisions from 22 mm group due to dislocations respectively. All revisions were performed due to malpositions of the components and both components were stable in all cases.

### 3.1.3 Data registration

All the data were registered prospectively. A special form was filled in for every patient after the total hip replacement was performed. All forms were filled up before patients discharge from the hospital. Patient’s unique personal identification number was used in the registration form. All the filed in forms were kept in paper manner and computerized when analysis of the data was started. Data registration form is presented in (Table 4 in Accessories section).

### 3.1.4 The end point assessments

The end-point was defined as revision of any component for aseptic loosening before the 2004 12 31. The revision was defined as additional operation after primary total hip replacement with exchange of one or more prosthetic components. All revisions were registered prospectively as separate operation. Patient’s identification code was used to find out information about primary THA. For revisions possibly performed in another center Swedish National Hip Register center was contacted. They informed that none of primary THA performed in Lund University Hospital were revised elsewhere.

Death date assessment is essential in statistical calculations of cumulative revision rates. The file with personal identification numbers of all THA patients’ was sent to Minister of health authorities and they provided us information about the patient’s death dates.

### 3.1.5 Implant design

The ScanHip femoral component is made of a vacuum moulded cobalt-chromium alloy and is available in four neck length (small, medium, large and Xlarge) and in 3 head diameters, 22, 28 and 32mm (Figure 5). The acetabular cup is made of machined, ultra-high molecular weight polyethylene molded from solid block (Figure 5).
Figure 5. ScanHip all polyethylene cup and ScanHip femoral stem.

Cups are available with or without posterior rim for increased stability. The inner diameter of the cups is available in 3 diameters (22, 28, 32 mm). Radiographic definition of the cup location is allowed by the indicator wire.

The polyethylene thickness in the 22mm head group varied from 9-13mm, in the 32mm group the range was 6-13 mm. 22 mm and 32 mm was used in Lund University Hospital for the entire period.

3.1.6 Surgical technique

The absolute majority of patients in Lund were operated on with posterolateral skin incision and posterior arthrotomy in lateral decubitus position. The incision was made at the posterior rim of the greater trochanter extending from 3 cm distal of the tip of the greater trochanter cranially. Incision passes the subcutaneous tissue to the fascia of the gluteus maximus. After the fascia of gluteus maximus incised we gently spread M. gluteus maximus cranially and Charnley frame-type retractor is inserted. Then the leg is placed in internal rotation, the fat pad behind the greater trochanter pushed dorsally with a swab. The external rotators and small vessels now come into vision and we cut them together with the capsule. With flexion, adduction and internal rotation the femoral head is dislocated. Femur is positioned in the axis of the operating table, internally rotated so that the tibia is vertical and the knee flexed in 90°. A saw cut is performed and the neck cut is completed with an osteotome. With a scalpel we clean the rim of te acetabulum from remnant labrum to fully expose the acetabulum rim. A Hohmann or slim curved retractor is placed around the anterior acetabular wall, thus taking greater trochanter with it. The acetabulum is then prepared
in usual manner with acetabular reamers. The cup is then cemented in place using cup walls for orientation to achieve 15-20° anteversion. For the femoral preparation the tibia is held vertically with the knee being flexed. The view in to the femur is free. The smallest femoral rasp was used to open medullary cavity. The smallest rasp was impacted into the femur until the superior surface of the rasp is in alignment with the resected femur. This rasp is then replaced by the next size rasp and the process repeated until the definitive rasp is seated at the resected femur level. A trial reduction with trial femoral components is performed to adjust leg length and stability and when the prosthesis is cemented. After the cement has cured, the hip was reduced. The wound was then closed in layers.

3.1.7 Cementing technique

The cementing technique consisted of cleaning the bone bed with pulsating lavage, plugging of the femoral canal, retrograde filling and pressurization of Palacos bone cement with gentamicin. Pulsative lavage not only renders white strands of any soft tissue remnants visible, but also effectively removes blood and bone marrow from the bone intersticies, thus aiding cement penetration and results very clean bone. Usually this step was repeated several times.

The plastic cement restrictor was inserted to a depth of 1cm. distal to the expected tip of the prosthesis. Usually restrictor size was chosen 2 mm large than largest olive passed the isthmus of the femur. After the cement in cement gun has reached the preferred viscosity, the cement was then rapidly applied in a retrograde fashion under pressure. When the proximal canal opening is occluded with a seal and cement pressurization procedure was performed for at least 2 minutes. After the cement was pressurized the definitive ScanHip Classic I femoral stem was inserted slowly in the line of longitudinal axis of the femur using sustained manual pressure. In contrast to the femur a higher cement viscosity at the time of cement application for the cup implantation was preferred. In prepared acetabulum the bone cement was applied en bloc. Immediately after insertion of cement ball, pressurization was commenced manually with a pressurizing device. After the cement was pressurized for approximately one to two minutes the pressurizer was be removed. The remaining excess of cement is removed. An acetabular cup size of at least 4mm smaller in diameter than the largest reamer used was chosen to ensure a minimum circumferential cement mantle thickness of 2 mm.
3.2 Survival study of THA in Klaipeda, Lithuania compared to THA in Lund, Sweden

Prior to 1991 there was no arthroplasty surgery as routine procedure in Klaipeda and in Lithuania. All the THA in the Klaipeda hospital were performed by 3 orthopedic surgeons who had received a short training in Sweden. At the Lund University Hospital, > 90% of the THA was performed by 6 experienced surgeons.

3.2.1 Inclusion criteria

We included OA patients admitted for elective total hip replacement in Lund University Hospital and Klaipeda hospital. Period of first 10 years after the introduction of ScanHip prosthesis in both centers was analyzed; i.e. patients operated with this particular implant in 1983-1993 in Lund and patients operated in 1991-2001 in Klaipeda were included in survival analysis.

3.2.2 Exclusion criteria

We excluded THA patients operated for other diagnosis than OA from survival analysis. Revisions for infections and for recurrent dislocations were also excluded in both centers.

10 revisions for recurrent dislocations and 4 revisions for infections were excluded from Lund University group, respectively 3 for recurrent dislocations and 4 revisions for infections were excluded from Klaipeda Hospital group.

3.2.3 Data registration

All the data were registered prospectively in the same manner in both countries. A special form was filled in for every patient after the total hip replacement was performed. All forms were filled up before patients discharge from the hospital. For Lithuanian patient’s unique operation number was given for each total hip replacement, for Swedish patient’s unique personal identification number was used. All the filed in forms were kept in paper manner and computerized when analysis of the data was started. Unified data registration form used in both centers is presented in (Table 4 in Accessories section).
3.2.4 The end point assessments

For patients operated in Klaipeda Hospital revisions were registered as a separate operation, with acknowledgment about primary THA. The unique number of primary THA was recorded on revision registration form. Thus provided us the information about all primary and revision THA performed in Klaipeda hospital. Since in Lithuania we do not have National Hip Register, 3 other centers performing hip revision surgery were contacted to obtain information if any of primary THA performed in Klaipeda were revised in these particular centers. We information we received, that 2 hips inserted in Klaipeda were revised elsewhere and these revisions were recorded.

