

Aseptic stem loosening in primary THA: migration analysis of cemented and cementless fixation

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Abstract Early migration has reportedly been predictive for later implant failure. Using four different migration patterns, this study aimed to analyse migration behaviour of the two types of implant fixation—cemented and cementless—throughout the process of loosening. Migrational behaviour of 69 revised stems (49 cemented, 20 uncemented) was analysed retrospectively with EBRA-FCA (Einzel-Bild-Röntgen-Analyse, Femoral Component Analysis). Uncemented stems failed after early and late onset migration alike, while late migration was the predominant pattern in cemented stems. Mean prosthetic failure after early migration occurred 5.8 (± 4.4) years postoperatively due to insufficient primary stability. Initially stable stems with late onset migration were revised after 12.4 (± 4.5) years. Measurement of early migration was found to be a valuable tool to screen short-term and mid-term failure. In the long run the method's sensitivity decreased. Late onset migration, however, preceded long-term failure by a mean of three years.

Résumé Le but de cette étude est de rapporter les migrations précoces en rapport avec une prévision d'échec des implants. Pour cela, nous avons utilisé quatre groupes de PTH avec différentes migrations à propos du devenir de deux types de fixation des implants, cimentés ou non cimentés. L'évolution de la migration sur 69 prothèses

(pièces fémorales 49 cimentées, 20 non cimentées) ont été analysées de façon rétrospective selon la méthode EBRA-FCA les pièces fémorales non cimentées peuvent présenter des échecs précoces et tardifs, alors que les prothèses cimentées ne présentent que des échecs tardifs. L'échec le plus fréquent est la migration qui se fait en moyenne à 5,8 ($\pm 4,4$) ans post-opératoire en relation avec une insuffisance de stabilité primaire. Les pièces fémorales stables ont une migration beaucoup plus tardive et ne sont révisées qu'après 12,4 ans ($\pm 4,5$). la mesure de la migration précoce permet de dépister les échecs à court et moyen terme. La méthode décrite est fiable, les migrations tardives cependant sont précédées d'un échec à long terme et ont évolué pendant au moins trois ans avant la reprise.

Introduction

Early migration has been shown to be predictive for late aseptic failure in numerous studies [4, 7–10, 13, 16, 17]. Previous publications primarily aimed to identify threshold values of early migration for prediction of later aseptic failure. Freeman and Plante-Bordeneuve [4] recognised a migration threshold of 1.2 mm per year during the first two years. Walker et al. [17] found a rate of failure of 95% for stems with a subsidence of more than 2.6 mm two years postoperatively. Kärrholm et al. [7] used RSA (radiostereometric analysis) [14] and calculated a risk of 50% if the implant had subsided more than 1.2 mm within the first two years. The risk increased to 95% if a threshold of 2.4 mm was exceeded. Krismer et al. [10] used EBRA-FCA (Einzel-Bild-Roentgen-Analyse, Femoral Component Analysis) [2] for migration analysis. The authors identified a threshold value of 1.5 mm after two years as a predictive

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factor for aseptic failure. Implants without migration, on the other hand, showed good long-term performance. These results were confirmed by other authors [3, 6, 12]. More importantly, Krismer and associates identified four types of migration patterns: early onset of migration with continuous subsidence, secondary stabilisation after early migration, late onset of migration after an initial stable period, and stability throughout the whole process of observation [10]. These patterns, however, were mainly derived from a large number of clinically stable stems. Due to lack of a greater quantity of failed stems, information about migrational behaviour throughout aseptic implant failure was poor.

The purpose of this study was to identify the modalities of subsidence in failing femoral components. Special attention was given to the influence of stem fixation (cemented versus cementless) on the overall migration pattern.

Material and methods

Patients

All patients undergoing primary total hip arthroplasty and consecutive revision surgery for aseptic loosening were included in the study. Between January 1996 and December 2004, 124 femoral components were revised and confirmed to be loose at the time of surgery. Implant infection was ruled out by bacteriological analysis in all cases. Retrospective migration measurement was obtained by using routine follow-up radiographs preceding revision surgery. As EBRA-FCA [2] was applied, radiographs which technically were not comparable were eliminated by the method's comparability algorithms. A minimum of four radiographs per series were needed to obtain representative results. Fifty-five patients had less than four comparable X-rays between primary implantation and revision, leaving 69 cases of 20 uncemented and 49 cemented stems for migrational analysis. All primary implantations had been performed by nine independent experienced surgeons via a standardised lateral transgluteal approach in supine position [1]. Implant types are listed in Table 1.

