We identified 1305 femoral impaction bone grafting revisions using the Exeter stem performed between 1989 and 2002 in 30 hospitals throughout Sweden. There were 1188 patients with a mean age of 71 years (29 to 94) followed up for between five and 18 years.

The participating departments reported 70 further revisions in total, of which 57 could also be identified on the Swedish National Arthroplasty Registry.

Kaplan-Meier survivorship for all causes of failure was 94.0% (95% confidence interval (CI) 92 to 96) for women and 94.7% (95% CI, 92 to 96) for men at 15 years. Survivorship at 15 years for aseptic loosening was 99.1% (95% CI 98.4 to 99.5), for infection 98.6% (95% CI 97.6 to 99.2), for subsidence 99.0% (95% CI 98.2 to 99.4) and for fracture 98.7% (95% CI 97.9 to 99.2).

Statistically significant predictors of failure were the year in which revision was conducted (p < 0.001). The number of previous revisions was slightly above the level of significance (p = 0.056). Age, gender, the length of the stem and previous septic loosening were not predictors of failure (p = 0.213, p = 0.399, p = 0.337, p = 0.687, respectively). The difference in survivorship between high- and low-volume departments was only 3% at ten years.

We conclude that impaction bone grafting with the Exeter stem has an excellent long-term survivorship following revision arthroplasty. The technique of impaction grafting appears to be reliable, can be learned rapidly and produces a predictably low incidence of aseptic loosening.

Cemented revision combined with impaction bone grafting has become an accepted method of dealing with the bone loss encountered in loosening of the femoral stem. The method was developed for the polished Exeter stem (Stryker Orthopaedics, Mahwah, New Jersey) but subsequently the technique has been successfully applied to other stems.2,3

Most authors agree that the method is technically demanding, sometimes time-consuming and has a significant learning curve.2,4 Although a number of both intra- and post-operative complications have been described, many have been shown to be of little or no consequence to the long-term result.4 The benefits of predictable relief from pain1,5 and the prospect of bone regeneration1 support the continued use of the method.

Long-term follow-up reports have emerged from the developing centres in Exeter, United Kingdom and Nijmegen, The Netherlands.6,7 The most common complications have been infection and periprosthetic fracture, whereas aseptic loosening has been notably uncommon6 or even absent.7 Good medium-term results have been reported from other centres, in Europe,8 North America9-11 and the Far East.12 However, there has been no report of the long-term results of this technique when performed in a large number of orthopaedic departments.

In 1992, the first dedicated impaction instruments became available in Sweden, and impaction grafting with the Exeter stem was then introduced on a wide scale. It has subsequently been used in 30 hospitals with varying experience of revision total hip replacement (THR).

In 2003, we drew up plans for a national survey of the results of this operation in Sweden, between 1989 and 2002. The aim was twofold: first, to document the long-term results and complications of this procedure and secondly to study the effect of an aggregate of learning experience on the outcome.

Patients and Methods
Meetings with Swedish users of the Exeter system were held in 2002. A proforma was developed on which to document the necessary details, and this was circulated in early 2003. Each department agreed to identify
retrospectively all femoral impaction grafting operations performed with the Exeter stem up to December 31, 2002.

We updated the material in 2007 by consulting the National Population Register to identify patients who had died between 2002 and 2007. We also asked the Swedish National Hip Arthroplasty Registry\textsuperscript{13} to identify further revisions reported to the Register during the same period. In so doing we have amended the observations censored in 2002, adding almost five years to the observation time.

A total of 30 orthopaedic departments identified at least one femoral impaction bone grafting revision. This yielded a total of 1352 revisions. However, in two cases the patients’ identification was missing and they could not be matched against the Swedish Hip Arthroplasty Registry. In another 45 cases, patient identification information, operation dates or operated sides were conflicting. A number of case notes could not be retrieved. Such loss of documentation reduced the number of analysed hips to 1305 of which 1071 were unilateral procedures and 117 bilateral. The 1188 patients (650 women and 538 men) had a mean age of 71 years (29 to 94) (Table I).

The patients were operated on between 1989 and 2002 (Table II). Our observation time thus spanned five to 18 years. The mean time \textit{in situ} of the individual stems was 97.3 months (0.1 to 210.9).

The indication for the primary THR was osteoarthritis (OA) in 874 hips (67\%), fracture of the hip in 96 (7.3\%), inflammatory disease in 94 (7.2\%), other reasons in 87 (6.7\%) and unknown in 154 (11.8\%). The indication for revision was aseptic loosening in 1157 hips (88.7\%), infection in 89 (6.8\%) and various other reasons in 55 (4.2\%). In four cases, the reason for revision was not documented.

