



Fifteen-year survival of the Cedior™ total knee prosthesis

Roger Erivan¹ · Edouard Fadlallah² · Guillaume Villatte¹ · Aurélien Mulliez³ · Stéphane Descamps¹ · Stéphane Boisgard¹

Received: 11 February 2019 / Accepted: 2 July 2019 / Published online: 6 July 2019
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Abstract

Total knee arthroplasty (TKA) is an effective treatment for advanced osteoarthritis of the knee. No large and long-term follow-up study has been done about Cedior® prosthesis. The study hypothesis was that 15-year survival for the Cedior™ prosthesis is at least as good as rates reported for other models. A continuous retrospective single-center study included patients managed by Cedior™ TKA with at least 15-year follow-up. The main endpoint was prosthesis survival; secondary objectives were to identify factors for implant revision and to assess functional scores at 15 years. In the present series, 15-year all-cause survival for the Cedior® knee prosthesis was 93.03%; comparable to rates in the literature, posterior-stabilized implants showed higher revision rates. No other factors for revision emerged. These findings are comparable with those of the literature.

Keywords Total knee arthroplasty · Total knee replacement · Survival · Knee

Electronic supplementary material The online version of this article (<https://doi.org/10.1007/s00590-019-02491-7>) contains supplementary material, which is available to authorized users.

✉ Roger Erivan
rerivan@chu-clermontferrand.fr

Edouard Fadlallah
edouardfadlallah@gmail.com

Guillaume Villatte
guillaumevillatte@hotmail.fr

Aurélien Mulliez
amulliez@chu-clermontferrand.fr

Stéphane Descamps
s_descamps@chu-clermontferrand.fr

Stéphane Boisgard
sboisgard@chu-clermontferrand.fr

- ¹ CNRS, SIGMA Clermont, ICCF, CHU Clermont-Ferrand, Université Clermont Auvergne, 63000 Clermont-Ferrand, France
- ² CHU Clermont-Ferrand, Université Clermont Auvergne, 63000 Clermont-Ferrand, France
- ³ CHU Clermont-Ferrand, Délégation à la Recherche Clinique et aux Innovations (DRCI), 63000 Clermont-Ferrand, France

Introduction

Prosthetic knee surgery is growing constantly in France, from 80,426 procedures in 2010 to 106,561 in 2015 according to the OECD [1], as in the rest of the world. Growth is expected to continue, by 673% in the USA from 2005 to 2030 [2], due to increasing life expectancy [1].

Results for modern TKA techniques are excellent, with 99% implant survival at 1 year [2, 3] and 92% at 10 years [4].

Patients' functional expectations are likewise rising: They wish to resume sometimes intensive sport and/or occupational activities which they above all wish to be enduring [5]. Predictive factors for return to sports after TKA are patient related rather than extrinsic [6]. These preoperative expectations also strongly influence satisfaction at 1 year [7]. No large and long-term follow-up study has been done about Cedior® prosthesis [8].

The aims of the present study were: to assess 15-year survival for the Cedior™ TKA prosthesis (Sulzer®, Winterthur, Switzerland); and to identify factors for survival.

The study hypothesis was that 15-year survival for the Cedior™ prosthesis is at least as good as rates reported for other models.

Materials and methods

Material: study population

A continuous retrospective single-center study included all patients operated on in our department for first-line TKA between December 1998 and April 2002, whatever the etiology.

The initial population comprised 183 patients: 57 males, 126 females; 202 knees: 111 right, 91 left. Mean BMI was $28.5 \pm 4.64 \text{ kg/m}^2$ (range 18.69–46.02). Mean age was 70.8 ± 8.21 years (range 27–90). Figure 1 shows Charnley score, and Fig. 2 Devane activity levels. On the International knee Society (IKS) score, preoperative pain was rated at a mean 16 ± 8.59 (range 0–40) and range of motion at $105^\circ \pm 18.5^\circ$ (range 10° – 140°), for a mean total score of 98 ± 23.2 (range 11–142). One hundred and eighty TKAs were implanted for primary osteoarthritis, 16 for inflammatory arthropathy, and 6 for post-traumatic osteoarthritis.

