Survival analysis of an asymmetric primary total knee replacement: A European multicenter prospective study

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\textbf{KEYWORDS}
Total knee replacement; Asymmetric base-plate; Survival analysis

\textbf{Summary}

\textit{Purpose of the study:} This multicenter prospective study objective is to provide midterm results and 10-year survival analysis of the original Natural Knee-I System\textsuperscript{TM} as experienced by a group of surgeons performing, within various settings, primary total knee replacement (TKR) in the general population.

\textit{Hypothesis:} The midterm experience with this TKR system in the hands of independent surgical teams can duplicate the satisfaction level that was already published by the designer’s group itself.

\textit{Material and method:} Two hundred and sixty-three primary TKR were performed by seven surgical teams (37 surgeons) and prospectively evaluated in four European countries. Mean age of the 263 patients (sex ratio, 2.7 females/1 male) was 69 years (range, 35—92) and diagnosis was primary osteoarthritis in 85%. For the 247 TKR with complete operative data, the approach was subvastus in 59%, posterior cruciate ligament was spared in 78%, patella was resurfaced in 56%, and 79% of reconstructions were totally cement-free. Fixation mode was only depending on the surgeon’s choice.
Results: At 76 months average follow-up (range 24–190 months), modified Hospital for Special Surgery knee mean score improved from 48 points preoperatively to 83 points. Four reoperations and five revision procedures were required for eight knees. Over the 14-year survey period, the overall revision rate burden was 2% and revision rate per 100 observed component/year, 0.32. At 10 years, survivorship (with revision for aseptic loosening as its end-point [two fully cementless knees]) was 98.6%.

Discussion: Both this multicenter study and data drawn from national registers provided outcomes with equivalent level of satisfaction at equivalent follow-up to those reported by the NK-I prosthesis designer. There was no significant difference between revision rates of cemented, hybrid or cementless reconstructions.

Conclusion: In non-designer orthopaedists’ hands, the Natural Knee-I System™, either with cemented or cementless fixation, provided satisfying midterm results as normally expected in primary TKR with such a modern modular prosthesis.

Level of evidence: Level IV. Prospective study.

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Introduction

Total knee replacement (TKR) is a fast growing activity in prosthetic surgery. In the USA, annual number of primary TKR increased from 129,000 in 1990 to 381,000 in 2002, and overall US nationwide projections indicated 3,482,000 TKR in 2030 [1]. In Europe, estimation from the Swedish Knee Arthroplasty Register (SKAR) indicated that TKR activity in Sweden will increase less, but nevertheless by at least one third until 2030 [2]. One can expect that a greater number of primary knee replacements will, in turn, result in a greater number of revisions. Indeed, projection of revision TKR increase in the US was estimated 601% from 2005 to 2030 and revision financial related burden previews of projected hospital costs might exceed $2 billion by 2030 [3].

Among the numerous TKR component design concepts and fixation techniques, well-known implant with the longest follow-up are regarded as an universal reference. The Insall-Burstein Total Condylar Knee introduced at the Hospital for Special Surgery in 1978 provided in the hands of its designer in this specialized center a 9.3% probability for revision at 21 years. This 90.3% survival rate at 20 years is a “gold standard” that all TKR systems have to compare with [4]. Despite the fact that other confounding factors, such as socioeconomic issues and demographics, can generate deviations in revision rates, TKR Registers reported pretty close crude revision rate (yearly number of revisions/yearly number of primaries + revisions) ranging from 7 to 9% in all seven countries able to run such an evaluation system [5,6].

Among the possible limiting mechanisms that could be implemented to reduce the future TKR revision burden, the debate about regionalizing total joint replacement to high volume centers remains central in many developed countries. Another approach is the development of universal TKR systems that would regularly provide satisfying functional results based on well-designed components with a reproducible implantation technique and friendly used ancillary jigs. For this purpose, the Natural Knee-I (NK-I) System™ (ex-Intermedics, now Zimmer, Warsaw, IN) has been designed by Hofmann et al. in the USA and commercialized since 1985. To date, only one designer’s study published in 2001 [7] had enough follow-up to provide 10-year survivorships in the general patient population.