For Klaipeda patients personal code was used to identify patient’s death date. We applied for the information in State Patient Fund and they provided us all information about Klaipeda THA patients deaths dates.

Patient’s registration procedures and death dates assessments in Lund University Hospital were described previously in 3.1.3 Data registration and 3.1.4 The end point assessments sections.

3.2.5 Implant design

The same Scan Hip implant as described in 3.1.5 Implant design section was used in Klaipeda Hospital. In the beginning 1991-1995 32 mm head was in the used. In 1996 28 mm femoral heads were introduced and were used for the entire period we analyzed. For Lund University Hospital patients 22 mm and 32 mm ScanHip prostheses were implanted.

3.2.6 Surgical technique

All patients in Klaipeda Hospital and absolute majority patients in Lund University Hospital were operated on posterolateral approach and posterior arthrotomy in lateral decubitus position. Detail procedure was described in 3.1.6 Surgical technique section.

3.2.7 Cementing technique

In Klaipeda Hospital the cementing technique consisted of plugging of the femoral canal with the plastic restrictor, retrograde filling with cement gun and pressurization. CMW1 bone cement with gentamicin was used.

For Lund University Hospital THA patients additionally cleaning of bone bed with pulsating lavage was applied and differently as in Klaipeda, Palacos bone cement with gentamicin was used.
3.3 Polyethylene wear and synovitis study

We analyzed 60 not revised THA patients operated in Klaipeda Hospital 1995 – 1996 with ScanHip Classic I prosthesis a subset of previously described survival study. Two groups consisting of 30 patients each was formed with respect to diameter of the femoral head. Thus 30 THA patients with 32mm diameter femoral head and 30 with 28mm diameter femoral head were analyzed.

3.3.1 Inclusion criteria

We included patients with OA diagnosis who underwent THA in 1995-1996 in Klaipeda hospital. 65 THA were performed in 1995 with 32mm femoral head and 134 THA in 1996 with 28mm femoral head. Before the end of the follow-up 2004 12 31, 10 patients died and 5 have been revised in 32mm group and 22 patients died and 8 have been revised in 28mm group respectively. Thus 50 in 32mm group and 104 in 28 mm unrevised patients group were available for further analysis. Our aim according to the statistical power calculations was 16 patients in each group, but to compensate for potential exclusions due to loosening of the components or other dropouts, we included 30 hips in each group. All not revised and still alive patients were grouped using random numbering method with Excel program in 2 groups (30 individuals in each) with respect to head size. All patients selected were called for review in June 2005. The patients we were not able to reach were excluded (6 patients) and the next patient in a row was taken.

3.3.2 Exclusion criteria

We excluded 6 patients from 28mm group and 4 from 32mm group because we were not able to contact them. These patients were replaced with the next patients in a randomly organized line. After we collected and examined all the patients 3 patients from 28mm group and 1 patient from 32mm group were excluded due to technical problems when measuring PE wear. The 32mm patient we excluded had acetabulum roof reconstruction with allograft fixed with a screw and it was impossible to identify the border of the cup in order to measure wear of the PE. 3 patients from 28mm group were excluded due to insufficient quality of radiographs for PE wear measurements. 8 cups, 2 stems and 2 both components we classified as loose in the 32mm group, 1 cup in the 28mm.

Thus 17 patients in the 32mm group and 26 patients in the 28mm group were analyzed.
3.3.3 X-ray assessments

The x-ray examination, i.e. standard anteroposterior pelvic radiograph was taken. The x-ray examination was performed in patients lying in supine position. The standard 1 meter distance from the source was consistent in all cases. The x-rays were evaluated by two orthopaedic surgeons and the implants were classified loose or stable according Carlsson et al. [34]. The femoral was defined as loose when number of changes was defined on x-rays: migration with or within the cement, cement fracture, localized endosteal bone resorption, bone cement lucencies surrounding the whole prosthesis. Acetabular cup was defined loose when migration and change of position of the socket was observed.

The cup inclination angle was calculated on anteroposterior pelvic radiographs. Inclination angle represents the angle between horizontal line through the center of the femoral head and line drawn from mid points of indicator wire of the cup, as presented in (Figure 6).

![Figure 6. Measurement of cup inclination angle (I is the angle measured).](image)

3.3.4 Linear and volumetric wear assessments

Linear wear was measured indirectly, by measuring the penetration depth of the femoral head on radiographs. The wear was measured on plain radiographs using a ruler, caliper, concentric ring templates. First step is to find the center of the femoral head using concentric ring templates (Figure 7A). Subsequently we identified the midpoint of the orifice of the cup (Figure 7B). In case of no wear of PE the center of the femoral head should mach the midpoint of the orifice of the cup.
When the center of the femoral head was identified we draw a line to measure the diameter of the femoral head “d” (Figure 8A). Subsequently we aimed the needle of the compass in the midpoint of the head and found the shortest distance from this point to the backside of the cup (the continuous yellow line). After the shortest distance was identified (P), we measured the distance (W1) i.e. the distance between center of the femoral head (H) to the most wearied point of the PE cup (P) (Figure 8B). To obtain higher accuracy the caliper was used for all measurements.

The distance W2 (Figure 9A) i.e. the distance between mid point of the cup C (Figure 7A and 9A) and the most wearied point of the PE (P) (Figure 8B and 9A) was then calculated. Angle \( B \) (the angle between cup inclination and most wearied PE point (P) (Fig. 9B) with represents the direction of there was also measured and used for subsequent volumetric wear calculations.
Figure 9A and 9B. Measurements of the penetration of the femoral head to the acetabular cup.

The x-ray magnification coefficient was calculated by dividing the real diameter of the femoral head i.e. 28 or 32 mm with diameter d (Fig. 9A) measured on x-rays. The linear wear was then calculated with formula \( w = (W2 - W1) \times k \). In this equation “\( w \)” is linear wear, “\( W2 \)” is the distance between mid points of the cup to the back side of the cup, “\( W1 \)” is the shortest distance between centers of the head to back side of the cup and “\( k \)” is x-ray magnification coefficient. Coefficient “\( k \)” was calculated using formula \( k = a/d \), in which \( a \) – actual diameter of the femoral head, \( d \) – diameter of the femoral head measured on x-rays.

The volumetric polyethylene wear was calculated with the formula

\[
V = \frac{r^2d}{2} \left( \Pi + \Pi \sin B + \frac{d}{r} \sin(2B) \right)
\]

in which \( v \) = volumetric wear, \( r \) = the radius of the femoral head, \( B \) = the angle of direction of wear and, \( d \) = the linear wear (51).

### 3.3.5 Sonographic examination of the hip

The sonographic examinations were performed with the patient supine in a sagittal plane, from the anterior aspect of the hip along the axis of the femoral neck. The anterior capsular distance, i.e. the capsular distension, was defined as the distance between the metallic echoes from the mid part of the anterior surface of the prosthetic femoral neck perpendicular to the echo from the anterior surface of the anterior capsule. The graph explaining the position of prosthesis and measurement points is presented in (Figure 10). A portable Sonosite 180 L38 (Sonosite®) with a 5-10MHz linear transducer was used for all examinations.
Fig 10. Schematic drawing of sonographic image of a THA hip.

