

Long-term survival and radiological results of the Duracon™ total knee arthroplasty

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Abstract

Purpose The aim of this study was to analyse the long-term (>ten years) survival rate and radiological results of the Duracon TKA.

Methods Between 1992 and 1999 159 Duracon TKA were implanted at our institution. A Kaplan-Meier survival analysis for the endpoints exchange, addition or removal of any component for any reason, revision due to aseptic loosening and mechanical failure was performed. Radiological long-term (>ten years) follow-up (FU) analysis was performed according to the Knee Society Radiographic Evaluation and Scoring System.

Results Mean age at surgery was 74.3 years, 28 % were male, and 89 % had primary osteoarthritis as diagnosis. Mean FU for survival analysis was 10.9 years (SD 4.2). A total of 58 % of the patients died during follow-up. Three patients (2.1 %) were lost to follow-up and five TKA (3.1 %) were revised. After ten years the mean survival was 97.7 %, 99.4 % and 98.3 % for the aforementioned endpoints, respectively. Mean radiological FU was 11.8 years (SD 2.3). We found no significant change in alignment of the components or axis over time. Progressive radiolucencies were found in nine TKA (17 %), mainly around the tibial component (95 %).

Conclusion The Duracon TKA showed excellent long-term survival comparable to data from national registers and to other successful designs. Radiological changes found on plain radiographs were scarce after almost 12 years of radiological follow-up indicating good implant stability.

Keywords Total knee arthroplasty · Duracon · Long term

Introduction

Total knee arthroplasty (TKA) is the standard treatment for end stage degenerative and rheumatologic knee diseases [3, 18]. The main reasons for revision are mechanical failure (instability, polyethylene wear, malposition, impingement, over-/undersizing), aseptic loosening and infection [9]. Most early revisions are for mechanical reasons or infection, whereas late failure is mostly due to aseptic loosening [2, 9].

The Duracon TKA (Stryker) is a posterior cruciate ligament retaining system and has a congruent articular surface aiming to maintain a substantial contact area throughout the whole range of motion and limit contact stress even in conditions of varus/valgus malalignment [12, 21]. The tibial component is cemented, while the femoral component can be implanted either cementless (hybrid) or cemented. No design changes have been made since it was introduced to market.

Only few studies on early (two to five years [12, 21, 29]) and mid-term (five to ten years [10, 13, 15]) survival results for the Duracon TKA have been published with survival rates between 97 and 99 % and 96–98.6 %, respectively. Long-term survival data is available mainly from the Scandinavian Knee Arthroplasty Registers [11, 24, 26].

The aim of this study was to analyse long-term (>ten years) survival and radiological results of the Duracon TKA (Stryker Howmedica, Rutherford, NJ, USA) for 159 consecutive cases.

Patients and methods

Between December 1992 and May 1999, 159 primary Duracon TKA were implanted in 137 patients at our institution (Table 1). During that period it was the most commonly used implant (85 %) at our institution.

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Table 1 Demographic data

Population characteristics	Value
Age (years) ^a	74, ± 7 , 40–93
Male:female ratio (no. of patients)	39:98
Duration of follow-up (years) ^a	11, ± 4 , 1–19
Diagnosis	
Osteoarthritis (n)	141
Other (n)	18

^a Mean, SD, range

Eleven surgeons performed the operations; 14 knees (9 %) had been operated with a closing wedge tibial valgus osteotomy (TVO) prior to TKA. A total of 153 cases (96 %) had a medial parapatellar approach, with three of them combined with an osteotomy of the tibial tubercle. Six (4 %) cases had a lateral parapatellar approach after previous TVO, whereby two were combined with an osteotomy of the tibial tubercle. All 159 tibial and 35 femoral components (22 %) were cemented using Palacos G bone cement (Haereus Medical, Weinheim, Germany) without antibiotics. The patella was resurfaced in 12 cases (8 %).