The aim of this multicenter prospective study was to provide midterm results and 10-year survival analysis of the original NK-I TKR system experienced by a group of surgeons in the general population and various settings. To the author’s knowledge, this report will be the first published in Europe about this TKR System, despite huge implantation use since 1992. Our hypothesis was that experience with this TKR system in the hands of independent surgical teams could provide the same level of satisfaction than that already published by the designer’s group.

Material and methods

The Natural Knee-I System™ implantation technique and mostly component designs (Fig. 1) were the result of many innovative and extensively published researches advocating:

- less invasive approach (subvastus);
- anatomic axis and rotational femoral alignment;

![Figure 1](a) Cementless and (b) cemented versions of the Natural Knee-I System™ used in the current study.)
European survival analysis of the NK-I system in primary TKR

Figure 2  The Cancellous Structured Titanium® (CSTi) porous surfaced covering the uncemented Natural Knee implants.

- asymmetric tibial plateau and anatomic tibial cut slope;
- deep trochlear groove and patellar component medialization and countersinking;
- ultracongruent polyethylene liner for posterior stabilization;
- stemmed tibial cementation;
- or cementless fixation through the Cancellous Structured Titanium® (CSTi) porous surface (Fig. 2) [8—20].

Over a 2.6-year period (April 1993 to November 1995), 263 NK-I TKR were implanted in 262 patients by seven orthopaedic teams (37 surgeons) in four European countries (France, three centers; Germany, two; Switzerland, one; and Great-Britain, one). All patients enrolled in the study gave informed consent for a minimum 10-year survey. Demographics of the patients who accepted to participate are summarized in Table 1. Mean age was 69 years (range, 35—92) with a female/male sex ratio of 2.7/1. Primary osteoarthritis was the main diagnosis (85%) and 30% of knees had sustained a previous surgical procedure, but no replacement of any type.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Demographics of the patients/TKR prospectively enrolled in the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients/TKR</td>
<td>262/263</td>
</tr>
<tr>
<td>Mean age in years (range)</td>
<td>69 (35—92)</td>
</tr>
<tr>
<td>Gender (F:M)</td>
<td>2.7:1 (191:72)</td>
</tr>
<tr>
<td>Side (R:L)</td>
<td>1.2:1 (146:117)</td>
</tr>
<tr>
<td>Mean Weight (kg)</td>
<td>76.2 (41-118; SD 13.2)</td>
</tr>
<tr>
<td>Mean BMI (range)</td>
<td>28.7 (16—42; SD 4.6)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Primary osteoarthritis (OA)</td>
<td>85%</td>
</tr>
<tr>
<td>Rheumatoid arthritis (RA)</td>
<td>9%</td>
</tr>
<tr>
<td>Post-traumatic</td>
<td>4%</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>2%</td>
</tr>
<tr>
<td>Previous surgery</td>
<td>30% (no knee replacement)</td>
</tr>
</tbody>
</table>

BMI: body mass index.

Sixteen knees were excluded from the study due to insufficient perioperative information or incomplete follow-up data forms. Technical choice regarding approach, posterior cruciate ligament (PCL) preservation, patella resurfacing and implant fixation was free, according to the surgical team habit, usual indications and convictions. For the final study group of 247 primary NK-I TKR, surgical technique, component designs and fixation are detailed in Table 2. Approach was subvastus in 59% of procedures, PCL was preserved in 78% of knees, 139 patella were resurfaced (56% of knees) and lateral release was performed in 20%. Overall, 15% of knee reconstructions were fully cemented, 6% were hybrids (cemented tibial base plate and/or cemented patella) and 79% (195 knees) were completely cement-free with an unresurfaced patella or a cementless button in 119 and 76 knees, respectively.