In the ideal US plane, the capsular distance in the THA hip should be measured when the echoes from the head and neck of the stem and the rest of the osseous neck are as distinct as possible, and are visible on one and the same US image (Figure 11). This situation ensures that the transducer is correctly placed in the plane of the central axis of the neck of the prosthetic stem. At each following examination this position of the transducer should be reproduced by identifying those three important echoes in the image.

Figure 11. Sonographic image of a THA hip
Ac - echo of the anterior surface of the anterior hip joint capsule.
Fn - echo of the prosthetic femoral neck.
Fh – echo of the prosthetic femoral head

All measurements of the “capsular distance” were performed for the 3 times and mean values were calculated.
3.3.6 Clinical evaluation

Patient’s body mass index was calculated with formula. \( \text{BMI} = \frac{w}{h^2} \) in with “BMI” – body mass index, “w” – patients weight and “h” – patients height in meters. The patients weight and height was determined at the time patients were investigated.

Patients’ activity level was estimated. Each patient was rated using the 10-point University of California Los Angeles (UCLA) activity-level rating [88]. The evaluation has 10 descriptive activity levels ranging from wholly inactive and dependent on others (level 1), to moderate activities such as unlimited housework and shopping (level 6), to regular participation in impact sports such as jogging or tennis (level 10) (Table 10) in Accessories section).

At the time of the evaluation the patient was asked about participation in the various activities described in the UCLA activity level rating. The UCLA score is based on participation in the highest-rated activity, regardless of the frequency or intensity of participation.

3.4 Statistical analysis

3.4.1 Survival study of 32 mm and 22 mm diameter femoral heads

CRR-curves were produced using the life table method at monthly intervals. The confidence intervals were calculated, using the Wilson quadratic equation with Greenwood and Peto effective sample-size estimates [36]. Curves were cut-off when 40 hips remained at risk. Cox regression was used to adjust for differences in age and sex when comparing femoral head size effect on cumulative revision rates.

A p-value of < 0.05 was considered significant. SPSS and Excel software was used for the calculations.

3.4.2 Comparison between countries study

CRR – curves were produced using the same method as in comparison between femoral heads analysis. Cox regression was used to adjust for differences in age and gender as well as for head size. The age of the patient at primary operation as well as the head size in mm were used as continuous variables in which the risk ratio expresses the change in risk if the variable increases one unit (one year or one mm). The factor (location) and gender were categorical variables with Lund as a reference against Klaipeda and with females as a reference against males.
A p-value of < 0.05 was considered significant. SPSS and Excel software was used for the calculations.

### 3.4.3 PE wear and synovitis analysis

The primary effect variable, used for power calculation analysis, was “capsular distance”. With an assumption of a difference in means of 3mm (20), and SD of 3mm for both groups, and aiming at a power of 0.80 and a risk of 0.05 for type-1 error, 16 patients were needed in each group. To compensate for potential exclusions due to loosening of the components or other dropouts, we included 30 hips in each group. T-test was used to compare age, activity level, “capsular distance”, and linear and volumetric polyethylene wear between groups. The Spearman correlation was used to calculate the correlation between variables. A p-value of < 0.05 was considered significant. SPSS 12.0 software was used for the calculations.
4. RESULTS

4.1 Survival analysis of 22 and 32mm diameter femoral heads

To assess the effect of head diameter on survival we analyzed cohort operated in Lund University only. The follow-up ranged from 9-21 years postoperatively. Patient's related data where effect of femoral head diameter was analyzed presented in (Table 6).

Table 6. Data on analyzed 1720 THA in 1550 patients operated at Lund University Hospital.

<table>
<thead>
<tr>
<th>Implant type</th>
<th>THA components revised</th>
<th>Patients died</th>
<th>Age</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic I 22mm</td>
<td>Cups 7</td>
<td>Stems 7</td>
<td>Both 13</td>
<td>122</td>
</tr>
<tr>
<td>n=308</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classic I 32mm</td>
<td>Cups 31</td>
<td>Stems 24</td>
<td>Both 81</td>
<td>727</td>
</tr>
<tr>
<td>n=1412</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Using the life table method we analyzed CRR for OA, FR and RA patients and found that the 32 mm head had higher CRR (p=0.04 (Wilcoxon)). The curves are presented in (Figure 12).

Figure 12. CRR for 22 mm and 32 mm diameter femoral heads with 95% confidence intervals.

Further analysis with Cox regression adjusting for age and sex showed that the 32 mm head had 2.8 times greater risk of revision (CI (95% CI) 1.7-4.6, p<0.001). For each year increase in age the risk of revision was reduced 0.96 times (0.95 – 0.97), p<0.001, males had 1.5 times (1.1 – 2.1), p=0.01 greater risk of revision than females.

We also analyzed the patients operated for OA only, but exclusion of the FR and RA patients did not change the CRR (p=0.04). Cox regression analysis for OA patients showed that the 32 mm
head had 3.4 times greater risk of revision than the 22 mm head (CI(95% confidence intervals) 1.9 - 6.0, p<0.001). For each year increase in age the risk of revision was reduced 0.94 times (0.93 – 0.96), p<0.001, males had 1.5 times (1.1 – 2.2), p=0.02, greater risk of revision than females.

4.2 Survival analysis of THA performed in Klaipeda Hospital and Lund University Hospital

When analyzing differences between countries we investigated whether introduction of new implant in two different experience in THA countries would reveal differences in CRR. Only patients with OA operated with Scan Hip Classic I prosthesis were included in survival study since Scan Hip prosthesis was first introduced at the University Hospital, Lund, Sweden in 1983 and in Klaipeda Hospital, Lithuania in 1991. After introduction of the ScanHip implant in each of the hospitals the first initial 10 years were analyzed in both locations. Exclusion of RA and FR patients reduced additional variables when comparing results between countries. Thus at the Lund University Hospital, Lund, 932 Scan Hip prostheses were implanted in 825 OA patients from November 1983 to December 1993. In Klaipeda 655 ScanHips were inserted in 582 patients from November 1991 to December 2001. The patients operated were followed up to14 years. Thus in both countries the follow-up ranged from 3 to 14 years. Patients and implant related data are presented in (Table 7, 8).