When comparing the two groups (cemented versus cementless) no significant differences were found in terms of patient gender or implant side (t-test: $p=0.85$ and $p=0.29$ respectively). Patients with cemented implants were significantly older than those with a cementless implant, at the time of the primary intervention ($60.2 \text{ years} \pm 8.7$ versus 55.4 ± 6.9 years; t-test: $p < 0.05$) as well as at the time of revision surgery (70.9 ± 8.2 versus $64.1 \text{ years} \pm 7.1$, $p < 0.01$). The two groups were comparable in terms of time to revision (cementless $8.7 \text{ years} \pm 5.4$; cemented $10.7 \text{ years} \pm 4.9$; $p=0.09$), showing a tendency towards earlier failure in cementless stems.

Table 1 Number and types of failed femoral stems in this study

Mode of fixation	Implant type (manufacturing corporation)	<i>n</i>
Cementless	Spotorno CLS stem (Sulzer, Baar, Switzerland)	10
	PCA stem (Howmedica, Rutherford, New Jersey, USA)	9
	Zweymüller stem (AlloPro, Baar, Switzerland)	1
Cemented	Lubinus SP II stem (Waldemar Link, Hamburg, Germany)	23
	M.E.Müller straight stem (Protek, Bern, Switzerland)	15
	M.E.Müller curved stem (Protek, Bern, Switzerland)	11

Migration measurement

Implant migration was measured in conventional anterior–posterior radiographs of the hip. Analogous images were digitised with a VXR-8 Film Digitizer (Vidar Systems Corporation, Herndon, Virginia, USA). Digitally archived radiographs were accessed with the IcoView 1.7.4.26 program (IcoServe Information Technologies, Innsbruck, Austria). EBRA-FCA (2003/SP2) was the method of choice for migration measurement in this retrospective study; it reaches a specificity of 100% and a sensitivity of 78% for detection of migration of one or more millimetres. The systemic error of the method is ± 1.5 mm, Cronbach's coefficient α for interobserver variance is reportedly 0.84 [2], and the method was shown to have sufficient precision to detect clinically relevant migration [18].

Migration behaviour was classified according to the four patterns (A–D) described by Krismer et al. [10]. Pattern A was defined by early onset migration with continuous subsidence, while pattern B represents a secondary stabilisation after two years. Pattern C was defined by late onset migration two or more years after implantation. Pattern D implied no detectable migration at all. Early migration was described as detectable migration within the first two postoperative years by Freeman and Plante-Bordeneuve [4]. Detectable migration was considered as migration of 1.5 mm or more according to the accuracy of the method.

Radiographic material consisted of a total of 584 X-rays in 69 series. Radiographs were taken three, six, and twelve months after implantation and at consecutive annual check-ups. The series contained a mean of 8.5 radiographs (± 3.7) without significant difference between uncemented and cemented implants (t-test $p=0.4$). Comparability limits of EBRA-FCA were set at 3 mm. For this reason a total of 23 radiographs (3.8%) were excluded from calculations.

The sensitivity of the method is defined as: $\text{sensitivity} = \frac{\text{true positive}}{\text{true positive} + \text{false negative}}$, employing migration patterns introduced by Krismer et al. [10] (see Table 2).

Table 2 Prediction of implant failure with early migration measurement. True positive, true negative, false positive, and false negative results are defined by employing migration patterns introduced by Krismer et al. [10]

Results	Early migration	Late migration	Failure	Migration pattern	Prediction of loosening
True negative	–	–	–	D	+
False positive	+	–	–	B	–
True positive	+	+	–	A	+
False negative	–	+	+	C	–
False negative	–	–	+	D	–

Pattern A: Early migration followed by continuous subsidence

Pattern B: Early migration followed by secondary stabilization

Pattern C: Initial stability followed by late onset migration

Pattern D: No detectable migration

Sensitivity was calculated for every year of the entire observation period. Specificity had already been identified at 80% by Krismer et al. [10] and was not re-evaluated here, as false positive and true negative groups (stable stems) were not subjects of this study.

Statistics

Statistical analysis was performed with the SPSS 11.0 statistical software package (SPSS Inc., Chicago, Illinois, USA). Gaussian distribution was tested with the Kolmogorov Smirnov test. Quantitative variables are described by mean and standard deviation (mean \pm SD) in cases of normal distribution, otherwise with median and interquartiles; mean values of the subgroups were compared with Student's *t*-test or Mann-Whitney test, respectively. A 0.05 level of significance was used for all analyses.