Radiologically, mean HKA (hip-knee-ankle) angle was $174^\circ \pm 9.36^\circ$ (range 158° – 202°). Regarding preoperative deformity, 158 knees (78%) were in varus ($\text{HKA} < 177^\circ$), 40 (20%) in valgus ($\text{HKA} > 183^\circ$), and 5 (2%) well-aligned. On the Ahlbäck radiologic knee osteoarthritis classification [9], 12 knees were grade I (6%), 47 grade II (23%), 92 grade III (46%), and 51 grade IV (25%). On the Iwano patellofemoral osteoarthritis classification, 51 knees were grade I (29%), 69 grade II (39%), 36 grade III (20%), and 22 grade IV (12%) (with missing data for 24 knees).

Sixty implants were posterior-stabilized (PS) (30%), 99 posterior cruciate ligament retaining (CR) (49%), and 43 ultracongruent (UC) (21%). The patella was systematically resurfaced using a resurfacing implant, except in 4 cases: 3 with no patellar surgery and 1 with resection of the lateral quarter of the patella.

There were 201 medial parapatellar approaches (99.5%) and 1 Keblish lateral approach (0.5%), the latter requiring raising the anterior tibial tuberosity.

Fig. 1 Charnley scores

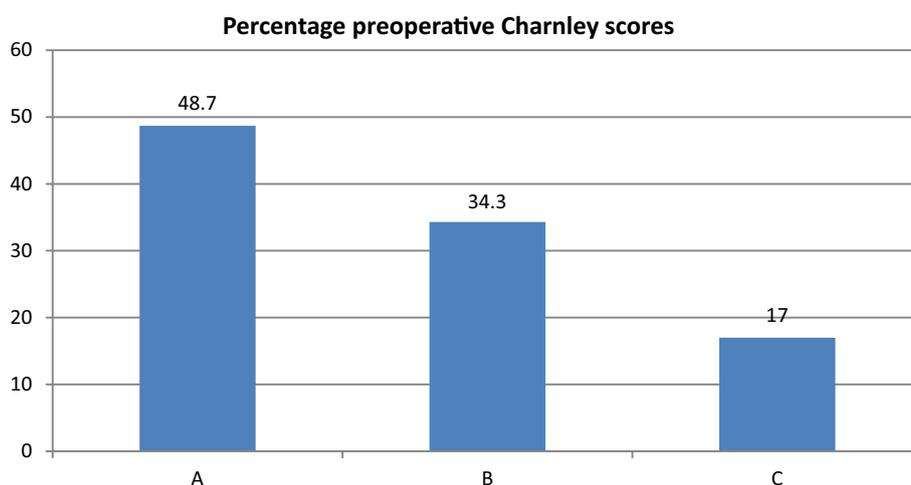
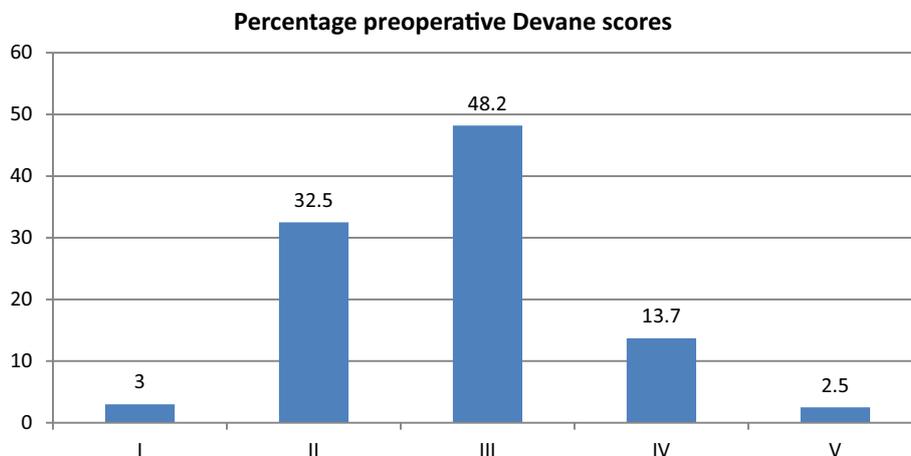


Fig. 2 Devane activity scores



Eight senior surgeons of the department performed the TKAs.

Method: data collection

Patients were either followed up in consultation or contacted by telephone.