Regularly monitored clinical and radiographic follow-up data were prospectively collected at 1, 2, 4, 7 and 10 years with use of a FDA-approved form with computer-centralization for statistical analysis. Clinical evaluation were performed with use of a Modified Hospital for Special Surgery Knee Score (MHSSKS) [17]. Radiographic analysis was conducted with use of a specified zonal form. Revision was defined according to the Swedish TKAR criteria, i.e., “...a new operation in a previously resurfaced knee during which one or more of the components are exchanged, removed or added (incl. arthrodesis or amputation).” [21]. Survival analyses were conducted with the Kaplan-Meier method and statistical analysis with use of the Chi², Fisher’s exact, Mann Whitney and Kolmogorov-Smirnov tests. Statistical significance was accepted with p value ≤ 0.05.

Results

During the 14-year (1993—2007) study period, 52 patients (21% of the index cohort) died. Including the last evaluation of the died patients, MHSSKS (maximum 100 points) improved from 48 points preoperatively (range, 9.8 to 73.4
Evolution of the average Modified Hospital for Special Surgery Knee Score over the 10-year survey period. Points) to 83 points at 76 months average follow-up, that indicated a highly significant improvement (Mann-Whitney U-Test: \(p < 0.0001\)). For the subgroup of 56 knees (23% of the index study group) that have overpassed the 10-year FU evaluation, average MHSSKS reached 77 points (range, 31 to 94 points) at last control. Fig. 3 detailed the evolution of median MHSSKS over the different time points. Stable over 80 points until the seventh year, it slightly decreased to 77 points at 10 years. One might consider that the mean age of these 56 patients who reached 10 years of survey was about 80 years old, that suggests probable interfering functional deficit other that from the operated knee.

Perioperative and subsequent complications are detailed in Table 3. Over the 14-year study period, there has been nine reoperations, giving a yearly crude reoperation rate of 0.6%. Five of these reoperations were real revisions according to the Swedish Knee register definition, giving an annual crude revision rate of 0.4%. The overall revision burden (\(N/\text{rev}/N/\text{primary} + N/\text{rev}/N\)) was 2%. At the 6.3-year mean follow-up, the revision rate per 100 observed component/year was 0.32 for the complete series, 0.24 for the 195 cementless reconstructions (3 revisions/195 TKRs), and 0.49% for the 52 cemented or hybrid reconstructions (2 revisions/52 TKRs). The difference in annual revision rate between cementless and cemented or hybrid reconstructions was not significant (\(p = 0.62\)).

Thus far, aseptic loosening was observed in two fully cementless TKRs that were both revised (Fig. 4). At 10 years, survivorship of the group of 247 primary NK-I TKR with reoperation for any reason and revision for aseptic loosening as the endpoints were 96.4 and 98.6%, respectively (Fig. 5). Again, the difference in revision rate for aseptic loosening between cementless TKR (2 of 195 knees, 2%) and cemented or hybrid reconstructions (0 of 52 knees) was not significant (\(p = 0.9\)).

Discussion

Operative technique

Firstly described in the German literature in 1929 and 1945, the “Southern” subvastus approach has been promoted for
TKR surgery by Hofmann since 1991 [8]. The author advocated that this more conservative approach led to improved patellar tracking and stability. Indeed, in the comparative study by Matsueda and Gustilo, there were 37% of knees in the subvastus group requiring a lateral retinacular release versus 67% in the parapatellar group (p < .0001) [22]. In our study, lateral release that was performed in 20% of knees did not correlate with the type of approach (Fisher’s exact test, p = 0.39), but significantly correlated with resurfacing of the patella (p = .0001). There is no clear explanation of this controversy, except that patellar resurfacing might have led to overhanging in some occasions. Nevertheless, this 20% rate of lateral release is quite low and supports positive effect of the actual trend for less invasive surgery [23,24].