Results

For cementless stems, the dominating pattern of implant loosening was early onset of migration (type A, 11/20 or 55%;

see Table 3); whereas the cemented stems tended towards a late onset migration pattern (type C, 30/49 or 61%). The share of prostheses with failure after early onset migration was far smaller in this group. For the remaining cemented implants, EBRA-FCA detected no migration throughout the entire process of loosening (pattern D). In these cases, implant failure was not a consequence of subsidence but of other factors (see Table 4). Despite the difference in mean onset of migration (*t*-test $p < 0.01$), cementless and cemented stems were comparable in terms of stem survival ($p = 0.07$) and total amount of migration ($p = 0.12$).

Stems with early migration (pattern A) showed analogous migrational behaviour in cemented and uncemented implants (onset of migration, $p = 0.67$; total migration, $p = 0.78$; stem survival, $p = 0.23$), as well as stems with late onset migration (pattern C; migration onset, $p = 0.09$; total migration, $p = 0.51$; and stem survival, $p = 0.63$).

If, however, implants with early migration onset (pattern A) were compared with late migrating implants (pattern C), differences became evident regardless of type of fixation. An implant with early onset of migration was revised before an implant with late migration onset had even started to subside (migration onset, $p < 0.01$). Stems with migration pattern A were revised at a mean of 6.6 (± 3.8) years earlier than stems

Table 3 Migration behaviour (migration onset, amount of migration two years after primary implantation and before revision surgery, stem survival) for subgroups defined by migration patterns and implant fixation

Mode of fixation	Group ID	<i>n</i> (%)	Migration onset (y)	Early migration (mm)	Total migration (mm)	Stem survival (y)
Cementless	Total	20	3.9 \pm 3.8	2.2 \pm 1.8	5.6 \pm 3.6	8.5 \pm 5.6
	Pattern A	11 (55%)	13.4 \pm 6.3	3.2 \pm 1.4	5.7 \pm 4.2	4.7 \pm 5
	Pattern C	9 (45%)	6.6 \pm 3.7	–	4.7 \pm 2.2	11.9 \pm 2.2
Cemented	Total	49	7.6 \pm 5.4	–	4.0 \pm 4.1	10.9 \pm 4.9
	Pattern A	9 (18.5%)	14.4 \pm 4.6	2.2 \pm 0.7	6.3 \pm 4.7	7.1 \pm 3.2
	Pattern C	30 (61%)	9.7 \pm 4.9	–	3.9 \pm 3.5	12.5 \pm 5
	Pattern D	10 (20.5%)	–	–	–	9.4 \pm 4.4
Total	Pattern A	20 (29%)	1.2 \pm 0.5	2.9 \pm 1.3	6 \pm 4.2	5.8 \pm 4.4
	Pattern C	39 (56.5%)	8.9 \pm 4.8	–	4.1 \pm 3.2	12.4 \pm 4.5
	Pattern D	10 (14.5%)	–	–	–	9.4 \pm 4.4

Table 4 Stem survival and indications for revision surgery of failed femoral stems without detectable migration (pattern D). In cases of radiolucent lines (RLLs) and focal osteolyses (FOs), the number of affected Gruen-zones [5] is given in parentheses

Implant ID	Implant type	Implant survival (y)	Indication for revision surgery
1	Lubinus SP II	4.2	Progressive pain, FO (1); stem was judged unstable during revision surgery of the cup
6	Lubinus SP II	9.6	Progressive pain, FO (6)
8	Lubinus SP II	4.3	Progressive pain, RLL (6)
19	Lubinus SP II	6.6	Progressive pain, RLL (5), multiple cement fractures
31	Lubinus SP II	6.4	Progressive pain, FO (1), massive cortical reaction; stem was judged unstable during revision surgery of the cup
42	Lubinus SP II	10.3	Progressive pain; RLL (6)
14	M.E.Müller (straight stem)	17.7	Progressive pain, RLL (6)
30	M.E.Müller (straight stem)	9.1	Progressive pain, FO (6)
53	M.E.Müller (straight stem)	15.2	Progressive pain, RLL (5)
40	M.E.Müller (curved stem)	10.3	Progressive pain, massive varus-tilting of the stem without subsidence