Control X-rays comprised AP, lateral and Merchant views to study lower-limb stasis. Patients filled out functional questionnaires: SF12 (Short-Form Medical Outcomes, 12 items) [10, 11] KOOS (Knee injury and Osteoarthritis Outcome Score) [12, 13] and OKS (Oxford Knee Score) [14]. Families of deceased patients were contacted to check date of death and whether the implant had undergone revision or presented any complications. The family doctor was contacted for data if the patient could not be reached. If neither the patient nor the family nor the family doctor could be reached, the patient was considered lost to follow-up.

Clinical examination in consultation collected data on weight, height, clinical and functional IKS scores [15, 16], and Devane [17] and Charnley scores [18] and HSS (Hospital of Special Surgery) patellar score [19].

On X-ray, HKA angle was measured, and radiolucencies were analyzed on the Knee Society scale [20, 21].

Statistical analysis used Stata software, v12. Tests were 2-tailed, with the significance threshold set at $p < 0.05$. Qualitative data were reported as number and percentage, and quantitative data as mean \pm standard deviation. Comparison of progression in IKS, Devane, Charnley and HSS patellar scores by subgroup (gender, posterior stabilization, etiology) used the Student test (or Mann–Whitney test in the case of non-normal distribution) between 2 groups and analysis of variance between 3 groups. Correlations between quantitative variables were assessed by Pearson or Spearman correlation coefficients. Normal distribution was checked graphically and on Shapiro–Wilk test. Survivorship was analyzed on the Kaplan–Meier estimator, with revision surgery as event, taking the interval between TKA and revision. Revision rates were studied at 5, 10 and 15 years, with 95% confidence intervals.

Results

The study flowchart is shown in Fig. 3. At 15 years, 63 patients had died (71 knees) and 14 TKAs had undergone revision (13 living patients and 1 deceased), i.e., 15-year all-cause survival of 93.03%, as shown in Fig. 4. Of patients who were still alive at 5/10/15 years after the primary TKA implantation, 96.35% (185 knees/192)/92.44% (159 knees/172)/89.31% (117 knees/131) had unrevised TKA, respectively.

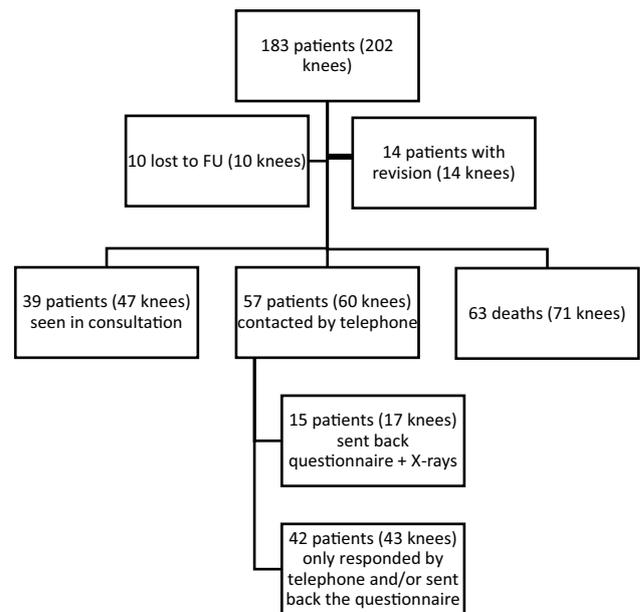


Fig. 3 The follow-up flowchart

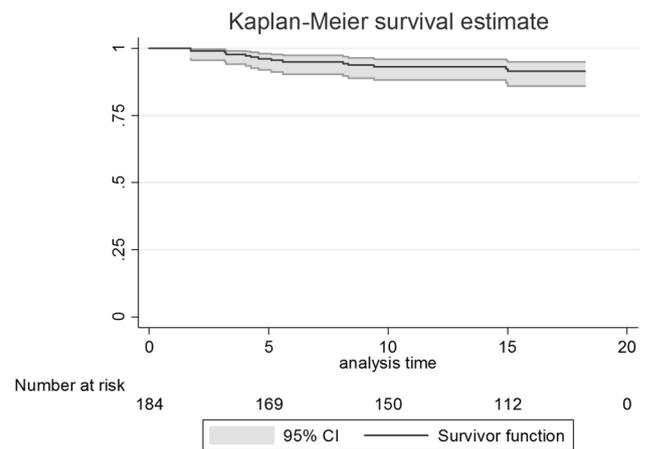


Fig. 4 All-cause survival curve

There were no intraoperative complications. There were postoperative complications in 10 TKAs: 5 supracondylar fractures (4 internal fixations, 1 non-operative treatment), 4 patellar fractures (3 treated non-operatively (Fig. 5) and 1 surgically) and 1 tibial loosening, not operated on due to the patient's refusal. It appeared at a mean of 6.37 years after surgery.