Table 7. Data on THA in both institutions operated for osteoarthritis and revised for aseptic loosening. SE – Sweden, LT- Lithuania

<table>
<thead>
<tr>
<th>Country</th>
<th>SE n=932</th>
<th>LT n=655</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cups</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>Stems</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Both</td>
<td>13</td>
<td>29</td>
</tr>
<tr>
<td>Patients revised</td>
<td>238</td>
<td>103</td>
</tr>
<tr>
<td>Patients died</td>
<td>69,36 (SD 10,5)</td>
<td>63,18 (SD 9,9)</td>
</tr>
<tr>
<td>Age</td>
<td>Female -486 Male – 446</td>
<td>Female -477 Male – 178</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 8. Data on diameter of the heads distribution in both countries. SE – Sweden, LT- Lithuania.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head diameter</td>
<td>LT</td>
</tr>
<tr>
<td>22mm</td>
<td>n=0</td>
</tr>
<tr>
<td>28mm</td>
<td>n=423</td>
</tr>
<tr>
<td>32mm</td>
<td>n=232</td>
</tr>
</tbody>
</table>
When analyzing the differences between countries the CRR analysis showed that THA inserted in Klaipeda had significantly higher CRR than those in Lund (p=0.003) (Wilcoxon)) (Figure 13)

![Figure 13. Cumulative THA revision rate in Klaipeda, Lithuania and Lund, Sweden (95% confidence intervals)](image)

The overall CRR for the initial 10 years was 11.3% (CI 8.4-18.3%) for the Klaipeda patients as compared to 5.8% (CI 3.7-10.3%) for the Lund patients. Further analysis with Cox regression adjusting for age and gender showed the Klaipeda patients had 1.7 times the risk of revision (CI 1.09-2.82), p=0.02 and that age also significantly decreased the risk of revision p<0.0001. When head size was added as a continuous cofactor, it was not found to have a significant effect (p=0.12), while hospital and age remained significant. Cox regression analysis data is presented in (Table 9).

**Table 9. Cox regression data.**

<table>
<thead>
<tr>
<th></th>
<th>Estimated revision risk</th>
<th>95% Confidence interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.962</td>
<td>0.943 - 0.981</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Location</td>
<td>1.640</td>
<td>1.007 - 2.670</td>
<td>p=0.047</td>
</tr>
<tr>
<td>Gender</td>
<td>1.074</td>
<td>0.661 - 1.745</td>
<td>p=0.772</td>
</tr>
<tr>
<td>Head size</td>
<td>1.072</td>
<td>0.983 - 1.168</td>
<td>p=0.115</td>
</tr>
</tbody>
</table>
4.3 PE wear and synovitis results

The differences in linear wear, volumetric wear and capsular distance for 28 and 32 mm diameter femoral heads was analyzed. Data distribution box for sonographically measured capsular distance in 28 mm and 32 mm diameter femoral heads is presented in (Figure 14).

![Figure 14. Data distribution on capsular distance values in 28 mm and 32 mm diameter femoral heads.](image1)

Data distribution box for volumetric PE wear per year in 28 mm and 32 mm diameter femoral heads is presented in (Figure 15).

![Figure 15. Data distribution box for volumetric wear in 28 mm and 32 mm diameter femoral heads](image2)
Data distribution box for linear PE wear per year in 28 mm and 32 mm diameter femoral heads is presented in (Figure 16).

![Data distribution box for linear PE wear per year in 28 mm and 32 mm diameter femoral heads](image)

**Figure 16.** Data distribution box for linear wear in 28 mm and 32 mm diameter femoral heads

T-test was performed to compare linear, volumetric wear and capsular distance values in 28 mm and 32 mm diameter femoral heads. The results are presented in (Table 10).

**Table 10.** Data on linear and volumetric wear and “capsular distance in 43 THA.

<table>
<thead>
<tr>
<th>n= 43</th>
<th>28 mm n=26</th>
<th>32mm n=17</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear wear/year, mm</td>
<td>0.09 (SD 0.05)</td>
<td>0.18 (SD 0.09)</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Volumetric wear/year, mm³</td>
<td>48.1 (SD 27.6)</td>
<td>138.6 (SD 68.0)</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Capsular distance, mm</td>
<td>13.1 (SD 2.5)</td>
<td>16.8 (SD 3.0)</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

We found highly significant (p<0.001) difference for linear, volumetric PE wear per year and capsular distance when comparing 28 mm and 32 mm diameter femoral heads.

The T-test was also performed to analyze the differences for other variables between groups. However these factors i.e. activity level, patient’s age, cup inclination angle, PE wear direction angle and BMI did not differ significantly between 28mm and 32 mm groups. T-test results are presented in (Table 11).

**Table 11.** Data on activity level, age, BMI, cup inclination angle and PE wear angle in 43 THA.

<table>
<thead>
<tr>
<th>n= 43</th>
<th>28 mm n=26</th>
<th>32mm n=17</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity level</td>
<td>5.1 (SD 1.3)</td>
<td>5.2 (SD 1.3)</td>
<td>p=0.66</td>
</tr>
<tr>
<td>Age</td>
<td>70.8 (SD 9.7)</td>
<td>73.7 (SD 6.6)</td>
<td>p=0.27</td>
</tr>
<tr>
<td>BMI</td>
<td>30.3 (SD 6.5)</td>
<td>27.8 (SD 3.9)</td>
<td>p=0.16</td>
</tr>
<tr>
<td>Cup inclination angle</td>
<td>51.1 (SD 7.4)</td>
<td>51.4 (SD 6.4)</td>
<td>p=0.52</td>
</tr>
<tr>
<td>PE wear angle</td>
<td>45.9 (SD 19.5)</td>
<td>55.1 (SD 12.3)</td>
<td>p=0.09</td>
</tr>
</tbody>
</table>
The correlations between linear, volumetric PE wear and sonographically measured capsular distance in prosthetic hip was analyzed. The graphs representing linear correlation between these variables are presented in (Figure 17 and Figure 18).

**Figure 17.** Linear correlation matrix between linear PE wear per year and sonographically measured capsular distance.

**Figure 18.** Linear correlation matrix between volumetric PE wear per year and sonographically measured capsular distance.
Spearman correlation coefficient and p value was calculated to assess the significance of correlation between linear, volumetric wear and sonographically measured capsular distance. We found highly significant correlation between PE linear wear per year and capsular distance (p<0.001) as well in volumetric PE wear per year and capsular distance (p<0.001). Spearman correlation data are presented in (Table 12).

**Table 12.** Spearman correlation table, r- correlation coefficient

<table>
<thead>
<tr>
<th>Variables</th>
<th>Linear wear/year</th>
<th>Volumetric wear/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsular distance</td>
<td>r= 0.58</td>
<td>r= 0.63</td>
</tr>
<tr>
<td></td>
<td>p&lt;0.001</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

The same Spearman correlation coefficient was calculated for other variables such as patient’s activity level, age, BMI, cup inclination angle, to investigate the correlations with linear, volumetric wear and capsular distance. The p – value was calculated. We found that BMI, age, patient’s activity level and cup inclination angle did not correlate with linear, volumetric PE wear and sonographically measured capsular distance. The Spearman coefficient values and p- values are presented in (Table 13).

