The Ringloc liner compared with the Hexloc liner in total hip arthroplasty

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Abstract

The aim of this study was to compare the 10-year survival rate, pelvic osteolysis frequency and linear head penetration rate of the Hexloc and Ringloc liners used together with a partially threaded porous and hydroxyapatite coated cup and the Bi-Metric uncemented femoral stem. The 15-year results for the cup with the Hexloc liner are also reported. We included 332 consecutive hips (166 Hexloc and 166 Ringloc) on 281 patients in the study. Revisions of prosthesis components were recorded and pelvic osteolytic lesions were assessed using radiographs and computed tomography. The linear head penetration rate was measured using the Martell method. The 10-year survival rate of the liner with revision due to liner wear and/or osteolysis as endpoint was 88% for the Hexloc liner and 98% for the Ringloc liner. The 15-year survival rate of the Hexloc liner was 67%. Pelvic osteolysis was found in 27% of the Hexloc and 19% of the Ringloc hips. After 15 years, 53% of the Hexloc hips had developed an osteolytic lesion. The linear head penetration rate was 0.16 mm/year for the Hexloc liner and 0.12 mm/year for the Ringloc liner. This paper is the first to describe the rapidly deteriorating osteolytic lesion. The linear head penetration rate of the Ringloc liner is a direct compression moulded liner which is a direct compression moulded liner that has a circumferential plasma-sprayed hydroxyapatite.

Materials and Methods

Patients and surgery

In this retrospective review of prospectively collected data, we included a consecutive series of 336 uncemented primary THAs performed in 285 patients between 1990 and 1997 at our department. We used uncemented implants for younger, active patients although no formal age-limit was used. Four patients (1 Hexloc and 3 Ringloc) were lost to follow-up. Thus, data for 281 patients (332 hips), 166 with Hexloc liners and 166 with Ringloc liner, are presented in this study. Seventeen patients had a Hexloc liner on one side and a Ringloc on the other. 19 had bilateral Hexloc and 15 had bilateral Ringloc liners. The mean age at surgery was 52 years in both groups. There were more males in the Hexloc group, 87 (52%) as compared to 61 (37%) in the Ringloc group (p=0.004). Antropometrical data on all patients are presented in Table 1.

Introduction

Total hip arthroplasty (THA) is one of the most cost effective and quality of life restoring surgical procedures in orthopedics. However, this development has not been without its historical pitfalls. Gamma-in-air sterilized ultra-high molecular-weight polyethylene (UHMWPE) used for cup liners, is one example of inferior design with both shelf and in vivo oxidation and concurrent degradation of the polyethylene. Sterilization in inert gas has been proven to enhance resistance to oxidation and became popular in the mid ‘90s.

At our department, between 1990 and 1997, a partially threaded hydroxyapatite (HA) porous-coated titanium shell was used for THA in younger patients. Between 1990 and 1994, a Hexloc liner manufactured from gamma-in-air sterilized UHMWPE was used with the shell. In 1995, the manufacturer changed the design of the shell to accommodate a more rigidly fixed Ringloc liner, compression moulded and sterilized in gas (argon), which was used between 1995 and 1997. In this study we wanted to see if we could confirm the earlier reported superior or survival and wear characteristics of the newer Ringloc liner in a larger patient cohort with longer follow-up.

All cups used in primary uncemented THA at our department have been followed-up for a minimum of ten years. In half of the cases the shell was combined with a Hexloc liner and in the other half a Ringloc liner was used. Survival rate and frequency of osteolysis as well as the linear head penetration rate for the two liners are reported in this study. The 15-year results for the cup in combination with the Hexloc liner are also presented.

Between 1990 and 1994, the shell was specifically designed to be used with the Hexloc liner. This liner was machined from extruded bar raw material UHMWPE and then gamma-sterilized in air. It is of cylindrical design and has a snap-fit locking mechanism in the bottom of the shell. Rotation of the liner is prevented by means of the hexagonal outer profile, which is located within a hexagonal recess machined in the shell. In 1995, the manufacturer changed the design to a Ringloc liner which is a direct compression moulded UHMWPE gamma-sterilized in argon (ArCom). The Ringloc liner has a hemispheric design that snaps into the circumferential of the shell (Figure 1). A standard posterior approach without repairing the external rotators or the posterior capsule was used, all patients received i.v. prophylactic antibiotics during the first 24 hours post-operatively. The patients were allowed to weight-bear according to the surgeon’s preference. Crutches were used for support and the patients were mobilized in accordance with a standard physiotherapy program.
Outcome measures and follow-up

The primary outcome measure was survival of the liner with revision for liner wear and/or osteolysis as endpoint.