Fig. 1 Anterior–posterior (AP) and lateral radiographs four months postoperatively of a 72-year-old patient; angles α , β , γ , δ and femoral and tibial radiolucency zones according to the Knee Society radiographic evaluation and scoring system

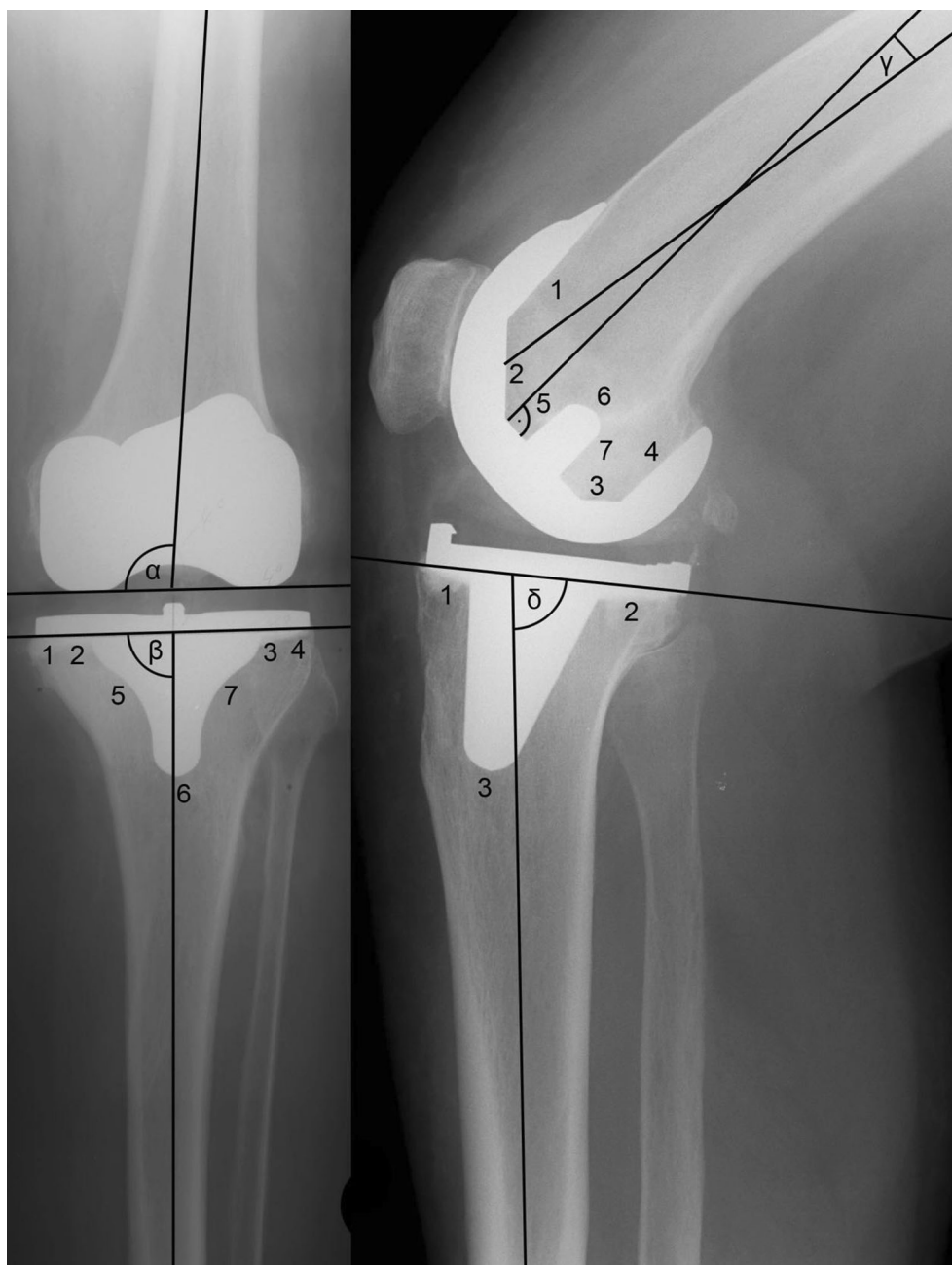


Table 2 Postoperative surgical procedures without exchange of prosthesis component

Postoperative complications	n (%)	Treatment	Time from surgery (days)
Infection	1 (0.6)	Open debridement, antibiotic therapy	18
Wound healing disturbance	6 (3.7)	Secondary wound closure	3, 7, 7, 8, 10, 15
Traumatic rupture of quadriceps tendon	1 (0.6)	Suture	547
Traumatic rupture of patellar ligament, traumatic	1 (0.6)	Suture	1190
Arthrofibrosis	3 (1.8)	Closed mobilization	118, 337, 396

Postoperatively, continuous passive motion exercise was started and full weight bearing ambulation was permitted under guidance of physical therapy as soon as possible. Clinical and radiological follow-up were scheduled prospectively at four months, one year, five years and every five years postoperatively according to our in-house register [5].

