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Core decompression in osteonecrosis of the femoral head: risk-factor-dependent outcome evaluation using survivorship analysis

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Abstract The results of core decompression of the femoral head in the treatment of osteonecrosis are analyzed. This study includes 94 hips in 74 patients with a followup time ranging between 18 months and 15 years (average 6 years). There had been no need for further surgery 2 years postoperatively in 85% of the hips with preoperative Steinberg stages 0, I and II when compared with 66% with preoperative stages III, IV and V. At 4 years postoperatively the corresponding figures are 73 compared to 55%; and 6 years postoperatively 69 compared to 49%. This difference was significant (P=0.0402). Further significant risk factors are corticosteroid administration, smoking and alcohol intake. The results of core decompression are good when the preoperative lesion is at Steinberg stage 0, I and II and the patient does not present with other risk factors. In cases with risk factors the outcome is significantly less good. The procedure is not indicated in the presence of advanced disease.

Résumé Dans cette étude nous avons analysé les résultats de la décompression de la tête fémorale chez des patients avec ostéonécrose de la tête du fémur. 94 hanches de 74 patients ont été analysées. La durée de suivi a varié entre 18 mois et 15 ans. Deux ans après la décompression les résultats ont été satisfaisants (aucune reintervention chirurgicale) dans 85% des cas avec une nécrose préoperatoire dans les stades de Steinberg 0, I ou II. Avec les stades III, IV ou V les résultats ont été satisfaisant dans 66% des cas. Quatre ans après la décompression les résultats satisfaisant ont été 73% (0, I ou II) et 55% (III, IV ou V). Six ans après la décompression les résultats satisfaisant ont été 69% et 49%. Les traitements avec corticoide, l'alccol et la nicotine augmentent le risque d'une ré intervention chirurgicale après la decompression d'une manière significative. Les résultats de la

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Tel.: +49 6221-965 Fax: +49 6221-96 6121 decompréssion sont bons, si la 1ésion de la nécrose n'excéde pas le stade II de Steinberg et s'il n'a pas autres facteurs risque. Avec des facteurs de risque les résultats déclinent significativement. Dans les stades de Steinberg III, IV ou V la décompression n'est pas indiquée.

Introduction

Osteonecrosis of the femoral head (ONFH) is a disease of unknown pathology. The natural history normally progresses to femoral head arthrosis with the need for total hip replacement (THR) [4]. Nonoperative treatment, such as limited weight-bearing, has been shown to be of little value. About 80% of conservatively treated patients require THR [21]. Core decompression (CD) is a treatment option that has been in use since the 1960s [4,10]. Although widely used, published clinical results are inconsistent and range from disappointing [1,8,14] to encouraging [3,25,27].

This study was undertaken to evaluate the postoperative success of CD as judged by the need for re-operation, radiographic progression and clinical outcome, by using survivorship analysis.

Patients and methods

In 1997 we performed a retrospective study of patients who had undergone a CD procedure as treatment for ONFH. Surgical treatment was performed between 1981 and 1996. The diagnosis was established by clinical history and radiography in two planes.

A total of 94 CD procedures (54 unilateral and 20 bilateral) were carried out in 74 patients. Nineteen of the bilaterally decompressed patients were operated on for both hips simultaneously. Fifty-seven patients (73 hips) were male and 17 patients (21 hips) were female, the average age at the time of operation was 40 years (16–76 years).

A direct lateral approach to the proximal femur was used. The entry point of the drill hole was made in the distal aspect of the greater trochanter, under image intensifier control. The track was drilled using either a 6 mm drill or an 8 mm trephine. When the trephine was used, one track was drilled through the cortical hole into the femoral head. When the drill was used two or three tracks

were drilled through one single cortical hole. In each case the position of the drill or trephine was controlled in two planes by image intensification. Partial weight-bearing was continued for 6 weeks postoperatively. Patients who underwent simultaneous, bilateral procedures used a wheelchair during this period.