Revision surgeries included 10 cases of aseptic loosening (9 tibial (Fig. 6) and 1 bipolar), 2 of septic loosening, 1 infection without loosening and 1 simple resection of the lateral quarter of the patella and change of patellar component. Mean time to revision was 6.3 ± 4.32 years (range 1.7–15.01 years). The revision rate was significantly higher for PS than CR or UC prostheses ($p = 0.003$), as shown in

Fig. 5 16 Years after left TKA. Left: patellar dislocation fracture, treated non-operatively

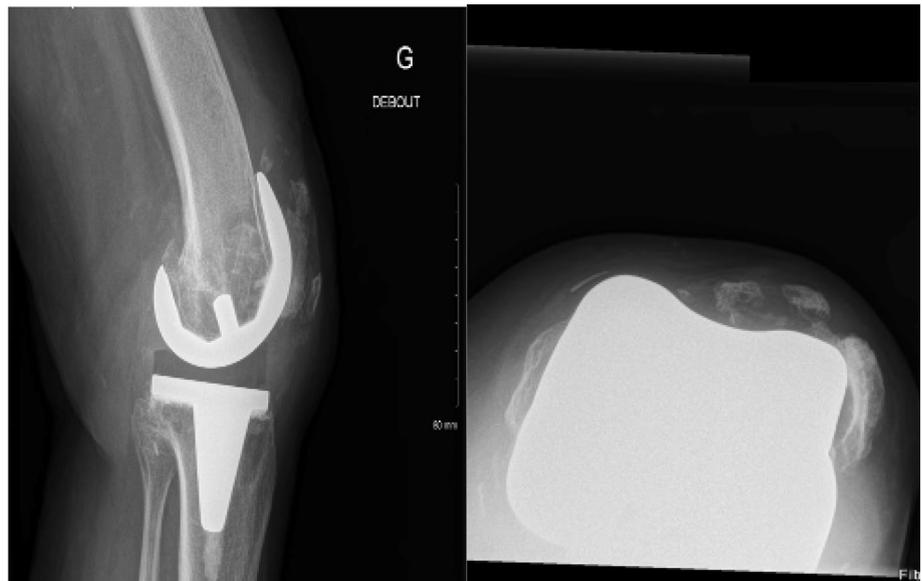


Fig. 7. The PS subgroup was comparable to the others in terms of age, gender, BMI, weight and height. Subgroup analysis found no other significant factors for revision: height, weight, BMI, gender or type or severity of preoperative deformity. Patients with changed postoperative alignment (varus to valgus or vice versa) showed no greater risk of revision.

Clinical parameters were modified. The progression in Charnley score shows a significant deterioration at 15 years ($p < 0.05$) (Fig. 8). Figure 9 shows significant deterioration in Devane score at 15 years ($p < 0.01$). Concerning the IKS score, mean pain scores was 14.26 ± 8.75 (range 0–40) preoperatively and 43.35 ± 7.35 (range 10–50) postoperatively. There was significant alleviation of pain at 15 years ($p < 0.001$). The mean range of motion was $100 \pm 18^\circ$ (range 10° – 140°) preoperatively and $104 \pm 13^\circ$ (range 65° – 125°) postoperatively. There was no significant improvement in the range of motion at 15 years ($p = 0.155$). The mean functional score was 73.0 ± 13.8 (range 10–80) preoperatively and 66.5 ± 25.8 (range 0–100) postoperatively. There was a nonsignificant deterioration in functional score ($p = 0.079$). The mean total IKS score was 103.9 ± 20.1 (range 11–142) preoperatively and 144.1 ± 31.4 (range 55–197) postoperatively. There was significant improvement in total score ($p < 0.001$). Concerning the postoperative SF12, mean physical score was 33.6 ± 9.0 (range 17.9–54.5), mean mental score was 38.4 ± 8.0 (range 22.3–60.5), and no data were available preoperatively. Concerning the postoperative KOOS, mean pain score was 842 ± 14.3 (range 53–100), mean symptoms score was 69.4 ± 9.7

(range 50–96), mean sports and leisure activities score was 20.9 ± 19.6 (range 0–55), mean daily living score was 64.9 ± 21.5 (range 0–100), mean quality of life score was 72.2 ± 25.7 (range 6–100), and no data were available preoperatively. Concerning postoperative Oxford score, mean score was 34.5 ± 7.8 (range 14–47) and no data were available preoperatively. Concerning, postoperative HSS patellar score, mean score was 86.0 ± 11.8 (range 50–100) and no data were available preoperatively.