Dates of death were crosschecked with the regional authorities. Survival analysis was performed using Kaplan-Meier analysis with endpoints (1) exchange, addition or removal of any component for any reason, (2) revision due to aseptic loosening and (3) revision due to instability and/or polyethylene wear.

Clinical data were retrospectively obtained from medical records and contained ROM (measured with a goniometer) and whether patients were scheduled for surgery due to problems with the TKA.

Standardized weight bearing short anterior–posterior (AP) and true lateral radiographs were taken. Radiological evaluation was done according to the Knee Society radiographic evaluation and scoring system [8] (Fig. 1). Changes in alignment of the components were analysed comparing the angles of the first and last available radiographs. All radiographs were examined for progressive radiolucencies as defined by Ewald [8] by two reviewers

(MB and MC) and were defined as a consensus if both found radiolucencies.

Statistics

Data are presented as mean, standard deviation (SD) and range. Statistical analysis was done using SPSS version 20 (IBM, Armonk (NY), USA). A p -value < 0.05 was defined as significant. Data was analysed for normal distribution using Kolmogorov-Smirnov analysis. As data for the angles α , β , γ , δ and varus-valgus were normally distributed, differences between groups were calculated using the Student's t -test for paired samples. Data for radiolucencies were not normally distributed thus the non-parametric t -test for independent samples was used.

Results

Follow-up

During follow up, three of 159 (2 %) TKA were lost to follow-up. For 92 (58 %) TKA the patient had died unrelated to the

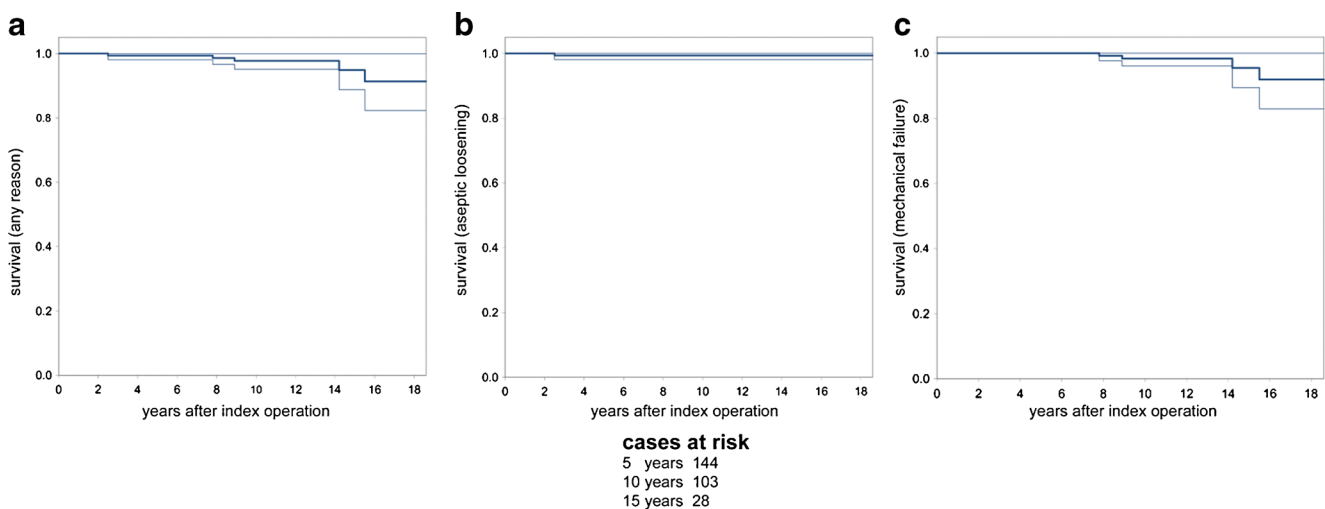


Fig. 2 **a** Survival rate with the endpoint of exchange, addition or removal of any component for any reason. **b** Survival rate with the endpoint of revision due to aseptic loosening. **c** Survival rate analysis with the endpoint of revision due to mechanical causes