Secondary outcome measures included survival of the liner with all reasons for revision as endpoint, development of pelvic periprosthetic osteolysis, linear head penetration rate, Harris hip score (HHS) and 15-year results for the Hexloc liner. Follow-up was carried out at one (SD 0.1), three (SD 0.3) and five (SD 0.4) years post-operatively and thereafter at 5-yearly intervals. Hips that showed excessive wear and/or pelvic osteolysis threatening the stability of the hip were revised. All revisions and complications registered in our medical records up till January 2008 have been included. With the help of the Swedish Hip joint registry it was possible to obtain data for all Swedish residents, i.e. those patients who had moved from the Stockholm area and also for those who did not attend follow-up visits at our Department. Therefore, the survival analysis is based on data from all 281 patients (332 hips) included in the study. Of these, 81 Hexloc hips had completed the 15-year follow-up by January 2008. All patients underwent standardized supine anteroposterior (AP) and lateral radiographs of the pelvis and proximal femur at all follow-up visits. The radiographs were examined for signs of osteolytic lesions around the cup in the DeLee and Charnley zones1 and when deemed necessary a computed tomography (CT) was performed to either confirm or rule out osteolysis. An osteolytic lesion was defined as definite when it was clearly visible on radiograph or CT-image with a size greater than 1 cm² or alternatively when discovered during cup revision surgery. Evaluation for the presence of pelvic osteolysis was possible for 153 (92%) Hexloc and 151 (91%) Ringloc hips ten years post-operatively and for 77 (99%) of the 81 Hexloc hips with a minimum of 15 years follow-up.

All radiographs performed between 1990-2000 were digitized using a flatbed scanner (Diagnostic Pro Plus, Vidar Systems Corporation, Herdon, VA, USA) and from 2001 and onwards with a digital radiographic technique was used (Bucky Diagnostic, Phillips, Eindhoven, Netherlands). All radiographs were in 150 DPI and saved in TIFF format.

The two-dimensional (2-D) linear head penetration rate was measured from the post-operative examination and 10-year examination using the Hip Analysis Suite™ software (University of Chicago, Chicago, Illinois, USA) version 8.0.4.1 developed by Martell. This method uses conventional AP radiographs and the software uses image analysis techniques, determination of bone landmarks and edge detection algorithms to determine the 2-D penetration value change in the position of the femoral head center with respect to the acetabular component center. Radiographs used for the measurement of linear head penetration rate were available for 138 (83%) Hexloc and 132 (80%) Ringloc hips. The rest were either missing or excluded by the software due to low image quality. There was an equal proportion of missing or excluded radiographs for revised/non-revised hips as well as hips with and without osteolytic lesions.

Post-operative radiographic femoral offset and cup inclination were measured with a digital templating software (mdesk™, RSA Biomedical, Umeå, Sweden). Harris hip score9 as determined with the student t-test; bas determined with the X² test. The demographic and implant factors used to analyze differences between the two groups and to adjust for potential confounding factors. A Cox regression model was applied to analyze the difference in polyethylene thickness.

Statistical analysis

The statistical analysis was performed using SPSS 15.0 for Windows software (SPSS, Chicago, Illinois, USA). The student t-test for normally distributed scale variables in independent groups and the X² test for nominal variables was used. The Mann-Whitney U test was used to compare categorical variables in independent groups as well as scale variables not distributed normally.

All tests were two-sided. The endpoint for the survival analysis was defined as revision for liner wear and/or osteolysis and the survival data were compared by the log-rank test. A Cox regression model was applied to analyze the difference between the two groups and to adjust for potential confounding factors.

The demographic and implant factors used to evaluate which factors increased the risk for revision were sex, age at surgery, weight, body mass index (BMI), Charnley class,10 indication for surgery, liner-type, radiographic femoral offset and cup inclination. All results were considered significant at p<0.05.