**Table 13.** Spearman correlation table, r- correlation coefficient

<table>
<thead>
<tr>
<th>Variables</th>
<th>BMI</th>
<th>Age</th>
<th>Activity level</th>
<th>Cup inclination angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsular distance</td>
<td>r= -0.15</td>
<td>r= 0.63</td>
<td>r=0.18</td>
<td>r=0.001</td>
</tr>
<tr>
<td></td>
<td>p=0.35</td>
<td>p=0.56</td>
<td>p=0.25</td>
<td>p=0.99</td>
</tr>
<tr>
<td>Linear wear/year</td>
<td>r=-0.09</td>
<td>r=-0.2</td>
<td>r=0.11</td>
<td>r=-0.44</td>
</tr>
<tr>
<td></td>
<td>p=0.57</td>
<td>p=0.19</td>
<td>p=0.48</td>
<td>p=0.78</td>
</tr>
<tr>
<td>Volumetric wear/year</td>
<td>r=-0.16</td>
<td>r=-0.17</td>
<td>r=0.13</td>
<td>r=-0.07</td>
</tr>
<tr>
<td></td>
<td>p=0.3</td>
<td>p=0.29</td>
<td>p=0.39</td>
<td>p=0.68</td>
</tr>
</tbody>
</table>
5. DISCUSSION

5.1 Survival study – comparison between femoral heads

We analyzed the outcome after total hip replacement and compared 22 mm and 32 mm femoral heads. The patients were followed from 9 to 21 years after the surgery. We found that THA with 22 mm femoral heads were associated with better outcome. One of the main factors affecting these results is higher PE wear in 32 mm group; however other influencing factor must also be taken in to the account.

The mean patient’s age in the 22 mm femoral head diameter group was 59 years and 71 years in the 32mm group (p<0.001). The early and recent literature in total joint arthroplasty clearly suggested that the results for younger patients are not nearly as good as the results for the older patients [89, 90] (Figure 19).

Figure 19. Kaplan-Meier survivorship curves are shown for patients receiving the cemented T28 or TR28 hip prosthesis separated by patients younger than 50 years and patients older than 60 years. [90]

S.P. Johnsen et al. [91] analyzed the association between patient – related factors and the risk of initial, short and long – term implant failure after primary total hip replacement. The authors used data from the Danish Hip Arthroplasty Register between 1 January 1995 and 31 December 2002, thus 36 984 THA patients were analyzed. The outcome measure was defined revision with included open surgery for any reason. When analyzing possible predictors for implant failure from 6 months
to 8.6 years after THA, they found that aseptic loosening if prosthetic hip was the most frequent reason for failure. Patients with younger age appeared to be associated with an increased risk of failure. The adjusted relative risk of failure for patients operated on in 50 – 59 years of age was 1.3 (95% CI 1.0 to 1.6), when compared with patients aged 60 to 69 at the time of the surgery. The similar results were observed in Swedish Hip Register report [5]. They analyzed the revision rates in THA patients operated from 1992 to 2000 in Sweden. All diagnoses were included and the end point was revision with exchange of one component for any reason. They compared survival after THA in three age groups i.e. less than 55 years, 55-75 years and over 75 years patients. The reason why younger patients were associated with higher risk for revision when compared with older THA patients could be the differences in physical activity level in these age groups. Older patients in general are less active than younger. Kilgus at al. [92] analyzed the outcome after total hip replacement in respect of patient’s activity level. They compared revision rates after THA in 80 very active patients with 248 less active patients. Patient’s activity level was estimated using UCLA [88]. They found that active patients group was at increased risk of revision surgery as a result of aseptic loosening compared to less active patients group (p<0.013).

The findings of S.P. Johnsen et al. [91] and the results from Swedish hip register[5] are in concordance with Cox regression results of our material, which showed that the risk of revision was decreasing with increasing age i.e. younger THA patients were associated with increased risk of revision. Thus, it should have been expected that the group of patients with 32 mm head with a higher mean age (72 (SD 10)) would have had a lower incidence of revision for loosening as compared with 22 mm head group with lower mean patients age (58 (SD 16)). However, our results showed the opposite i.e. 22 mm head patients showed lower cumulative revision rates as compared with 32 mm. One possible explanation for the association between large head size and high revision may be the amount of PE particles. Kesteris et al. [32] analyzed 62 matched OA ScanHip THA patients with 22mm and 32 mm diameter femoral heads a subset of patients included in our survival study. He measured radiographic polyethylene wear in patients with Scanhip arthroplasty and no clinical or radiographic signs of loosening. The patients he divided into 2 groups according to head sizes. 32 patients (33 hips) had an implant with a 22 mm and 30 patients (34 hips) with a 32 mm head. The groups were matched for diagnosis, sex, weight, age, and time of follow-up. The mean linear wear with a 22 mm head was 1.1 mm and with a 32 mm head 1.5 mm (p = 0.004), which corresponds to a yearly wear rate of 0.15 mm and 0.18 mm, respectively. The mean difference in volumetric wear was greater, 420 mm$^3$, as compared to 1239 mm$^3$. The author did not find the correlation between patients’ body weight and linear, volumetric polyethylene wear. This might be also associated with patients’ activity level because obese patients are likely less active than normal body weight patients. Thus, our findings that THA performed with 32 mm femoral
heads showed higher cumulative revision rates support the theory that polyethylene wear affects long-time survival.

Kesteris et al. [18] analyzed the cumulative revision rate in 1,474 patients (1,660 hips) operated on with a cemented Scan Hip Classic I prosthesis from November 1983 to January 1994 at Lund University Hospital. The revision rate was analyzed for 3 diagnoses - osteoarthritis, rheumatoid arthritis and complication after a hip fracture, for 2 head diameters--22 and 32 mm. The author compared cumulative revision rates for aseptic loosening with 22 mm and 32 mm femoral heads depended on head size. The author did not found any differences in CRR between groups after the material was followed up to 12 years. Our material we analyze is an update and extended follow-up of the material reported by Kesteris et al.[18]. Our results disclosed the differences in cumulative revision rates when compared 22 mm and 32 mm femoral heads. 22 mm femoral heads showed superior results versus 32 mm femoral heads when follow up was extended up to 21 years after THA.

The reason that Kesteris et al. [18] did not find any significant difference in cumulative revision rates depending on head size in his study may be the time it takes for wear particles to induce the chain of events, eventually ending up in loosening. In the stable, well-fixed implant the release of ultra high molecular weight polyethylene particles during articulation of prosthetic hip acts as one of the main triggers for macrophagic osteolysis. In THA patients with polyethylene on metal bearings releases approximately 20 million to 40 billion polyethylene particles are released in to the joint space annually [93]. The accumulation of such large numbers of particles could cause the major bone lysis occurring even in elderly patients.