Table 3 Distribution of progressive radiolucencies

Radiograph	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7
Tibial (AP view)	5 (22)	2 (9)	4 (18)	4 (18)	0 (0)	0 (0)	0 (0)
Tibial (lateral view)	3 (14)	3 (14)	0 (0)				
Femoral (lateral view)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Values given as n (%)

TKA. Five TKA (3 %) were revised: one for aseptic loosening of the tibial component at 2.5 years and four for mechanical failure (two because of instability at eight and 14 years; two because of excessive polyethylene wear at nine and 15 years). Sixteen cases (10 %) had postoperative complications that required surgical procedure without exchange, addition or removal of any component (Table 2).

Survival analysis

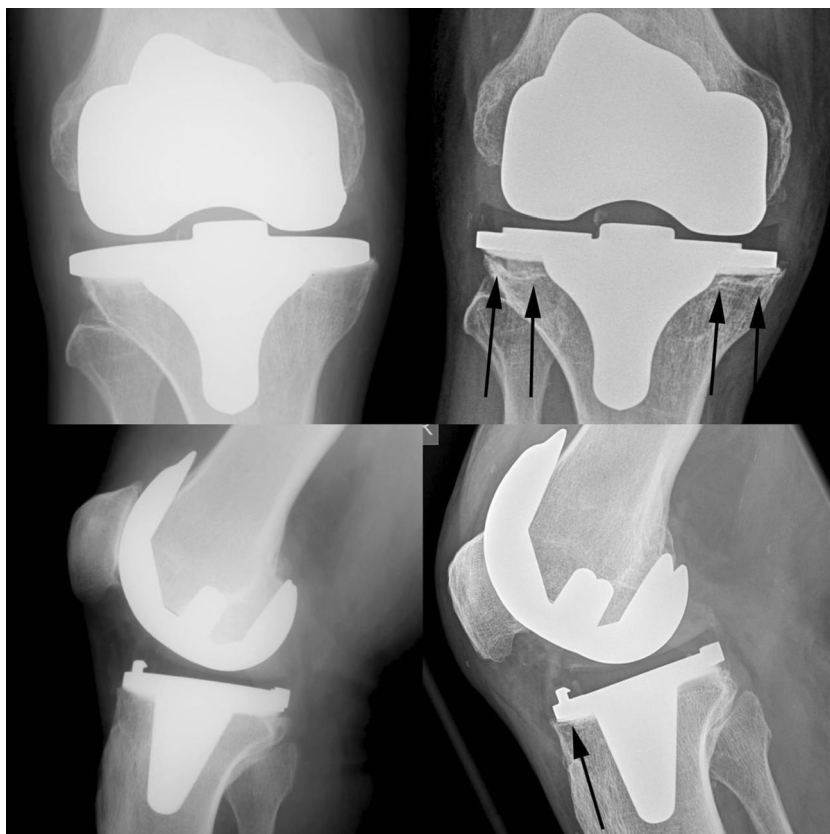
Survival with the endpoint exchange, addition or removal of any component for any reason was 97.7 % (95 % CI, 95.1–100 %) after ten years and 94.8 % (95 % CI, 88.7–100 %) after 15 years. Survival for revision due to aseptic loosening was 99.4 % (95 % CI, 98.1–100 %) after ten and 15 years. Survival for revision due to mechanical causes (excessive wear, instability) was 98.3 % (95 % CI, 96.1–100 %) after ten years and 95.5 % (95 % CI, 89.4–100 %) after 15 years (Fig. 2).

Clinical and radiological results after more than ten years follow-up

Sixty-one TKA had a clinical and radiological follow-up of more than ten years. The mean TKA follow-up was 12 years (SD 2, range 10–19). The mean ROM was flexion/extension 113/0/0 (SD 13/0/5) and none of the patients was scheduled for revision surgery. There was no difference in ROM for TKA with a prior tibial valgus osteotomy (flexion $p=0.7$, extension $p=0.5$).