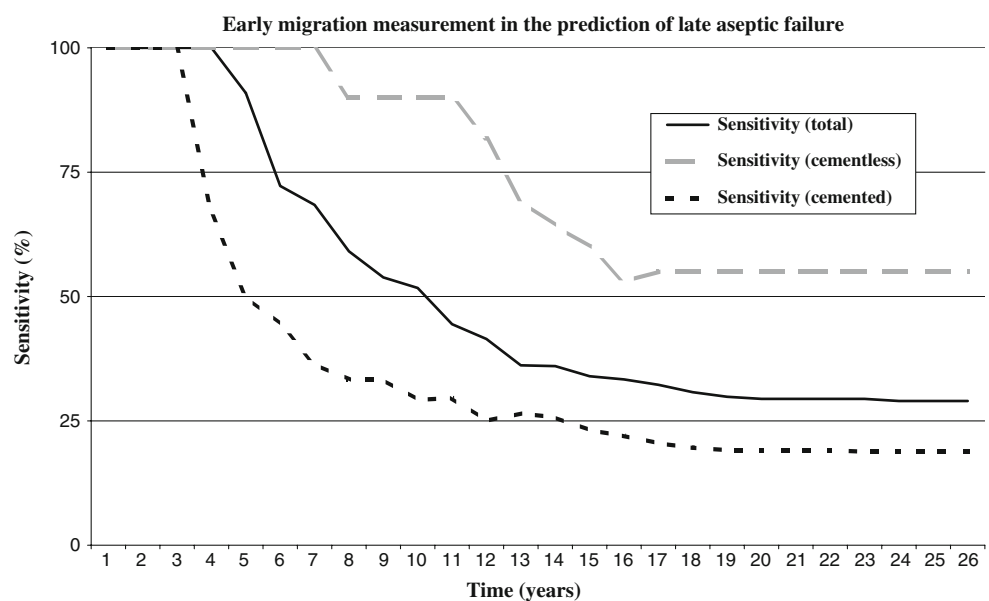
with migration pattern C (stem survival, $p < 0.01$). Late onset subsidence preceded revision surgery at a mean of 3.4 (± 0.3) years (cementless 5.4 ± 1.5 years; cemented 2.8 ± 0.2 years).

In a second analysis, sensitivity of migration measurement was calculated for every year of the entire observation period. All implants, which had been revised during the first three years, had undergone early migration. Sensitivity was 100% throughout this follow-up period, but decreased subsequently (see Fig. 1). Uncemented implants showed a higher percentage of early migrators. Consequently, migration measurement was more sensitive for cementless stems. For these stems, sensitivity of the method was 100% through seven postoperative years and was still 90% by the 12th year. Due to the higher share of late migrating stems in cemented implants, sensitivity decreased much faster in this group.

Discussion

Migration measurements as a method of evaluating implant performance have been shown to correlate with the incidence of late aseptic failure [8, 11, 13]. However, the main weakness of these studies was their relative short-term follow-up, rarely covering the first postoperative decade [4, 7, 10, 15, 17], whereas the majority of the stems in our study (39/69 or 56.5%) demonstrated late onset migration with a mean survival of 12.4 years. Migration of these implants did not occur before implants with early migration had already been revised for aseptic failure. By following a collective of failed stems throughout the entire time span from implantation to revision surgery, this study was able to observe the patterns of migration. Our results confirmed previously published threshold values for prediction of

Fig. 1 Sensitivity of early migration measurement in the prediction of later aseptic failure. The method's sensitivity in percent decreases with a prolonged period between primary and revision surgery and is given for cementless implants (grey, interrupted line) and cemented implants (black, dotted line), as well as for the total collective implants (black, continuous line). The method is more sensitive in the detection of failure of cementless rather than cemented implants



aseptic loosening [4, 7, 10, 11, 17] with one important exception. They were only valid for implants which had undergone short-term to mid-term failure. Implants with prolonged survival had rarely shown early migration. These findings are in contrast to Mjöberg's postulation [11] that late migration does not exist and was only late detection of early migration. He saw migration as a result of lacking primary osteointegration and attributed it to thermal necrosis during intraoperative polymerisation of bone cement. Our study outlines the existence of late onset of migration, independent from stems with early migration, occurring with both cementless and cemented fixation techniques. These findings have important implications in the understanding of the durability of implant fixation. More specifically, late onset migration probably represents a fatigue failure of the bone-implant interface in cementless stems, fatigue failure at the cement-bone interface, or cement cracking in cemented stems. Early migration, on the other hand, can be interpreted as a consequence of primary instability due to poor technique or implant design.

Due to its high sensitivity throughout the first postoperative years, the measurement of early migration is a reliable screening method for short-term and mid-term implant failure. Late fatigue failure cannot be predicted by measuring early migration. Late migration onset during long-term follow-ups, however, preceded implant revision by three years.

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