The cross-sectional study was carried out after an average follow-up of 6 years (1.5–15) for successfully treated hips. Early treatment failures, such as re-operation within the first 18 months, were also included. Re-operation was a primary outcome measure. Clinical failure and radiographic progression were secondary outcome measures. Clinical failure was defined as a "poor" Merle d'Aubigné or Postel grade [20]. This grading system includes pain, ability to walk and mobility. Points for pain and ability to walk combined to a maximum of 12. Grades of 12 or 11 points are considered very good, 10 as good, 9 as medium, 8 as fair and 7 or less as poor. If mobility is reduced to 4 points, the result is classed one grade lower; if mobility is reduced to three or less points the result is classed two grades lower. Underlying disease (systemic lupus erythematosus, psoriasis, Perthes' disease, gout, etc) was recorded as well as steroid therapy, alcohol intake and cigarette smoking. Severe underlying disease was present in 63 patients

The preoperative radiographs were scored in two planes according to Steinberg and co-workers [26] in order to determine the stage and extent of the lesion. We scored 86 preoperative radiographs (91%) that were available. In 8 cases (9%) preoperative radiographs were not available. These hips were classified into two groups based on the medical records (either Steinberg stage 0, I and II or Steinberg stage III, IV and V).

Patients were contacted either by mail or telephone and asked to answer a standardized questionnaire that included the Merle d'Aubigné score. The primary and secondary outcomes for all hips were determined. In 70 cases (74%) we were able to contact the patients. In 24 cases (26%) postoperative data were taken from the medical records, as these patients had undergone a THR (3 hips), had died (6 hips), or had moved (15 hips).

The most recent available radiographs were analyzed and scored. Radiographic progression, compared to the preoperative status was considered as deterioration. In 61 cases postoperative radiographs were available; thus, 61 complete pairs of pre- and postoperative radiographs were scored.

Survivorship analysis is an appropriate method of analyzing long-term results of surgical procedures [2,13]. Probability of reoperation, clinical failure and radiographic progression were calculated according to Kaplan and Meier [12]. The standard error

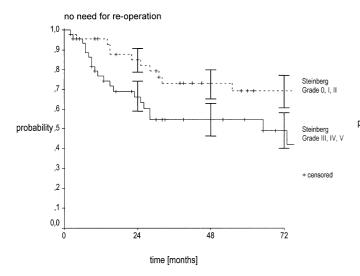


Fig. 1 Survival distributions of preoperative Steinberg grade 0, I, II and Steinberg grade III, IV, V hips. Error bars represent one SE above and below the estimated probabilities for 24, 48 and 72 months

(SE) was calculated for 2, 4 and 6 years. We also performed a Cox regression analysis with sex, age, radiographic stage and risk factors as variables. The analysis was performed with the statistical software SPSS.

Results

Thirty-two re-operations were performed; 30 THRs, 1 varus osteotomy and in 1 case CD was repeated. Twelve re-operations were performed in the Steinberg 0, I, II group; and 20 in the Steinberg III, IV, V group. The survival distributions of early and advanced state hips differed significantly (P=0.0402 log rank test, Fig. 1).

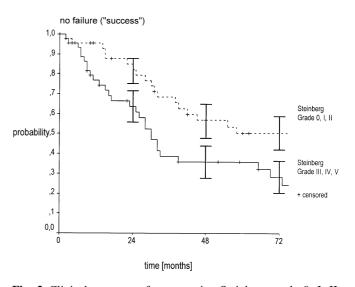


Fig. 2 Clinical outcome of preoperative Steinberg grade 0, I, II and Steinberg grade III, IV, V hips (no re-operation and at least a fair Merle d'Aubigné grade). Error bars represent one SE above and below the estimated probabilities for 24, 48 and 72 months

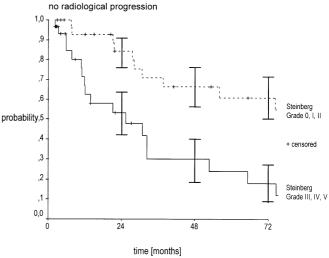


Fig. 3 Radiographic outcome of preoperative Steinberg grade 0, I, II and Steinberg grade III, IV, V hips. Error bars represent one SE above and below the estimated probabilities for 24, 48 and 72 months