The impaction bone grafting revision was the first in 1044 hips (80\%), the second in 184 (14.1\%), the third in 21 (1.6\%) and the fourth in two (0.2\%). In 54 hips this information was unavailable. Standard-length Exeter stems were used in 1081 hips (82.8\%) and long stems (205 mm or longer) in 145 (11.1\%). In 79 stems the length was unknown.

When impaction bone grafting was introduced, the bone graft was milled into comparatively small chips (2 mm to 4 mm) and squeezed by hand to remove excessive fat. Gradually, many departments began using bone mills which produced larger chips, and also began to rinse the graft in warm saline before impaction to displace the fat. We have no record of when or if at all this change was implemented in the departments in our study.

The cement almost exclusively used in revision surgery in Sweden during the period of study was Palacos with gentamicin (Heraeus Ltd, Wehrheim, Germany), possibly with the addition of vancomycin in some cases. The cement was chilled, vacuum-mixed, injected in a retrograde manner and then pressurised with a proximal seal.

\textbf{Statistical analysis.} The data were entered into an SPSS version II database (SPSS Inc., Chicago, Illinois) and analysed by the Cox’s regression and the Kaplan-Meier survival methods with log-rank testing. All statistical calculations were performed using STATA version 10.0 for Unix (StataCorp, College Station, Texas). Statistical significance was set at a p-value ≤ 0.05. All confidence intervals (CI) were set at the 95\% level.

\begin{table}[h]
\centering
\caption{Age and gender distribution of the 1305 hips} 
\begin{tabular}{|c|c|c|c|}
\hline
Age in years at revision in five-year intervals & Female & Male & Total \\
\hline
25 to 29 & 1 & 0 & 1 \\
30 to 34 & 1 & 0 & 1 \\
35 to 39 & 1 & 1 & 2 \\
40 to 44 & 11 & 5 & 16 \\
45 to 49 & 3 & 12 & 15 \\
50 to 54 & 26 & 18 & 44 \\
55 to 59 & 41 & 28 & 69 \\
60 to 64 & 72 & 62 & 134 \\
65 to 69 & 120 & 95 & 215 \\
70 to 74 & 175 & 147 & 322 \\
75 to 79 & 171 & 113 & 284 \\
80 to 84 & 77 & 80 & 157 \\
85+ & 24 & 21 & 45 \\
\hline
Total & 723 & 582 & 1305 \\
\hline
\end{tabular}
\end{table}

\begin{table}[h]
\centering
\caption{The 1305 analysed hips according to the year of revision} 
\begin{tabular}{|c|c|c|c|}
\hline
Year of revision & Female & Male & Total \\
\hline
1989 & 0 & 3 & 3 \\
1990 & 5 & 2 & 7 \\
1991 & 5 & 4 & 9 \\
1992 & 7 & 6 & 13 \\
1993 & 28 & 29 & 57 \\
1994 & 49 & 59 & 108 \\
1995 & 55 & 46 & 101 \\
1996 & 77 & 51 & 128 \\
1997 & 67 & 57 & 124 \\
1998 & 65 & 55 & 120 \\
1999 & 83 & 50 & 133 \\
2000 & 90 & 70 & 160 \\
2001 & 97 & 75 & 172 \\
2002 & 95 & 75 & 170 \\
\hline
Total & 723 & 582 & 1305 \\
\hline
\end{tabular}
\end{table}

\begin{table}[h]
\centering
\caption{Causes of further revision} 
\begin{tabular}{|c|}
\hline
Aseptic loosening & 11 \\
Subsidence & 13 \\
Infection & 16 \\
Fracture & \\
\textit{Femoral} & 17 \\
\textit{Pseudarthrosis} & 3 \\
\textit{Dislocation} & 3 \\
Hip dislocation & 1 \\
Stem fracture & 2 \\
Stem penetration & 1 \\
Unknown & 3 \\
\hline
\end{tabular}
\end{table}
Results
Of the 1188 patients, 143 (84 women and 59 men) died without further revision and 70 (41 women and 29 men) had a further revision for indications listed in Tables III and IV. Of the 70 further revisions, 57 could also be identified on the Swedish National Arthroplasty Registry. The most common causes of failure were infection and fracture of the femur, together comprising 33 cases (47%). Aseptic loosening was seen in 11 (15.7%), and subsidence sufficient enough to require further surgery in 13 (18.6%). The nature of the complications varied between hospitals. However, because of the small number of failures in general, and the rarity of failure in any one hospital in particular, we have not found it meaningful to compare individual departments.

Survival related to cause of failure. Using the Kaplan-Meier survival analysis for all causes of failure, the survivorship at 15 years was 94.0% (95% CI 92 to 96) for women and 94.7% (95% CI 92 to 96) for men (Fig. 1). The survivorship at 15 years with aseptic loosening as the endpoint was 99.1% (95% CI 98.4 to 99.5), with infection 98.6% (95% CI 97.6 to 99.2), with subsidence 99.0% (95% CI 98.2 to 99.4) and with fracture 98.7% (95% CI 97.9 to 99.2) (Fig. 2). In all 65 of 70 recorded complications occurred within 48 months. Later complications included one case of aseptic loosening, two of infection, one of stem fracture and one unclassified.