Table 1. Demographic data for the hips in the study. p are for comparison between the Hexloc and Ringloc groups including 17 patients with one Hexloc and one Ringloc liner that are part of both groups. The total number of patients in the study is 281. Mean (SD) values are shown.

| N. of hips | Hexloc N=166 | Ringloc N=166 | p |
|-----------|-------------|--------------|---|
| Male n (%) | 87 (52%) | 61 (37%) | 0.004* |
| Age at surgery (years) | 52 (8) | 52 (9) | 0.943* |
| Weight (kg) | 77 (16) | 73 (15) | 0.011* |
| Body mass index | 26 (4) | 25 (5) | 0.184:* |
| Charnley class (%/A/B/C) | 33/45/22 | 37/40/23 | 0.664* |
| Indication for surgery (%) | | | |
| Osteoarthritis | 100 (60%) | 110 (66%) | 0.389 |
| Inflammatory arthritis | 26 (16%) | 25 (15%) | |
| Sequel after fracture | 11 (7%) | 11 (7%) | |
| Hip dysplasia | 12 (7%) | 14 (8%) | |
| Other indication | 17 (10%) | 6 (4%) | |

*as determined with the student t-test; as determined with the X² test.
Results

Before they had completed their 10-year follow-up, 8 patients (10 hips) with Hexloc and 6 patients (7 hips) with Ringloc liners died of causes unrelated to their surgery. Surgical complications registered before the ten year follow-up are outlined in Table 2.

Seven patients (4 Hexloc and 3 Ringloc) of the 332 hips sustained a peri- or post-operative periprosthetic femoral fracture within ten years; 3 of these were treated with internal fixation and none required implant revision. The post-operative femoral offset was mean 41 mm (range 17-55) in both groups. The cup inclination was 44°C (range 16-75) and 40°C (range 16-64) in the Hexloc and Ringloc groups, respectively.

Survival

There was a significant ($p<0.0001$) difference in the 10-year survival rate of the liner with revision for liner wear and/or osteolysis as endpoint; 88% (95%CI 83-93%) for the Hexloc liner and 98% (95%CI 96%-100%) for the Ringloc liner. Out of a total of 22 cup and/or liner revisions carried out because of liner wear and/or osteolysis, 15 (70%) were asymptomatic. A Hexloc liner or age below 52 years at surgery significantly increased the risk for revision due to liner wear and/or osteolysis in the first ten years post surgery; hazard ratio (HR) 6.8 (95% CI 2.0-22.9, $p=0.002$) and 4.6 (95% CI 1.8-11.7, $p=0.001$), respectively (Figure 2). There were more males in the Hexloc group and, therefore, also a slightly higher body weight in that group (Table 1). When adjusting for sex and age at surgery the body weight did not influence the survival of the liners.

There was a significant ($p=0.034$) difference in the 10-year survival rate of the liner with all reasons for revision as endpoint; 87% (95%CI 83-91%) for the Hexloc and 94% (95%CI 92-96%) for the Ringloc liner. All revisions performed prior to the 10-year follow-up are summarized in Table 3.

The 15-year survival rate of the Hexloc liner with all reasons for revision as endpoint was 67% (95%CI 59-76%). All revisions performed within 15 years post surgery for the Hexloc liner are summarized in Table 4.

No liners were revised due to aseptic loosening of the metal shell. No revisions of any stems were required during the study period.

Pelvic periprosthetic osteolysis

Forty-two (27%) Hexloc and 28 (19%) Ringloc hips ($p=0.065$, X² test) had developed at least one pelvic osteolytic lesion in one of the Delee and Charnley zones at the 10-year follow-up (Figure 3). All osteolytic lesions were

| Table 2. Surgical complications within ten years. |
|-----------------------------------------------|
| Complication N. (%) of hips                    |
| Hexloc (N=166)                                 |
| Ringloc (N=166)                                |
| Dislocation < 6 months                         |
| 1 (0.6%)                                      |
| 3 (1.8%)                                      |
| Dislocation > 6 months < 10 years              |
| 8 (4.8%)                                      |
| 10 (6.0%)                                     |
| Venous thromboembolic events                   |
| 6 (3.6%)                                      |
| 1 (0.6%)                                      |
| Deep infection                                 |
| 2 (1.2%)                                      |
| 1 (0.6%)                                      |
| Superficial infection                          |
| 1 (0.6%)                                      |
| 4 (2.4%)                                      |
| Transient sciatic nerve palsy                  |
| 1 (0.6%)                                      |
| 2 (1.2%)                                      |