On the other hand, anatomic tibial cut slope and use of asymmetric tibial plateaus that perfectly matches the tibial cut edge, help the surgeon in choosing appropriate tibial implant size and axial orientation [10,17]. In addition, deep trochlear groove, patellar component medialization and countersinking allow for better patella tracking [9,11,12,17]. All these design characteristics may have played a positive role to achieve correct overall implantation at a time where surgical navigation tools were not available. These specifications also question the exact need for navigated instrumentation with this type of anatomic designs.

**Comparative clinical results**

Clinical results with the NK-I TKR were mostly published by the designer and his team [12,17,19,20,25,26], but only one of these studies has reached a 10-year follow-up [7]. In that paper, 300 NK-I TKR implanted without cement by the single designer surgeon (Hofmann) in a general population showed at 10 years a 93.4% survival rate with revision for any reason as the end-point. In an independent series of 109 cementless knees, there was no revision at 2 to 5 years, too short a follow-up to be conclusive [27]. Nevertheless, another multicenter prospective study was performed in the US with the same protocol as the one used in the current European study. In that US experience, 304 cementless NK-I TKR implanted for only osteoarthritis by 13 surgeons showed at 8 years a 98% survivorship with revision for aseptic loosening as the endpoint [28]. In this European trial, the 10-year survivorships with revision for aseptic loosening as endpoint of 98.6% is well in accordance with these data. Currently, except for the Swedish Register, TKR multicenter studies that provides 10-year survival data are sparse in the literature. In the Norwegian Arthroplasty Register-2002, the 5-year survival of the six most used cemented tricompartmental knee prostheses brands varied between 95 and 99% [29].

Comparison of cemented and cementless fixation also shows controversial issues. At early 5-year follow-up, there is no significant difference between cemented or cementless TKR, neither in the Basset [30] personal retrospective series (1000 TKR), nor in the randomized prospective study by McCaskie et al. [31]. At longer follow-up, in a large international multicenter studies of 4743 primary TKRs with the Low Contact Stress (LCS, DePuy, Warsaw, USA) mobile bearing design, with failure defined as revision or reoperation for any reason, the overall survivorship was 92% at 10 years, thus decreasing to 76% at 16 years, with no difference between tibial fixation type [32]. Conversely, another large multicenter series of 5760 TKR performed by 53 surgeons reported that cemented TKR showed more than 95% 10-year cumulative survival, better than hybrid (89% survival) and ingrowth TKR [33]. In the current study, there was no significant difference between revision rates of cemented, hybrid or cementless reconstructions. All these confounding data support the fact that, in common clinical use and settings, implant design and specifications are at least as important as fixation type for the achievement of a correct overall reconstruction survival.

In the Swedish TKA Register, where implants are quasi exclusively cemented, results are expressed and compared with use of the Cumulative Revision Rate (CRR) which describes what percentage of the operated patients was expected to become revised with time (100 – x% survival). In the annual Swedish TKR 2009 annual report, in which the Natural Knee prosthesis represents only 0.7%, of the 70,972 primary TKRs mainly performed for osteoarthritis (92.6%) and rheumatoid arthritis, the 10-year CRR for all reason
often in multicenter international studies, above all sched-

younger (≤ 65 years old) patients, respectively [6]. In this
ranges between 3 and 7% for the older (> 75 years old) and

European trial, where patient mean age was 69 years (range,
35—92 years), the NK-I 10-year CRR of 2% (100%—98%) remains in that same range. In the Australian National Joint Replacement Registry 2009-annual report, the NK-II TKR, that represented 2.6% of all primary TKRs implanted in Aus-

tra利亚 over the period 1999—2008, indicated revision rates
that represented 2.6% of all primary TKRs implanted in Aus-

tralia over the period 1999—2008, indicated revision rates
per 100 observed "component" years ranging from 0.5 to

0.8 for cemented and cementless fixation, respectively [34].
In the current European study, the NK-I TKR revision rate per

100 observed component/ year was 0.32 for the complete
study group, 0.24 and 0.49 for cemented and cementless

fixation, respectively. These rates are remarkably low and

in accordance with the Australian data.