Survival related to primary diagnosis. With the primary diagnosis of OA, the survivorship at 15 years was 94.0% (95% CI 92 to 96) for women and 94.7% (95% CI 92 to 96) for men (Fig. 1). The survivorship at 15 years with aseptic loosening as the endpoint was 99.1% (95% CI 98.4 to 99.5), with infection 98.6% (95% CI 97.6 to 99.2), with subsidence 99.0% (95% CI 98.2 to 99.4) and with fracture 98.7% (95% CI 97.9 to 99.2) (Fig. 2). In all 65 of 70 recorded complications occurred within 48 months. Later complications included one case of aseptic loosening, two of infection, one of stem fracture and one unclassified.

Table IV. Causes of failure and year of re-revision

<table>
<thead>
<tr>
<th>Year of re-revision</th>
<th>Aseptic loosening</th>
<th>Subsidence</th>
<th>Infection</th>
<th>Femoral fracture</th>
<th>Other</th>
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Kaplan-Meier survivorship curve showing the total survival at 15 years for all causes of failure with 95% confidence intervals. Most failures occurred within the first four years.
then one case failed, reducing the survivorship at 15 years to 90% (95% CI 79 to 95). The number of patients in this group was small, with 94 at the outset and 40 at the final census. Patients with previous hip fracture did almost as well as the OA group (93% at 15 years (95% CI 85 to 96)).

**Survival related to previous mode of failure.** Grafting was undertaken because of previous aseptic loosening in 1210 hips. The survival of these was 95% (95% CI 93 to 96) at 15 years. Hips on which grafting had been done after an infection had a survival of 94% (95% CI 87 to 98) at 13 years. However, there were 56 hips in which the cause of failure was classified as ‘other’, and these had a combined survivorship of 82% (95% CI 69 to 90).

**Surgical experience.** This was shown to be a significant factor for a successful outcome (Cox-regression trend-test, p = 0.021). Departments which had carried out 100 operations or more were found to be statistically significantly better as a group compared with the others (log-rank test, p = 0.03). For all causes of failure, the survivorship at ten years was 96.1% (95% CI 93.5 to 97.5) and 93.5% (95% CI 91.4 to 95.0), respectively.

Calculating the relative risk (RR) of further revision per calendar year proved to be problematic because of the small number of failures (Tables III and IV). Instead, we calculated the survivorship for all causes of failure of hips revised before and after January 1, 1998. The reason for choosing this date was twofold. In 1998 the new instrumentation was introduced and this date also provided a reasonably even-sized division of the material. The survival at nine years of the hips revised after January 1, 1998 was 96.5% (95% CI 94 to 98) and that of the hips revised before 1998 was 91.1% (95% CI 87 to 94).

**Other analyses.** No statistically significant differences in survival could be found with respect to the technique of impaction or stem length (RR = 1.7, 95% CI 0.7 to 4.2), for impaction without versus with instruments (p > 0.427), and for long versus standard-length stems (RR = 0.7, 95% CI 0.3 to 1.7). Age at revision and gender also had no statistically significant influence on the risk of further revision (age at revision RR = 1.01; 95% CI 0.95 to 1.07 per year and gender RR = 1.4; 95% CI 0.5 to 3.7). Comparing the survivorship of two sub-groups, age < 50 versus age > 50 years and age < 60 versus age > 60 years for both men and women, no statistically significant difference was seen, although numbers were sometimes small (p = 0.403 and p = 0.422, respectively).

Entering gender, age, stem length, year of revision (before/after 1998) and the number of earlier revisions as factors in a Cox regression analysis, we found that only the year of revision and the number of previous revisions were statistically significant predictors of failure (p < 0.001), whereas the number of previous revisions was slightly above the level of significance (p = 0.056).

**Discussion**

Our study is the first to provide a comprehensive overview of the outcome of femoral impaction bone grafting in general. The results are biased towards poorer outcomes on clinical practice, since the accumulated learning experience of 30 orthopaedic departments in Sweden, is included. They provide a baseline for discussions on the relative merits of impaction bone grafting for femoral revision. Impaction bone grafting can be seen as an example of the step-wise introduction of new technology as suggested by Malchau. It was first tried in vitro and then in vivo in the originating centres before being introduced on a national scale with supplementary radiostereogrammetric analysis (RSA) in a few centres and finally evaluated in the present register study.