The radiologic analysis showed that 6 knees (9.23%) showed femoral radiolucency at 15 years: 6 in zone 1, 2 in zone 2, 4 in zone 3, 3 in zone 4, 2 in zone 5, 2 in zone 6 and 1 in zone 7. Twenty knees (30.77%) showed tibial radiolucency at 15 years: 13 in zone 1, 10 in zone 2, 13 in zone 3, 16 in zone 4, 5 in zone 5, 6 in zone 6 and 7 in zone 7 (Fig. 6). There were no patellar radiolucencies on 15-year X-rays. The mean postoperative HKA angle was $178.2 \pm 3.6^\circ$ (range 172° – 186°).

Discussion

In the present series, 15-year all-cause survival for the Cedior[®] knee prosthesis was 93.03%, comparable to rates in the literature, which ranges between 90% and 100% [22–28], as shown in Table 1. This is the largest and longest follow-up study about Cedior[®] total knee arthroplasty. This implant is not used anymore, but many patients have this prosthesis and need a follow-up.

All cases of loosening involved the tibial component, which was non-cemented.

Fig. 6 **a** 12 Years after right TKA. Mechanical tibial loosening with fracture of the medial tibial plateau. **b** 12 Years after TKA. Tibial radiolucency in all zones on AP and lateral views, corresponding to mechanical tibial loosening. Revision at 12 years

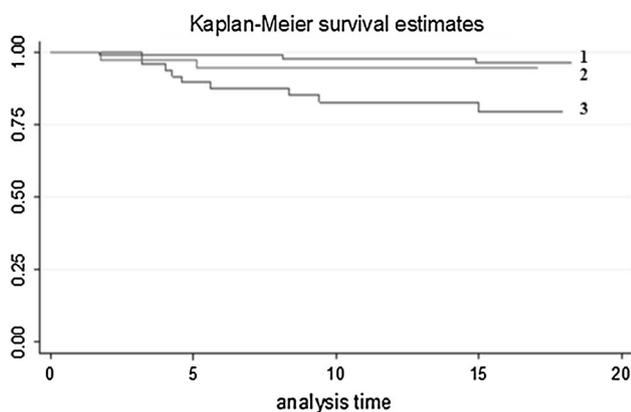
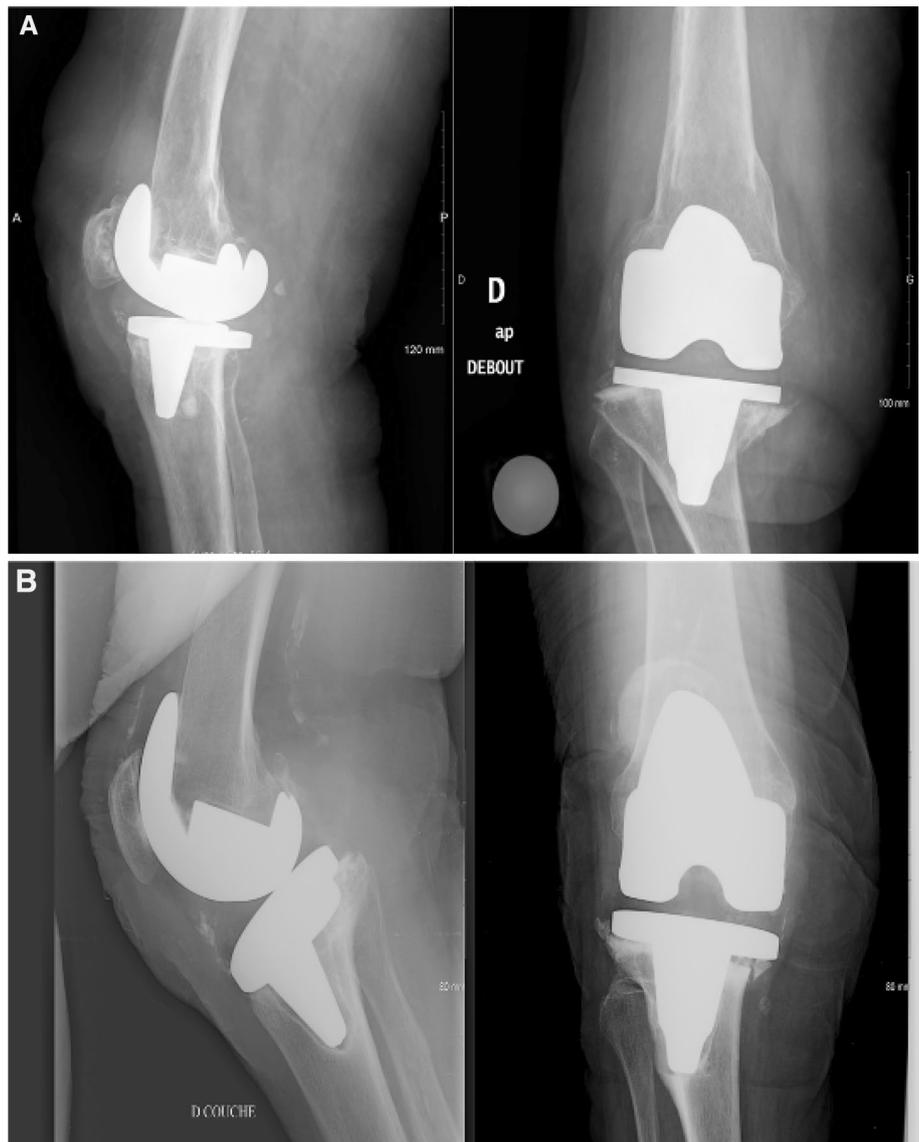