The findings reported by Kesteris et al [18] in 1996, i.e. that there is no difference in cumulative revision rate in 22 mm and 32 mm femoral heads after 12 year follow up and our current study [94] where we found a difference in CRR, after the same patients were followed up to 21 years is in concordance with Malchau and Herberts [95] and Oparaugo et al. [96] findings. Malchau and Herberts from the National Swedish hip register data analysis noticed that 10 year follow-up does not guaranty the same results after the patients are followed longer [95]. Some major changes can occur when comparing cumulative revision rates for different period of times. The similar results reported Oparaugo et al. [96], who analyzed 8 literature reports focused on PE wear and osteolysis in total hip replacement. They stated that follow-up duration of less than 10 years was not enough to distinguish between various designs of THA unless these had unusually high wear-rates. Such disparities increased continually with follow-ups and were even evident 20 years later. The reason for that is polyethylene wear induced osteolysis is time depended process. The difference in volumetric wear between 22 mm and 32 mm diameter group was 91 mm³ per year [32] . This certain difference in volumetric polyethylene wear between these two different diameter femoral
heads could disclose difference in CRR after 12 years, however our material confirmed that after 21 years the difference in CRR was obvious in favor of 22 mm diameter femoral head THA.

There were 7 isolated stem revisions in the 22 mm group and 24 in the 32 mm group. It could be argued that such revisions are not related to wear of the acetabular cup. However, it has been shown that PE particles can migrate down to the femoral cavity via the bone-cement or cement-stem interface and have been found distally in the femur [97]. The Pazzaglia et al. [97] in his report presented a singular case of pathological fracture through a large osteolytic lesion of the mid-femur consequent on reaction to a hip prosthesis. Not only metal particles but also polyethylene fibres were found at this site, some 15 cm from the prosthesis. These polyethylene particles induce osteolysis of the bone and subsequent loosening of the femoral stem. The polyethylene wear and following release of polyethylene particles in THA hip is present in well fixed polyethylene cups. Thus increased amount of volumetric wear may cause an isolated aseptic loosening of the stem although the cup is well fixed.

Initial thickness of the polyethylene was greater in the 22 mm group. It has been repeatedly reported than the thickness of the polyethylene inversely correlates with wear (Bartel et al. [62], Oonishi et al. [61]). Greater thickness of PE cup is associated with reduced PE wear. These findings are in concordance with the results of our study. The majority of implanted cemented cups we analyzed were about 48 – 52 mm in size. The polyethylene thickness for 32 mm inner diameter cups varied from 8-10 mm and for 22 mm inner diameter cups from 13 – 15 mm for particular cups sizes. As the report of Oonishi et al. [61] suggested the polyethylene thickness should be at least 11 mm. Thinner polyethylene cups were associated with increased linear wear rates and subsequent osteolysis and prosthetic loosening. That was the case in our study, where we found that 22 mm femoral heads were associated with lower CRR.

However the selection of cup size is mostly based on the anatomical features of the patient and in a randomized group of patients, a larger head size on average should have the effect of reducing the thickness of the polyethylene. Therefore it can be argued that the best way the surgeon can affect thickness of the polyethylene is by varying the head size. Thus our finding that head size affects results is of importance as it can be affected by the surgeon’s choice.

5.2 Survival study – comparison between countries

Our material included the first 10-years experience in total hip replacement in Klaipeda Lithuania. The revision rates in country with no previous experience in THA surgery was compared to that of the Lund University Hospital, Sweden, with long experience in THA. We found that the THA from the Klaipeda Hospital had significantly higher CRR than those from Lund which had
similar results to that found on a national level according to the Swedish Hip Register. (CRR of 6.6% ± 0.9 % after 10 years during 1983-1992) [5].

Our finding suggests that the differences in implantation technique, cementing technique could cause the superior outcome for THA patients in Lund University Hospital.

Implantation technique remains important factor affecting long term outcome after THA. Malik et al. 2005 [98] analyzed the association between immediate post-operative radiological appearances of prosthetic stem and early aseptic failure of total hip replacement. They found that thickness of the cement mantle around the stem was associated with increased failure rate (p=0.040). These findings suggest that surgical mistakes in cementing technique of the femoral stem during the surgery can predict inferior outcome after THA. Greater surgical experience would reduce cementing technique failure rate and thus will ensure superior outcome after THA. The findings these authors provide us with one of the explanations of our results; i.e. higher CRR in Klaipeda.

Correct positioning and cementing technique of polyethylene cup remains important factor affecting long term outcome after THA. Insufficient cement pressurization and medialisation of the cup causes increased wear rates [63]. It is well established that higher wear rates causes osteolysis and subsequent loosening of the prosthesis [29, 30]. Experience in positioning and cementing technique affects long term outcome and are in concordance with our comparison results between Lund and Klaipeda THA patients.

Another important factor affecting long term results after THA is primary stability of the cup and the stem immediately after the implantation. Not many instruments exist in the market which could quantify objectively primary stability of the implant. Such instrument is radiostereophotogrammetric(RSA) analysis of prosthetic hip. RSA studies showed that a subsidence of 0.33 mm of a femoral component and >1mm migration of the cup during the first postoperative 6 months predict revision surgery after 5-8 years [12, 99]. Karrholm et al. [12] analyzed 84 cemented THA followed for a 4-7 years. During the operation, three to seven spherical tantalum markers 0.8 mm were inserted in proximal femur. RSA analysis was used to measure prosthetic migration. They found that these implants which showed greater subsidence, medial migration and posterior migration during the first two postoperative years had greater commutative revision rates. These implants with minor or none subsidence or migration in first two years after THA had significantly lower cumulative revision rates.

Krismer et al. [99] reported a prospective, stratified study of 60 PCA-cups and 60 RM-polyethylene cups which have been followed for a median time of 90 months, with annual radiography. The radiological migration of cups was measured by the computer-assisted EBRA method. A number of threshold migration rates from 1 mm in the first year to1 mm in five years
have been assessed and related to clinically determined revision rates. A total of 28 cups showed a total migration of 1 mm or more within the first two years; 13 of these cups have required revision and been exchanged. The survival curves of cups, which had previously shown early migration, were considerably different from those without early migration. Early migration is a good predictor for late loosening of hip sockets. These findings suggest that the outcome of THA could be already predicted at the implantation of the prosthesis. Technical mistakes during implantation related to less surgical experience may result in primary instability and/or micromotion of the prosthesis and finally result in aseptic loosening of the implant. As there was no previous experience with arthroplasty surgery in Klaipeda, but ample experience in Lund, our comparison results may reflect the influence of surgical experience and technique on results.

Although ScanHip implants were used at both centers there were differences with respect to the head size used. For the Lund University Hospital patients 22 mm and 32 mm femoral heads and for the Klaipeda patients 28 mm, 32 mm femoral heads were used. As it has previously been suggested that increased head size is associated with increased volumetric wear and possibly osteolysis, we also included head size in the Cox regression, but did not find that it significantly affected the CRR. However, we have found in our head diameter analysis study that an extended follow-up beyond 10 years was needed to demonstrate a significant increase in CRR with the 32mm head [94].

Cementing technique remains an important factor affecting long term outcome after THA.

In Lithuania, no pulsating lavage, no vacuum mixing and no cement pressurization was used. Cementing technique is known to be of importance for long-term results. Cleaning of the bone bed with pulsating lavage, and cement pressurization each have been associated with approximately 20% reduction of the risk of revision for aseptic loosening [95]. These differences in cementing technique between two countries could also be one of important factors explaining differences in cumulative revision rates after THA.

