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Original article

Unilateral versus bilateral total knee arthroplasty: A registry study on survival and risk factors

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ABSTRACT

Background: Bilateral cases, representing at least 25% of total knee arthroplasties (TKA), could convey a statistical bias linked to dependency. Registries allow exploring this issue, susceptible to question surgeon validated protocols. Do bilateral total knee arthroplasties behave differently than unilateral knees in terms of implant survival?
Hypothesis: Bilateral TKA have a better survival than unilateral TKA.
Patients and methods: A number of 14,652 bilateral and 27,440 unilateral TKAs were compared. Influencing factors were tested with hazard ratios applied on bilateral knees.
Results: Bilateral knees had a better survival ($p < 0.001$). Delay between first and second side surgeries had an influence on survival of the first knee: if below a year, the first knee survival was superior to the second knee; more than three years between both arthroplasties significantly decreased the survival of the first implant. If the first knee was revised, the hazard ratio for revision of the second implant was 3.5.
Discussion: Series should include separate evaluations of bilateral cases, because they have a better survival than unilateral knees. A long delay between both knee replacements could impact both implant survivals.
Level of Evidence III, Cohort Comparative Study.

1. Introduction

Total Knee Arthroplasty (TKA) has been proven to be a safe and reliable surgical procedure, relying on extensive literature on approaches [1,2], surgical techniques [3,4], physiotherapy[5] and clinical follow-up[6]. The improvements made to optimize the knee procedure were obtained with the help of statistical evidence [7,8].

Bilateral cases represent 15% of total hip arthroplasties [9] and 25% of total knee arthroplasties [10] in registries. From an orthodox statistical point of view, these cases represent a bias, as the samples are not all independent, as shown by Park et al. [11].

Registries allow obtaining statistical knowledge of influencing factors on implant survival, information hard to extract from conventional studies, even randomized controlled trials. A few registry studies have tackled the issue of bilateral case dependency biases on risk factors, with the use of alternative Cox regression models such as shared gamma frailty models, more appropriate to deal with dependency issues, but with mixed results. In hips, Lie et al. [9] found an influence of bilaterality on the risk of revision for the remaining hip if the opposite hip had been revised. The influence of bilaterality was found negligible for standard risk factors, these results sharing the conclusions of Schwartzer et al. [12]. Robertsson et al. [10] applied the shared gamma frailty regression model to knee arthroplasty and concluded of an absence of bias of ignored bilaterality. But their conclusions only could be applied on the factors they researched, i.e. the influence of unicompartimental arthroplasty on knee arthroplasty survival.

No cohort study was only performed on bilateral total knees to look for differences on implant survival and risk factors. As bilateral cases in TKA represent a quarter of the knees, there remains an interest to focus on these knees to look for survival differences, in order to assist both patient and surgeon in choosing the implant characteristics and scheduling both surgeries. A registry was used to select only bilateral cases.

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Do bilateral total knee arthroplasties behave differently than unilateral knees in terms of implant survival? What are the factors affecting survival of bilateral total knee arthroplasties?

Our hypothesis was bilateral cases have a better survival than unilateral cases.

2. Material and methods

2.1. Patients

This study was designed as a comparative study using a registry of orthopedic implants. Patients were included from 01/07/2000 to 31/12/2015.

All analyses presented in this report are based on primary operations in patients resident in a specific region (Emilia-Romagna, Italy). The analysis was limited to this cohort of patients, with the exclusion of patients living outside the region, to avoid the bias of possible lost to follow up. The RIPO registry (Registro Implantologia Protesica Ortopedica, Bologna, Italy, https://ripo.cineca.it) covers the area of Emilia-Romagna region (4.5 million inhabitants) and has a capture rate of more than 95% on implants performed in all orthopedic departments of the region, both public and private (65 centers).

Each event (death, revision of any type) was strictly recorded and cross-checked with regional administrations; a period of time of one year after the last inclusion was included to allow collecting all data from the different centers and administrations. Loss of follow-up was evaluated to be below 2%.

The inclusion criterion was the recording of a primary total knee arthroplasty during the inclusion period. Was considered bilateral a primary TKA performed on each knee during the time of the study.

On the contrary, a knee arthroplasty was considered unilateral when only one side benefited from a knee implant during the time of the study. Only bi (without patellar resurfacing) or tricompartimental arthroplasties were included. The registry did not record arthroplasties before the inclusion period. Unicompartimental knees were excluded, due to survival differences that could tamper with the results and provide an unwanted confusion bias. Pre-operative data was comparable in both groups.