Fig. 7 Survival curves according to type of constraint: 1: UC, 2: CR, 3: PS

The rate of revision for infection (1%) was comparable to other reports [29–31].

Most IKS scores (pain and total) showed significant improvement, as in the study by Chana et al., who reported improvement from 64.1 preoperatively to 140.5 postoperatively [28, 31–33].

The postoperative HSS score of 86 was comparable to the score of 89 found by Bistolfi et al. (25) at 13.5 years.

The 40% radiolucency rate was higher than reported elsewhere: Metsovitis et al. (29) found a 4% rate on control X-ray; this may be due to improved radiographic quality in the intervening period.

The only factor for revision to emerge was the type of constraint, PS designs showing a significantly greater risk of loosening. As Parratte et al. have recently reported [27], postoperative HKA angle was not a risk factor for revision for loosening.

Fig. 8 Progression in Charnley score at 15 years

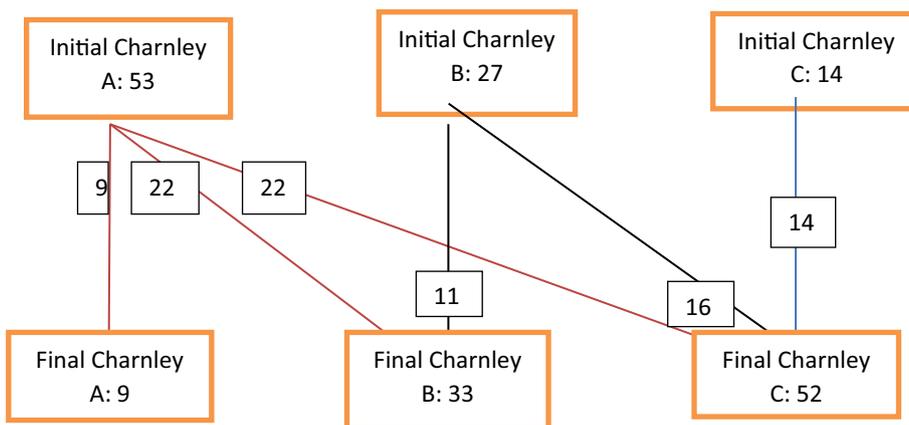
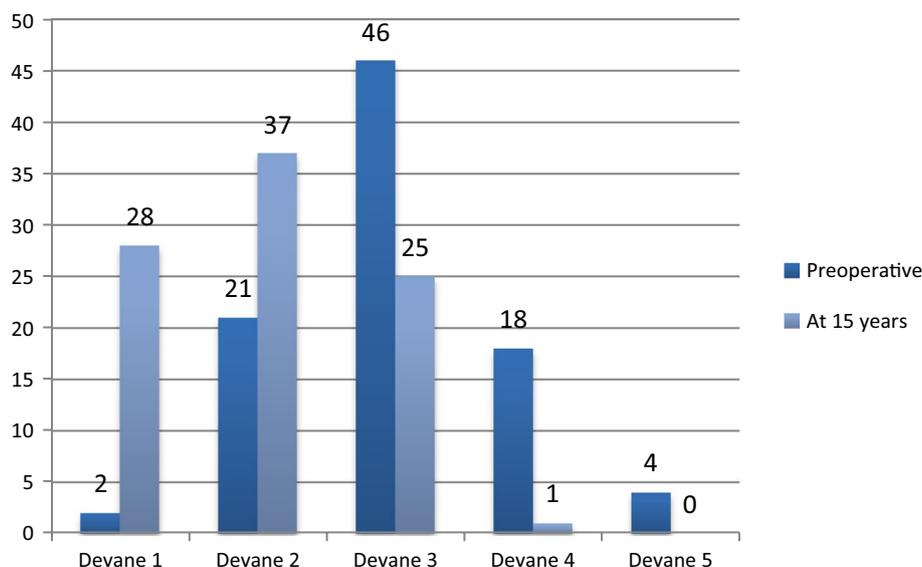


Fig. 9 Progression in Devane score at 15 years



Postoperative range of flexion was satisfactory, but smaller than reported elsewhere. Moreover, flexion did not significantly improve after TKA. Mean preoperative flexion was 100°, which is greater than that reported elsewhere (19,21,22).

Functional IKS score decreased postoperatively, unlike in several other studies and meta-analyses [2, 28, 31, 32]. This may have been due to patient age and comorbidities affecting functional scores, as reported in some studies [34] but not others [2, 32]. In our experience, patients were bothered by comorbidities hindering task performance that could have given them a better IKS functional score; total IKS score, in contrast, increased significantly postoperatively, as in other studies (1.27–29).