Furthermore, although both containing gentamicin, the cement types used were different in the two hospitals, in Lund Palacos and in Klaipeda CMW1. This may also contribute to the increased revision rate since Espehaug et al. [79] reported that CMW1 had an increased risk of long-term failure as compared to Palacos (Figure 20).
Figure 20. Survival curves calculated for 17 323 Charnley THRs with type of cement as the strata factor and any failure of either component as the endpoint.

Marston et al. [19] reported that the risk of revision for trainees was 11 times greater than that of experienced surgeons. The risk of revision in Klaipeda was 2 times higher than in Lund. That the difference was not that high as in Marston et al. [19] report may be related to the fact that as only 3 surgeons were performing the arthroplasties they quickly gained surgical skill. Another important factor is volume of THA performed per year per surgeon. It is well described that increasing volume of THA surgeries per surgeon is associated with better long term results after total hip replacement [76]. Since only three orthopaedic surgeons performed all THA in Klaipeda hospital, the number of THA per surgeon was rather high.

Normally at the introduction of a new type of surgery, less severe cases are chosen for surgery and later when surgeons have gained experience the more difficult cases are selected. However, as THA surgery had not been available in Lithuania before there had been an accumulation of severe cases and therefore it is probable that the average THA case was more severe in Lithuania as compared to Sweden. Nilsdotter et al. [3] investigated whether patients with severe radiographic osteoarthritis have a different outcome at one year after total hip replacement than patients with moderate radiographic OA. Radiographs were analyzed by two independent observers using radiographic atlas, OA hip function was determined with 2 self administered questioners. All patients, regardless of preoperative radiographic OA stage, showed significant postoperative improvement and at one year achieved a health related quality of life similar to that of the reference group. However findings of this particular author do not answer the question if the severity of osteoarthritis affects long term outcome after THA. Our hypothesis is that more severe osteoarthritis
cases are more demanding in surgical experience. More surgical skills required in correct positioning of the cup and the stem. Ample experience in THA could cause surgical mistakes and might be related to higher cumulative revision rates in Klaipeda Hospital.

We found that the introduction of the Total Hip Arthroplasty in Lithuania was associated with a higher risk of revision as compared to that in Sweden. Although we were not able to identify any specific reason for this finding, many factors may explain the differences, such as different cementing technique, cement type and surgical experience. However monitoring of the introduction of a new type of surgery is important because precise registration and follow-up allow for early identification of problems. Such identifications of the problems will stimulate to analyze the reasons of failures and further to improve the surgical technique. As we showed the improvement of surgical technique will reveal in lower cumulative revision rates after THA.

5.3 PE wear synovitis capsular distance

There are several theories on the causes of aseptic loosening in THA. First theory presented describing the development of aseptic loosening was “cement disease” theory introduced in 1977 [100]. The author analyzed the tissue samples taken from the newly formed capsules surrounding artificial joints. He found the small particles of plastic, metal and acrylic cement in the capsule tissue. He believed that these particles could initiate foreign body reaction and formation of granulation tissue. The author suggested this foreign body response could cause osteolysis and subsequent development of aseptic loosening. In 1984 was introduced the “PE particle disease” theory [24]. Howie et al.[24] presented a study in rats in which a plug of polymethylmethacrylate was inserted into each femur and then exposed to ultrahigh-molecular-weight polyethylene particles 2, 4, 6 and 8 weeks after insertion. The aim was to mimic the bone-cement interface in cemented implants. Bone resorption was found around the implant, and at the interface the bone had been replaced by connective tissue. Based on these findings authors postulated that particles alone cause bone resorption in the absence of motion and infection. However these results have not ever been repeated. Sundfeldt et al. [101] investigated the effect of repetitive injections of UHMWPE particles in rabbit knees with a weight-bearing, articulating osseointegrated prosthetic joint. Despite the high load of particles, no radiographic, histological or biomechanical differences between test and control were detected, and they concluded that additional factors are required to initiate loosening process. Based on these findings increased intraarticular pressure inTHA hip was suggested as additional factor affecting development of aseptic loosening.

The theory of “increased intracapsular fluid pressure”, describing the effective joint space and its role in the development of aseptic loosening, was presented in 1994. Linder et al. [102]
discussed the effect of high pressure as part of the loosening/osteolytic process that happens when implant becomes loose. He suggested that intraarticular pressure in THA hip may act as mechanical factor and stimulate wear or polyethylene and subsequent bone resorption and further development of aseptic loosening.

Aspenberg and Van der Vist [103] demonstrated that oscillating fluid pressure induced osteolysis and osteocyte death. They reported 700 mmHg intraarticular pressure in prosthetic hip during walking, stairs climbing or rising from sitting position. The question they raised was if this intraarticular pressure in THA hip can be responsible for osteolysis. The authors investigated this in an experimental study. They applied a titanium surface onto cortical bone in rabbits after excising the periosteum. After 6 weeks there was a tight fit between titanium and bone what is common in uncemented THA hips with full osteointegration. After that a small area under the implant was subjected to a constant fluid pressure of 200 mmHg for a period of 2 weeks. This led to a massive bone resorption, exactly under the pressurized area. The granulation tissue replacing parts of the resorbed bone was found to be similar to the loosening granuloma. There were large amounts of macrophages containing particles. The findings of Aspenberg and Van der Vist [103] are in concordance with our study i.e. THA with 32 mm femoral heads had greater sonographically measured “capsular distension”/ intraarticular pressure as compared with 28 mm femoral heads (p<0.001). We also found that 32 mm femoral heads were also associated with higher polyethylene wear and higher cumulative revision rates when compared with 22 mm femoral heads. The correlation we found between PE wear what is known is associated with loosening after THA and sonographically measured “capsular distension”/ intraarticular pressure as compared with 28 mm femoral heads suggests the certain role of intraarticular fluid pressure in development of aseptic loosening after THA. However it is still unknown exact relationship between PE wear, osteolysis and increased intraarticular pressure in THA hip.

Robertsson et al. confirmed the relation between aseptic loosening of the prosthesis and increased intraarticular pressure [21]. He compared sonographically measured “capsular distension” in prosthetic hips with or without radiographic signs of loosening. He found that THA hips with radiographic signs of loosening were associated with increased “capsular distension”. Besides that he measured intraarticular pressure in hips with radiographic signs of loosening prior to revision surgery. The correlation between increased “capsular distension” and intraarticular pressure in THA hip was reported. Thus is in concordance with our theory that increased sonographically measured “capsular distension” reflects intraarticular pressure in prosthetic hip.

Aspenberg and Van der Vist [103] also raised hypothesis that loosening process is unrelated to wear particles. Thus, the initiation of the loosening process has other causes. After this process has started (i.e., the prosthesis migrates), particles may play a role, at least by inhibiting new bone formation at the membrane, but the hypothesis of pressure-induced bone resorption appears easier
to support by animal experiments and accords with mechanical risk factors. After the inaarticular fluid and related pressure are present in THA hip it is very likely that capsular tension and cyclic loading during gait function act as a pump that distributes particle-containing joint fluid through the port of least resistance – i.e., along the interfaces between the bone and the cement. This process affects the fixations of femoral stem also. If increased intraarticular pressure is present the fluid can migrate along the femoral stem in bone-cement or stem-cement interface. Thus femur gets exposed to the intraarticular fluid and this factor could cause subsequent osteolysis and failure of the femoral stem.