A number of 14,652 bilateral implants (7326 patients) and 27,440 unilateral implants were performed in the period on 7326 patients and 27,440 patients, respectively (Fig. 1). 34.8% of the total knee arthroplasties were bilateral cases; 21% of total knee patients had bilateral total knees. Thirty knees (15 patients) benefited from a simultaneous bilateral knee arthroplasty.

Unilateral knees served as a reference group.

Bilateral TKAs had a mean follow-up of 5 years (0–14.7). Average time between the first and the second operation was 2.7 years (95% confidence interval 2.6–2.8), (min and max 0–14). Unilateral TKAs had a mean follow-up of 5.5 years (0–16),

Mean age was 72 years for females and 71 years for males. Primary etiology was osteoarthritis (88%). Concerning the bilateral group, 64% of polyethylene inserts were fixed, 36% mobiles. 44% of implants were cruciate retaining, 56% were posterior-stabilized (Table 1). Concerning the unilateral group, 62% of polyethylene inserts were fixed, 38% were mobiles. 44% of implants were cruciate retaining, 56% were posterior-stabilized. Both groups were comparable in terms of per operative characteristics.

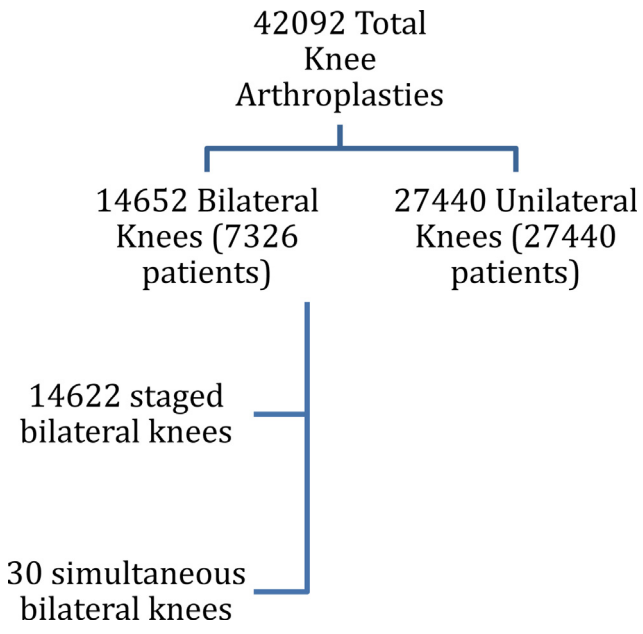

Fig. 1. Flow-chart.

Table 1
Repartition of implanted TKA (the two groups were found comparable with regard to implants).

Type of insert	Implant name	Number (%)
Bilateral knees		
Fixed 9328 implants	Nexgen LPS (Zimmer)	2398 (29.9%)
	Nexgen CR (Zimmer)	421 (4.5%)
	Genesis II PS (Smith&Nephew)	721 (7.7%)
	Genesis II CR (Smith&Nephew)	332 (3.6%)
	Profix Conforming (Smith&Nephew)	748 (8%)
	Vanguard PS (Biomet)	764 (8.2%)
	Other	3944 (42.3%)
Mobile 5324 implants	TC-PLUS (EndoPlus)	719 (13.5%)
	PFC-RP-PS (DePuy)	616 (11.6%)
	Gemini MK-II (LINK)	610 (11.4%)
	LCS (Complete&Universal) RP (DePuy)	268 (5%)
	Genus (Adler)	326 (6.1%)
	Other	2785 (52.3%)
Unilateral knees		
Fixed 17,122 implants	Nexgen LPS (Zimmer)	4184 (24.4%)
	Nexgen CR (Zimmer)	846 (4.9%)
	Genesis II PS (Smith&Nephew)	1642 (9.6%)
	Genesis II CR (Smith&Nephew)	603 (3.5%)
	Profix Conforming (Smith&Nephew)	1117 (6.5%)
	Vanguard PS (Biomet)	1528 (8.9%)
	Other	7202 (42.1%)
Mobile 10,313 implants	TC-PLUS (EndoPlus)	1146 (11.1%)
	PFC-RP-PS (DePuy)	1042 (10.1%)
	Gemini MK-II (LINK)	1310 (12.7%)
	LCS (Complete&Universal) RP (DePuy)	462 (4.5%)
	Genus (Adler)	566 (5.5%)
	Other	5787 (56.1%)

2.2. Methods

Failures were recorded up to 31/12/2015. The recording of a revision and/or a complication is mandatory for a hospital in the registry region; a period of time of a year was included in the study to allow collecting all events (death, revision, complication). Revision for any cause was set as the endpoint; revision was defined as the removal or change of any implant and would impact the survival rate.