| Table 3. Revision surgery performed within ten years. |
|------------------------------------------------------|
| Surgery N. (%) of hips                               |
| Hexloc (N=166)                                      |
| Ringloc (N=166)                                     |
| Cup and liner revised                               |
| Because of pelvic osteolysis in combination with liner wear |
| 15 (9.0%)                                          |
| 3 (1.8%)                                           |
| Because of liner wear                               |
| 3 (1.8%)                                           |
| 0 (0.0%)                                           |
| Because of dislocation                              |
| 0 (0.0%)                                           |
| 3 (1.8%)                                           |
| Because of deep infection                           |
| 0 (0.0%)                                           |
| 1 (0.0%)                                           |
| Only liner exchange                                 |
| Because of pelvic osteolysis in combination with liner wear |
| 1 (0.6%)                                          |
| 0 (0.0%)                                           |
| Because of dislocation                              |
| 1 (0.6%)                                          |
| 2 (1.2%)                                           |
| Overall revisions                                  |
| 20 (12.0%)                                         |
| 9 (5.4%)                                           |

| Table 4. Revision surgery performed for the 81 Hexloc hips that have completed the 15-year follow-up. |
|------------------------------------------------------|
| Surgery N. (%) of hips                               |
| Hexloc (N=81)                                       |
| Cup and liner revised                               |
| Because of pelvic osteolysis in combination with liner wear |
| 22 (27.2%)                                         |
| Because of liner wear                               |
| 2 (2.5%)                                           |
| Only liner exchange                                 |
| Because of pelvic osteolysis in combination with liner wear |
| 1 (1.2%)                                          |
| Because of dislocation                              |
| 1 (1.2%)                                           |
| Because of deep infection                           |
| 1 (1.2%)                                           |
| Overall revisions                                  |
| 27 (33.3%)                                         |

Figure 2. Cox adjusted survival curve with revision of the liner because of liner wear and/or osteolysis as endpoint. Adjustment was made for age and sex.
classified as stage IIB or III according to Hozack et al.\textsuperscript{11} indicating wear and lysis (stage IIB) or wear, lysis and pain (stage III). After 15 years, 41 (53%) Hexloc hips had developed a pelvic osteolytic lesion.

Hips with a linear head penetration rate over 0.1 mm/year had a significantly increased risk for development of a pelvic osteolytic lesion before the 10-year follow-up; OR 5.2 (95% CI 2.2-12.0, \(p<0.0001\)).

**Linear head penetration rate**

The median linear head penetration rate was 0.16 (range 0.00-2.06) mm/year in the Hexloc group compared with 0.12 (range 0.00-0.85) mm/year in the Ringloc group (\(p=0.002\), Mann-Whitney U test). There was not a normal distribution in any of the groups for the linear head penetration rate. There were more outliers among the Hexloc hips (Figure 4). The median volumetric penetration rate was 72.9 (range 0.3-366.6) mm\(^3\)/year in the Hexloc group compared with 58.1 (range 0.1-308.9) mm\(^3\)/year in the Ringloc group (\(p=0.011\), Mann-Whitney U test).

**Harris hip score**

The Harris hip score, including revised hips, improved from median 50 (range 13-69) preoperatively to 95 (range 57-100) at the 10-year follow-up for the Hexloc group. In the Ringloc group, also including revised hips, HHS improved from median 51 (range 12-73) preoperatively to 96 (range 63-100) at the 10-year follow-up. Hips that had been revised before the 10-year follow-up had a significantly (\(p=0.001\), Mann-Whitney U test) lower median HHS than hips not revised; 88 (range 67-100) and 96 (range 57-100), respectively.

**Discussion**

**Survival**

In this study, we compare the 10-year results for the Romanus HA cup with the Hexloc and Ringloc liner. We found a significant difference in the 10-year survival rate in favor of the newer Ringloc liner; 87% vs. 94%. The difference in survival rate was even higher when comparing revisions carried out solely for liner wear and/or osteolysis; 88% vs. 98%. After ten years, the survival curve for Hexloc deteriorates rapidly (Figure 2) with a 15-year survival rate of 67%. We were able to verify these findings in a Cox regression model after adjustments for difference in male/female ratio between the groups. The large proportion of patients in the Hexloc group that required revision due to liner wear and/or osteolysis before ten years suggests that the 15-year results for the Ringloc liner will be better than the Hexloc liner.