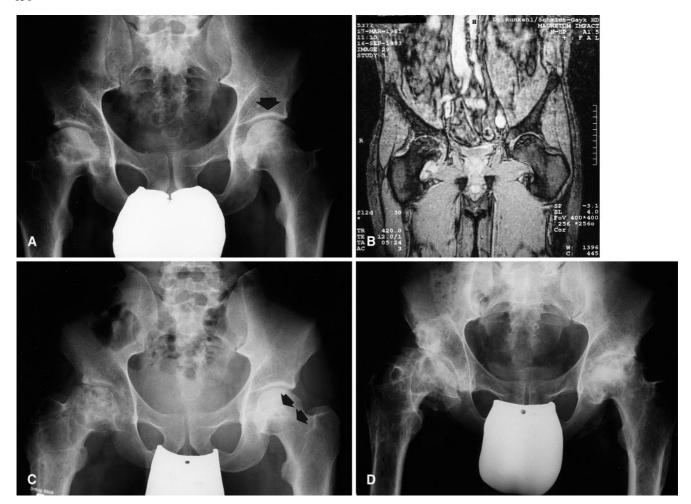


Fig. 4A–D Radiographic course of a 33-year-old man suffering from bilateral osteonecrosis of the femoral head (ONFH). The patient was presently receiving corticosteroid medication. At the time of diagnosis the left hip (*arrow*) was painful but in an early stage (**A, B**). **C** Two years postoperatively the outer form of the head is maintained, the track is visible (*arrows*). **D** Eight years postoperatively, there is severe deterioration of the hip, pain and decreased range of motion

Survival distribution based on the extent of the lesion (A: <15% of head involvement, B: 15–30%, C: >30%) showed inferior results in cases with extensive lesions; but these results were not statistically significant.

In addition to the 32 re-operations, 18 hips had a poor Merle d'Aubigné grade; 8 in the Steinberg 0, I and II group and 10 in the Steinberg III, IV and V group. Again, the survival distributions of early and advanced stage hips differed significantly (*P*=0.0117, log rank test, Fig. 2).

Radiographic progression was found in 32 (52%) of 61 hips with pre- and postoperative radiographs; none of the hips had improved. In the Steinberg 0, I and II group, 13 (43%) of 30 hips progressed; in the Steinberg III, IV and V group 19 (61%) of 31 hips progressed. Survival distributions of early and advanced stage hips differed significantly (P=0.0012, log rank test; Fig. 3).

We performed a Cox regression analysis in order to estimate the influence of several risk factors on survival.

Table 1 Variables associated with an increased risk of re-operation. All risks are adjusted for each other

Variable	Relative Risk (RR)	95% Confidence interval of RR	P-value
Cigarette smoking	2.6	1.2–5.5	0.0120
Persistent corticosteroid medication	2.5	1.1–6.1	0.0369
Preoperative Steinberg stage III, IV, V	2.0	0.9–4.3	0.0732

We chose a stepwise (backward) procedure. A variable was removed from the model if the probability of its removal was statistically 0.10 or more. The following variables were entered: underlying disease, regular alcohol intake, cigarette smoking, corticosteroid medication since initial operation, sex, stage and age at operation.

Five cases were excluded from the analysis. In two cases data were missing (cigarette smoking and regular alcohol intake) and three cases were censored from the outset. The results of the remaining 89 hips (95%) are shown in Table 1. Variables not entered in the model (underlying disease, regular alcohol intake, sex and age at operation) are omitted.

Regular alcohol intake was not significantly associated with re-operation (P=0.5649). We therefore repeated

Fig. 5A,B Course of a 25-yearold man suffering from osteonecrosis of the femoral head (ONFH) without risk factors. A At diagnosis the left hip was painful. B Two years postoperatively the patient is pain free. The drill track is still visible (arrows)



the analysis with an interaction term of cigarette smoking and regular alcohol intake. This interaction term (smoking and alcohol intake) became highly significant (P=0.0039) and the re-operation rate was three times higher for those who drank and smoked (95% confidence interval: 1.4–6.3).

There were two minor complications involving delayed wound healing and six major complications. Two patients suffered from pulmonary embolism one with a fatal outcome (all patients received prophylactic anticoagulation with low molecular weight heparin). Two fractures of the proximal femur were recorded after a fall. In two patients wound infections occurred and were treated conservatively.

Discussion

Four conclusions may be drawn: firstly, advanced stage, steroid therapy, regular alcohol intake and cigarette smoking are important risk factors for the outcome after CD [6,7,9,19,32,33]. Regular alcohol intake was only a significant risk factor when combined with smoking. This finding may be a results of patient inaccuracy in the answering this part of the questionnaire. To date, only Hirota et al. [7] have identified cigarette smoking as a risk factor in the development of ONFH.