Conclusion

In the present single-center retrospective study of 202 TKAs performed in 183 patients in our department between December 1998 and April 2002, the Cedior® prosthesis showed 93.0% 15-year survival, which is thoroughly satisfactory and comparable with the data in the literature considering the state of the art 20 years ago. PS models showed greater risk of loosening; no other factors for survival emerged. Clinical assessment showed good results on IKS and HSS patellar functional scores, with significant improvements in IKS pain and total scores. The 40% radiolucency rate was higher than that reported elsewhere, but without clinical impact.

Table 1 Comparative table

Series	Follow-up	Initial cohort	Final cohort	Implant	Pre-op age	Lost to FU	Death	Pre-op flexion	Post-op flexion	Revision (%)	All-cause survival (%)
Nakamura et al. [21]	15 years	507	167	Bi-Surface Knee System, Kyocera Medical®	68.5	30	242	118.1°	123.7°	6	94%
McCalden et al. [22]	16 years	469	422	Genesis II, Smith and Nephew®	68	47	184	–	–	3.6	96.4%
Karachalios et al. [23]	13.4 years	284	251	Advance Medial Pivot, Microport Orthopedics Inc.®	71	10	23	101°	117°	2.7	96.4%
Rajesh et al. [23]	10–13 years	133	97	PFC Σ Sigma rotating platform, DePuy®	64.8	12	24	106.8°	127°	0	100% at 11 years
Bistolfi et al. [25]	13.5 years	223	179	Press-fit condylar TKA, Johnson and Johnson®	68.4	37	15	86.5°	108°	9.4	90.6%
Parratte et al. [26]	15 years	398	280	PFC, Johnson and Johnson®/Genesis, Smith and Nephew®/Kinematic condylar2, Howmedica®	–	–	–	–	–	14.8	85.2%
Metsovitis et al. [27]	18 years	260	–	Rotaglide, Cozim Medical®	66.7	–	–	92.3°	112.1°	13	87%
Present series	15 years	202	121	Cedior, Sulzer®	70.8	10	70	100°	104°	6.97	93.03

Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests

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