**Table 5. Studies on the Hexloc and Ringloc liner with the present study as a comparison in the bottom of the table. Survival rate is reported for revision of the cup and/or liner for any reason.**

| First author | Follow-up (years) | N. of hips | Age at surgery (years) | Cup - liner | Survival rate | Osteolysis | Wear rate (mm/year) | Comments |
|--------------|-------------------|------------|------------------------|-------------|---------------|------------|---------------------|----------|
| Cautilli\textsuperscript{12} | 3 | 303 | 61 | Universal - Hexloc | 97% | 5.5% | 0.5 | Taperloc stem, Ti |
| Hozack\textsuperscript{13} | 6.1 | 105 | 61 | Universal - Hexloc | 89% | 25.5% | 0.25 | Taperloc stem, Ti |
| Puolakka\textsuperscript{14} | 7.5 | 148 | 6.0 | Universal - Hexloc | 85% | n.r. | n.r. | Bi-Metric stem, CrCo, Register study |
| Puolakka\textsuperscript{15} | 6.2 | 107 | 57 | Universal - Hexloc | 87% | 8.4% | 0.17 | Bi-Metric stem, CrCo |
| Yamamoto\textsuperscript{16} | 6.8 | 25 | 55 | Mallory-Head - Hexloc | n.r. | 12% | 0.13 | Bi-Metric stem, CrCo |
| Eskelinen\textsuperscript{17} | 10 | 68 | <55 | Romanus - Hexloc | 71% | n.r. | n.r. | Bi-Metric stem, CrCo, Register study |
| Isaac\textsuperscript{18} | 7.6 | 58 | 57 | Universal - Ringloc | 87% | 17% | n.r. | Bi-Metric stem, CrCo |
| Sköldenberg (2008) | 10 | 166 | 52 | Romanus - Hexloc | 88% | 27% | 0.16 | Bi-Metric stem, CrCo |

n.r, not reported; Ti, Titanium head, CrCo, Crome Cobalt head.
liners. However, at ten years, also the Ringloc hips have an alarmingly high proportion of osteolysis around the cup, not significantly different to the Hexloc hips; 27% vs. 19%, p=0.065.

The 7 patients (4 Hexloc and 3 Ringloc) that sustained a peri- or post-operative femoral fracture did not differ from the other patients in terms of Harris hip score, radiological outcome or linear head penetration rate.

Several shell designs have been used in combination with Hexloc and Ringloc liners, most of which have been of a press-fit design. A summary of the published reports is presented in Table 5. When comparing the results between press-fit shells and our results with the Romanus HA shell, the survival rate is similar, indicating that it is not the screw-in concept, as such, that fails.

Puolakka et al.14 and Isaac et al.17 reported in their studies of Hexloc and Ringloc liners, respectively, several cases of liner fractures as a reason for revision. We have had no revisions due to liner fracture in our study.

In an analysis of younger patients (<55 years) who received an uncemented THA, Eskelinen et al.16 report 10-year survival rates of 71% and 79% for the Romanus HA and Universal cup in combination with the Hexloc liner. The poor survival rate for this younger cohort is confirmed in our study where the Hexloc group had more males, but after adjustments had been made, the risk factors for revision because of liner wear and/or osteolysis before ten years were a Hexloc liner and an age below 52 years at surgery.

Pelvic periprosthetic osteolysis

The frequency of osteolytic lesions around the cup was evaluated using a combination of plain radiographs and computed tomography and a trend difference (p=0.065) was found in the frequency of pelvic osteolytic lesions after ten years for the Hexloc and Ringloc hips; 27% and 19%, respectively. After 15 years, the frequency for the Hexloc liner was 53%. The precision of detecting osteolytic lesions on plain radiographs is poor; once a lesion is evident radiographically, however, the likelihood that it truly exists is high. Osteolysis rate are also more reliable and accurate if they are determined by a single reviewer who is analyzing a series of radiographs as opposed to just examining the most recent radiograph. The fact that one of the authors (OS) evaluated all radiographs, and that computed tomography was also carried out on a large number of the hips, help to support our claim that the frequency of the osteolysis rate is correctly described in this study.