In 2003, US National Institute of Health (NIH) reported
assessment of currently available data regarding TKR. One
of the clearest associations with better outcomes appears
to be the procedure volume of the individual surgeon and

the hospital [35]. This has been demonstrated in the US
Medicare population, with significant association between hospital (less than 25 annual TKR) and surgeon (less than
12 annual TKR) lower procedure volumes and higher risks
of perioperative adverse events [36]. In the US study by

Katz et al., one quarter only of surgical procedures were
done by surgeons who performed ≤ 12 TKRs annually. In the
current study, over the 2.6 years NK-I implanting period,
the index 263 primary NK-I replacements were performed in
seven centers by 37 surgeons with quite different expertise
in knee surgery. Three surgeons only performed > 25 TKRs
each, while 34 surgeons (92%) performed < 10 TKRs annually
(Fig. 6) that represents 70% of surgical procedures. Despite
this, we have not observed select adverse events in our
patients outcome (no pulmonary embolism, no myocardial
infarction, one infection and one perioperative death) giving
an overall perioperative adverse events rate of less than
1%, versus 4% in the group of the less busy (1—12 annual TKR)

US surgeons.

Limitations of the study

We acknowledge the obvious limitations of this study. As
often in multicenter international studies, above all sched-
uled to last 10 years like this one, collection of updated
data is of a tremendous difficulty. Some departments have
changed their orientation (1), participants of the first days
retired or died (4), institution closed (1), etc. Thus, while 263 NK-I TKR were enrolled in the index trial, only 247 reconstructions had sufficient information and follow-up to
remain in the study group. The reasons for the loss of these
16 implantations are unknown and some of them could be
related to early failure that were not reported. In the same
hand, the exact number of patients who were enrolled but
finally refused to participate is also unknown. In addition,
the number of primary TKRs performed in course of the
implanting period with other knee prostheses systems is
also unknown, thus introducing another possible selection
bias. At last, radiological data analysis could not be per-
duced due to frequent missing information in the follow-up
charts. Nevertheless, the quality of the survey with use of
a common FDA approved form, patient informed consent,
centralized monitoring and statistical analysis support the
average excellent quality of data collection.

It could also be said that the heterogeneity of the series
is confusing. It is obviously true as technical choices have
been various according to surgical team habits, indications
and convictions according to the mid-1990s knowledge. But
this absence of consensus is still currently a reflection of
the real clinical practice. The British audit by Malik et al.
[37] reported in 2005, showed a large variation of prac-
tice in knee arthroplasty across the UK North West region
and significant divergence from the British Association for
Surgery of the Knee (BASK) and British Orthopaedic Associa-
tion (BOA) statement of best practice. A modern TKR must
accommodate all these situations, and this multinational
series showed that this requirement could be achieved with
the NK-I original system.

Above all, the fact that this multicenter study, that does
not include the designer’s institution, and data from national
registers both provided results at the same level of satisfac-
tion than those reported by the prosthesis designer’s team,
is a strong evidence in favor of the real universal quality
of the complete system (i.e., implant design, surgical jigs
and friendly use of ancillary tools to provide easily repro-
ducible implantation technique). The value of sample-based
clinical studies in comparison to register data is the base
of the new methodology developed by the European Arthro-
plasty Register to assess arthroplasty outcome measurement
[38].

Conclusion

We can conclude that in non-designer orthopaedists’ hands,
the Natural Knee-I total replacement system, either with
cemented or cementless fixation, provided overall satisfying
midterm results as expected in primary TKR with such a
modern modular prosthesis. This study also provides base-
line results for better appraisal of further developments
introduced with the Natural Knee-II replacement system,
i.e., rotating platform, all in one cutting blocks, use of
highly cross linked polyethylene [39] and minimally invasive
implantation tools, that are currently under the scope of
ongoing studies.
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Conflict of interest statement

Dr Delaunay is a consultant for Zimmer. No benefits or funds were received from Zimmer in support of this study.

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