There was no difference in alignment between TKA with a follow-up of greater than or less than ten years. Seven of 61 TKA with a follow-up greater than ten years had incomplete radiographs and were excluded from radiological analysis. On the latest postoperative radiograph the mean femoral flexion (α) was 98° (SD 3°, range 91–106°), the mean tibial angle (β) was 88° (SD 3°, range 78–95°), the mean femoral flexion (γ) was 2° (SD 2°, range -6 to 4°) and the mean tibial slope (δ) was 85° (SD 3°, range 75–93°). The femorotibial angle

Fig. 3 Postoperative radiograph (left side) of a female patient and after ten years follow-up (right side) showing progressive radiolucent lines in tibial zones 1, 2, 3 and 4 (AP view) and zone 1 (lateral view). No symptoms were recorded in the medical records



was 6° varus (SD 4°, range 4° valgus to 7° varus). Mean differences between first and last postoperative femoral and tibial radiological angles were: $\Delta\alpha=0.4^\circ$ ($p=0.14$), $\Delta\beta=0.2^\circ$ ($p=0.45$), $\Delta\gamma=-1^\circ$ ($p=0.06$), $\Delta\delta=0.1^\circ$ ($p=0.8$) and Δ femorotibial angle=0.5° ($p=0.4$). Overall alignment of the knee (femorotibial angle) was neutral ($\pm 4^\circ$) in 45 (83 %) TKA, varus in four (8 %) TKA and valgus in five (9 %) TKA. Overall alignment was independent from diagnosis ($p=0.08$), gender ($p=0.42$) and previous tibial valgus osteotomy ($p=0.41$).

Progressive radiolucencies were found in nine TKA (17 %) mainly on the tibial side (95 %, Table 3, Fig. 3) and were detected after a mean time of seven (SD 2) years. Femoral radiolucencies were uncommon, and we found no difference between cemented and uncemented femoral components ($p=0.661$). Five (8 %) of 61 TKA had an initial patella resurfacing, none of them showing radiological changes over time.

Discussion

Our long-term survival study confirms the excellent short- and mid-term survival data for the Duracon TKA. Furthermore, this study is the first to present radiological long-term data for this specific design.

The average age in our series was rather high (74 years), thus scoring systems analysing global function might have been inferior in this group. In any case, the observed results concerning ROM and especially the low flexion rate are comparable with the literature [28] and confirm the results of the short-term studies [12]. Additionally, the results are acceptable for the setting of a teaching hospital with 11 surgeons being involved in 159 TKA. Functional results might be better in a specialized high volume setting. None of the patients was scheduled for revision surgery at final follow-up.

Plain radiographs are the most commonly used modality determining alignment of the components, although gold standard is 3D-CT [14, 25]. We used the “Knee Society total knee arthroplasty radiological evaluation and scoring system” [8] which is an accepted tool for radiological analysis [1, 25]. Restoration of alignment is thought to play an important role in improving survival of TKA [23] and functional outcome [4, 19]; thus we focused our radiological analysis on TKA with a minimum follow-up of more than ten years. The radiological angles we measured did not differ from the angles other studies measured [27] and showed no (clinically relevant) changes during follow-up. As in other studies, alignment was not influenced by prior tibial valgus osteotomy [20]. Progressive radiolucencies were scarce and found in nine TKA (17 %) mainly located on the tibial side, which is comparable to other studies [8, 17, 22]. Femoral

radiolucencies were rare and independent from fixation of the component (cemented vs. uncemented). Difficulties observing radiolucent lines around femoral components is a well-known problem but independent from the type of fixation [7, 27]; thus, from our data we cannot recommend the use of cemented or uncemented components.

A limitation of the study is that the clinical evaluation was done retrospectively, using medical records only, but no clinical scoring system like, for example, the Knee Society clinical rating system [16] or Oxford Knee score [6].

Conclusion

The Duracon TKA showed excellent long-term survival comparable to data from national registers and to other successful designs. The ROM with an average flexion of 113° was comparable to the literature and acceptable for most daily living activities, but inferior to modern high-flexion designs. Radiological changes found on plain radiographs were scarce after almost 12 years of radiological follow-up indicating good implant stability.

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