The open screw holes in the acetabular shell, in our study, is a design feature that offers an unobstructed migration route for wear particles to the pelvis that could start particle-induced osteolysis. Most of our detected osteolytic lesions have evolved from the region behind the open screw-holes. Hypothetically, an added cause contributing to this osteolytic pattern may be induced by a hydrostatic pressure effect due to poor locking of the liner in the shell. The process of osteolysis is multifactorial, however, and the simple elimination of screw-wholes in the cup shell would not eliminate osteolysis.25 The partially threaded porous-coated Romanus HA shell was designed to give immediate, stable fixation in the pelvis, thereby providing good conditions for osseous growth. In our opinion, the screw-holes in the shell are an unnecessary design feature. In fact, in none of the 232 hips described have we had to use supplementary screws to augment the fixation of the metal shell during surgery and none of our revisions were performed as a result of aseptic loosening.

Stress-shielding and subsequent bone resorption around acetabular cups has been postulated to increase the risk for osteolysis.26 The screw-in concept with a partially threaded shell for peripheral initial fixation may contribute to this, since the bone behind the dome initially is unloaded. However, the similar frequency of osteolysis in other studies with press-fit designs (Table 5) does not strengthen this theory.

The cell mediated inflammatory response to polyethylene wear debris resulting in periprosthetic osteolysis is, in this study as well as in others, the most important factor leading to long-term failure of joint implants. A number of studies have confirmed the relationship between wear of the cup-liner and osteolysis; a correlation that is confirmed in our study where the strongest risk factor for development of osteolysis was a linear head penetration rate over 0.1 mm/year.

Linear head penetration rate

The Martell method to measure linear head penetration rate was used in this study. It has clearly better repeatability and higher accuracy than the Livermore technique and is almost as precise as radiostereometric analysis (RSA). A recent comparison between RSA and the Martell method showed that there is good agreement between the two methods in terms of penetration rates with time and the steady-state wear rates.

The Hexloc liner has several design features that can explain its high wear rate. Firstly, the gamma-in-air sterilized UHMWPE used in the design of the liner has been shown to be vulnerable to both in vitro28 and shelf4 oxidation with concurrent degradation of the UHMWPE. Secondly, the cylindrical, and thereby thinner, design of the Hexloc liner (Figure 1) may, together with the inferior locking mechanism, create less stable conditions and thus lead to a higher wear rate than with the more stable Ringloc liner. Finally, the manufacturing process of the polyethylene, machined from extruded bars for Hexloc and the compression moulding process used in the ArCom™ polyethylene in the Ringloc liner, is also of importance. Compression moulding for tibial components used in total knee arthroplasties has shown very low revision rates and wear when compared to machined polyethylene.20-24

Radiographic femoral offset over 40 mm are claimed to reduce linear wear rate26 and cup inclination over 55° have been reported as a bad prognostic factor for wear26 but we have not been able to verify these findings in this study.

The recently developed highly-crosslinked UHMWPE25 has proven its durability in vitro and in a number of randomized clinical trials and is now becoming a standard implant. RSA-data indicates that the wear is reduced by 90-95% up to five years as compared to the liners in this study. There are, however, many thousands of patients with gamma-in-air UHMWPE liners in situ. Puolakka et al.15 for instance report that 6,924 Hexloc type liners were sold with different cup designs between 1986 and 1996 in Finland. According to information from the Swedish Hip Arthroplasty Register and contact with Dr. Romanus, at least 1,372 Hexloc liners and 1,272 Ringloc liners used with the Romanus HA cup have been implant ed in Sweden between 1989 and 1999. The present study is, therefore, a good example of why stepwise introduction of new implants should be carried out.27

In conclusion, the previously well known excellent long-term result of the uncemented Bi-Metric femoral stem is confirmed in this study. This paper is, however, the first to describe the rapidly deteriorating survival up to 15 years with the old generation gamma-in-air sterilized polyethylene used in Hexloc liners. The newer Ringloc liner with the ArCom™ polyethylene has superior results in terms of survival, but a linear wear rate and frequency of osteolytic lesions that is higher than expected. Whether the new generation highly-crosslinked polyethylene will solve this problem remains to be seen.

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