Despite our efforts to ensure the completeness of the data it is of note that only 57 of the 70 further revisions (81.4%) were detected through the Swedish National Hip Arthroplasty Registry. The discrepancy is of concern and its causes are unknown, but our material is a form of external audit of the National Registry and highlights the value of future similar endeavours.

The projected survivorship at 15 years of 94% (95% CI 92 to 96) for all causes of failure must by all standards be regarded as good.

Aseptic loosening when it occurred was shown to be an early phenomenon, almost always appearing within four years post-operatively. From earlier studies it seems, both radiologically and histologically, that very little change takes place after that time. However, Linder showed in a retrieval study that the impacted allograft was not always replaced by living bone and the various supporting tissues were apparently mechanically sufficient. It is not clear where the division lies between aseptic loosening and subsidence. In an RSA study of 15 impaction-grafted Exeter stems it was shown that three were stable at between two and five years post-operatively, 11 showed minimal migration and one was asymptomatic but migrating continuously, and therefore by definition loose, even though it had not been revised. It might therefore be appropriate to consider aseptic loosening and subsidence requiring further revision as a single entity of aseptic failure. Our failure rate was no more than about 2% at 15 years.

Although experience with the technique of impaction bone grafting is one factor behind the reduction of complications, the difference between experienced and inexperienced departments respectively undertaking more than or fewer than 100 impaction bone grafting revisions, was less than 3% (96.1% vs 93.5%) at ten years.

Seen in this perspective, our results are not dramatically different from those of the originating centres. Contrary to the opinion that impaction bone grafting requires considerable time to learn, our data suggest that the technique is standardised and can be learned quickly. The most common aseptic complication was fracture, similar to that of most studies. The reason for this probably lies in the difficulty of adequately preparing the highly variable femur for the impaction, highlighting the need for careful pre-operative planning.

At the inception of impaction bone grafting oversized trial components were used as impactors. Subsequently, dedicated instruments were produced with the intention of...
using only standard-length stems, with the aim of re-establishing the anatomy of a primary THR. However, this might have contributed to several fractures about the tip of the impacted stem since this is a common site of endosteal lysis. In principle, cortical defects of Endoklinik grades 3 and 4\textsuperscript{18} heal well even when short stems are used,\textsuperscript{1} provided that proper post-operative precautions are taken.\textsuperscript{19}

Although a number of insufficiency fractures undoubtedly did occur at the tip of the short stem, we agree with Schreurs et al\textsuperscript{17} that such fractures should not be seen as a failure of impaction grafting as such, but rather as a failure of our means of assessing cortical bone regeneration.

It was not until 1998 that a comprehensive array of implants, impactors and meshes were available, and this has coincided with a reduction of early failures. However, we were unable to find a difference in survivorship for short and long stems, indicating that there might be additional reasons for this apparent cause-and-effect relationship. This reduction in failures may also have been due to a gradual change in patient selection, such as a preference for distally-fixed uncemented prostheses in some revision situations.

We recognise the weakness of our study. Like all other complications based on a register in which there has been no analysis of clinical scores or radiography, potential failures or ominous radiological appearances may have been missed. Additionally, the severity of bone loss is unknown which might have influenced the outcome. The prevailing revision method at the time of the introduction of impaction bone grafting was the re-cementing of a longer stem into the femur. From register studies it was known that this gave a 75% survival at eight years in active patients,\textsuperscript{20} but was perceived to be better in the elderly, as subsequently confirmed by Hultmark et al.\textsuperscript{21} It is therefore likely that re-cementing and impaction bone grafting were used in parallel during the course of our study, impaction bone grafting being reserved for the more advanced cases. When impaction bone grafting was introduced it was advised for revision when it was unlikely that bone cement could achieve successful interdigitation.\textsuperscript{1}

Initially, impaction bone grafting was met with much scepticism in Sweden with concerns over viral transmission, graft resorption and re-infection from dead allograft placed in a previously infected bone bed. Such concerns led a number of departments opting for uncemented distally-fixed stems. It seems now that both methods are accepted, and that comparison of their benefits is possible.

Today, distally-fixed, uncemented stems are increasingly used for expediency in addressing extensive proximal femoral pathology. There is no doubt that this is a very rewarding technique, combining good fixation and proximal bone regeneration, but nevertheless requiring experience to perfect.\textsuperscript{22} Longer term analyses of distally secured uncemented stems indicate a survival rate from all causes of failure between 86% and 95% at ten to 15 years.\textsuperscript{23,25}

Overall, the results of our survey suggest that the survival of femoral impaction bone grafting revision THR using the Exeter stem is on a par not only with uncemented revision methods, but even with primary THR. Most of the early misgivings about the method have been allayed since there have been no reports of an accelerating incidence of late failures, endosteal lysis or infection. We conclude that there is no reason for surgeons who are comfortable (with the method) and experienced in its use to abandon impaction bone grafting.


No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