Secondly, survival of the hip after CD is time dependent. As shown by Kaplan-Meier survivorship analysis, survival rates of decompressed hips are time dependent [3,14]. During the first 6 years we observed deterioration in all subgroups of our study population. Some of the disparity in the results following CD might be explained by the fact that most of the published studies do not use survivorship analysis and life tables when describing their results [8,16–18].

There are two studies using survivorship analysis and life tables [3,14]. Koo et al. [14] report inferior results with a medium radiographic failure time after CD of 9 months with no difference between decompressed and conservatively treated hips. There was a difference in the operative technique. Koo et al. filled the deep part of the decompression tunnel with canellous bone from the trochanteric region. This may result in decreased revascularization of the decompressed femoral head as cancellous bone may prevent vessel ingrowth. In contrast, Fairbank et al. [3] report superior results with an average follow-up of 11 years. As ONFH is a progressive condition with time-dependent radiographic and clinical deterioration, primary failure of the procedure was defined by Fairbank et al. and by our group as when a further operation was required. Despite the good long-term results, 56% of the decompressed hips progressed radiographically in their series.

Thirdly, the results of CD are superior to the results of conservative treatment [21,26,27]. The overall success rate including late stages and risk factors, after 2, 4 and 6 years are 73, 46 and 39%, respectively. The results of CD are better than the results of nonoperative treatment collected by Mont et al. [21]. In this meta-analysis 21 studies with 819 hips treated nonoperatively were reviewed, with a clinical success rate of 22.7%. Our data confirm the superiority of CD over the natural history, although the power of the comparison of our data with the historical control group of Mont et al. [21] is limited, as most of the data reviewed by this group were collected from retrospective studies with a wide range of follow-up periods.

Two prospective randomised clinical trials have compared CD and conservative treatment. Stulberg et al. [28] achieved a clinical success rate of 74% (20/28) after CD

compared to 90% (2/22) after conservative treatment; whereas Koo et al. [14] were not able to detect any difference between 18 hips treated by CD compared to 19 conservatively treated hips; the success rates in this study were 22compared to 21%.

Theoretically, there is a need for prospective studies, but the available data seem to be sufficient to confirm the superiority of surgery over conservative treatment. From the ethical point of view, it is difficult to justify further prospective and randomized clinical studies which compare surgically and conservatively treated patients.

Fourthly, CD is successful in the treatment of the early stages of ONFH [17,31]. Hips in early stages do significantly better than hips in advanced stages, independent of the treatment method. In our series of CD, overall success rates for hips in Steinberg stages 0–II are 82% after 2 years, 57% after 4 and 50% after 6 years. Although the follow-up periods are different, these figures are comparable to those reported by Powell et al. [23] and Warner et al. [31], better than those reported by Camp et al. [18], Kristensen et al. [15], but worse than those reported by Fairbank et al. [3], Lederer and Knahr [17] and Smith et al. [25].

As time-dependent survival rates are not reported in most of the studies cited, the comparison of these data is of limited value. This fact underlines the importance of using survivorship analysis and life tables.

In our study the clinical success rates (no reoperation and score > 7) in the early stages were 82% after 2 years, 57% after 4 and 50% after 6 years. After exclusion of risk factors corresponding data are 100% after 2 years and 75% after 4 and 6 years, respectively. Thus, in patients suffering from ONFH in Steinberg stages 0, I and II without risk factors CD is the treatment of choice. Other treatment options show similar long-term results in these stages, i.e. vascularized bone grafting [5,24,30] or transtrochanteric rotational osteotomy [11], but are technically demanding and time and cost intensive.

In the early stages of ONFH where there is underlying disease or risk factors, our results justify core decompression as the treatment of choice. In these patients, short-term radiographic or MRI controls are recommended to detect progression early. When the condition progresses other operative techniques are required (varus osteotomy, rotational osteotomy, vascularized bone grafting). Patients should be aware that continuing steroid medication, smoking and alcohol intake increase the risk of failure.

In advanced stages our results were not satisfactory compared with the published results of other procedures, i.e. angulation and rotational osteotomy, "trap-door" procedures or vascularized bone grafting [15, 11, 22, 24, 29, 30]; therefore, in advanced stages of ONFH core decompression cannot be recommended.

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