The finding of increased PE wear in the 32 mm group and it’s correlation with an increased “capsular distension” also suggests that an increased amount of PE particles increases synovitis and volume of fluid in the THA hip. PE particles may act as a trigger mechanism to start an inflammatory process in the THA hip, leading to the production of more fluid, increasing the pressure as demonstrated with increased “capsular distance” in our results.

Another theory was presented that increased intracapsular pressure induces osteolytic lesions of the bone due to disturbed circulation [102] with resulting cysts and subsequent bone loss.

These increased osteolytic lesions in larger diameter femoral heads eventually result in aseptic loosening and should show increased cumulative revision rates. However few studies have analyzed the influence of head diameter on CRR and they found no difference when different femoral heads were compares and followed up to 12 years. Marston et al. [19] followed 413 THA patients for 5 to 10 years and did not find that survival was affected by head size. Kesteris et al. [18] followed 1,660 patients for 2-12 years and did not find a significant difference between the 22 and 32 mm heads. However extended follow-up to 21 years postoperatively in our survival study disclosed the difference in cumulative revision rates when 22 mm and 32 mm femoral heads we compared.

The differences in PE wear and sonographically measured “capsular distension” in relation to head size were found in THA hips with no radiographic signs of loosening. This indicates that increased pressure/”capsular distension”, inflammation and subsequent loosening process start long before it can be detected radiographically. We cannot claim that combination of PE particles and high pressure is the main factors which results the aseptic loosening. However our findings show their importance in complex of different events with affects development of aseptic loosening in THA.

The differences in linear and volumetric wear we found in 28 and 32mm groups showed that 28mm head resulted decrease in volumetric wear about 90mm³ per year. Previously published studies reported about the same decrease in wear rates between groups when comparing 22mm vs. 32mm femoral heads [32, 16]. Thus our finding suggests that 28mm head reduces PE wear the
same as 22mm but provides better stability and less dislocation risk of the THA hip [104]. The authors studied 21,047 primary total hip arthroplasties performed with 22, 28 and 32 mm diameter femoral heads in 17,186 patients. Patients were routinely evaluated in person, by telephone, or with a mail questioner at two months, one year, two years, five years, ten years, fifteen years, twenty years, twenty-five years, and thirty years after the hip arthroplasty. At each time point patients were asked specifically whether a dislocation had occurred. A dislocation was defined as an event in which the hip required reduction by a physician. In multivariable analysis of dislocation risk authors found that 22 mm vs. 32 mm diameter femoral heads had greater dislocation risk (p<0.0001), and respectively 22 mm vs. 28 mm also showed greater risk for dislocation (p=0.037). Thus the results of our study suggests that 28 mm femoral head in THA is optimal to use with respect to PE wear and dislocation risk.
6. CONCLUSIONS

1. THA with 22 mm diameter femoral heads showed lower CRR than 32 mm when followed 9-21 years postoperatively.
2. We found better implant survival rates in THA performed in Lund University hospital as compared with less experienced in such type of surgery Klaipeda Hospital.
3. Polyethylene wear rate was greater in THA with 32 mm femoral heads that in 28 mm femoral heads, but we found no correlation between patients activity level, body mass index, age, cup inclination angle and wear rates.
4. We found that “capsular distance” i.e. joint effusion/synovitis was greater in 32 mm THA group as compared with 28 mm THA group.
7. PRACTICAL RECOMMENDATIONS

Smaller diameter femoral heads should be used in THA as a daily routine procedure. This will ensure lower PE wear rates and lower cumulative revision rates after total hip replacement. Optimal diameter femoral head is 28 mm and is recommended to use total hip replacement surgery.

Teaching is very important when new type of surgery is introduced. Knowledge of modern cementing technique and surgical applications will help to improve long term results after total hip replacement.
8. REFERENCES


81. Engesaeter LB, Lie SA, Espehaug B, Furnes O, Vollset SE, Havelin LI. Antibiotic prophylaxis in total hip arthroplasty: effects of antibiotic prophylaxis systemically and in


9. ACCESSORIES

**Table 4.** Data registration form

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>THA number</td>
<td>__________________________</td>
</tr>
<tr>
<td>Personal number</td>
<td>__________________________</td>
</tr>
<tr>
<td>Name and Surname</td>
<td>__________________________</td>
</tr>
<tr>
<td>Gender</td>
<td>Male          Female</td>
</tr>
<tr>
<td>Address</td>
<td>__________________________</td>
</tr>
<tr>
<td>Hospitalisation date</td>
<td>__________________________</td>
</tr>
<tr>
<td>Operation date</td>
<td>__________________________</td>
</tr>
<tr>
<td>Discharge date</td>
<td>__________________________</td>
</tr>
<tr>
<td>Age</td>
<td>_____</td>
</tr>
<tr>
<td>Side</td>
<td>Left           Right</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>__________________________</td>
</tr>
<tr>
<td>Implant type</td>
<td>__________________________</td>
</tr>
<tr>
<td>Bone cement</td>
<td>Yes            No</td>
</tr>
<tr>
<td>Cement type</td>
<td>__________________________</td>
</tr>
<tr>
<td>Cementing technique</td>
<td>Distal plug     Cement gun   Vacuum mixing   Lavage</td>
</tr>
<tr>
<td>Complications</td>
<td>__________________________</td>
</tr>
<tr>
<td>Activity level</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Wholly inactive: dependent on others; cannot leave residence</td>
<td></td>
</tr>
<tr>
<td>2. Mostly inactive: very restricted to minimum activities of daily living</td>
<td></td>
</tr>
<tr>
<td>3. Sometimes participates in mild activities such as walking, limited housework,</td>
<td></td>
</tr>
<tr>
<td>and limited shopping</td>
<td></td>
</tr>
<tr>
<td>4. Regularly participates in mild activities</td>
<td></td>
</tr>
<tr>
<td>5. Sometimes participates in moderate activities such as swimming and can do</td>
<td></td>
</tr>
<tr>
<td>unlimited housework or shopping</td>
<td></td>
</tr>
<tr>
<td>6. Regularly participates in moderate activities</td>
<td></td>
</tr>
<tr>
<td>7. Regularly participate in active events such as bicycling</td>
<td></td>
</tr>
<tr>
<td>8. Regularly participate in very active events such as bowling or golf</td>
<td></td>
</tr>
<tr>
<td>9. Sometimes participate in impact sports such as jogging, tennis, skiing,</td>
<td></td>
</tr>
<tr>
<td>acrobatics, ballet, heavy labor, or backpacking</td>
<td></td>
</tr>
<tr>
<td>10. Regularly participates in impact sports</td>
<td></td>
</tr>
</tbody>
</table>
AUTHORS PUBLICATIONS 2002-2007