Bilateral and unilateral knees were compared with regard to survival rates.

First and second knees of the bilaterals were also compared via the same methods.

Table 2
Bilateral arthroplasties: Sub-groups of knees with regard to the duration between both arthroplasties.

	Number of primary implants	Mean Follow-up (min-max) in y	Number of revision at 31/12/2015
First implants – < 1 year	1917	6.5 (0–15.3)	35 (1.8%)
First implants – 1–3 years	3037	7.1 (0–15.5)	83 (2.7%)
First implants – > 3 years	2372	9.2 (0–15.4)	138 (5.8%)
Second implants	7326	5.0 (0–14.7)	142 (1.9%)

Three sub-groups were designed to look for survival differences with regard to the time between both surgeries: from 0 to 1 year, between 1 and 3 years, and over 3 years. The 3 sub-groups were set based on sub-group size comparability, as these thresholds allowed dividing the cohort into three groups of almost equal numbers. An amount of 1.6% of the first sub-group (30 cases) were simultaneous bilateral cases.

All three sub-groups were found comparable with regards to all the influencing variables listed below, i.e. age, sex, Body Mass Index (BMI) and cause for revision. Table 2 shows the population of the 3 sub-groups.

To look for influencing variables on the outcome of the surgery, patient characteristics such as sex, weight and age at surgery, or implant characteristics such as the type of tibial insert (fixed or mobile) were extracted from the database when available.

2.3. Statistical analysis

The statistical analysis was performed using SPSS 14.0 for Windows, version 14.0.1 (SPSS Inc, Chicago, IL, USA) and JMP®, Version 12.0.1. (SAS Institute Inc., Cary, NC, 1989–2007). Kaplan Meier survival curves were used for survival analysis; log-rank tests looked for statistically significant differences between the survival curves. The significance threshold was set at $p < 0.05$. Hazard ratios were calculated via a Cox multivariate regression model.

3. Results

Survival analysis of unilateral knees was plotted against bilateral knees, without using statistical means to account for the dependency bias (Fig. 2). Log-rank test was found significantly different ($p = 0.0001$), in favor of bilateral cases. At 5 years, survival was 97.8% for bilateral TKAs [97.5–98] against 96.3 for unilateral TKAs [96.1–96.6]; at 10 years, survival was 96.0% for bilateral TKAs.

As the first side of the bilateral knees had functioned as a unilateral knee before the second surgery, we also tested unilateral knees against only the second knee of the bilateral knees. The results were even more in favor of the bilateral knees (Table 3, $p = 0.0001$).

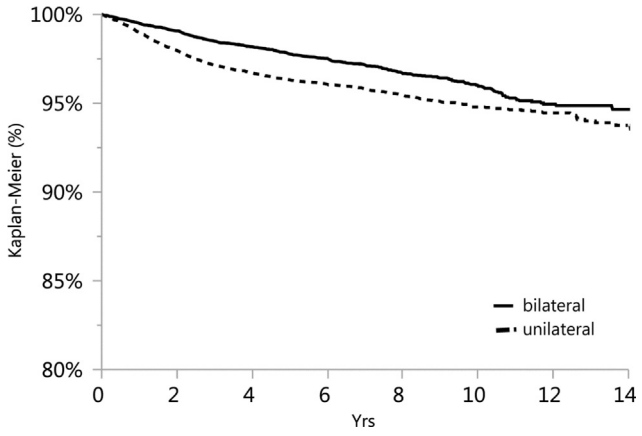

Fig. 2. Kaplan-Meier survival of the first TKA according to the duration between both arthroplasties was compared with the survival of the second TKA.

Table 3
Comparison of the number of revisions of bilateral second knee versus unilateral knees.

	Number of primary implants	Mean Follow–up (min–max) in years	Number of revision at 31/12/2015	% survival (Confidence interval 95%)
Bilateral-second side only	7326	5.0 (0–14.7)	142 (1.9%)	96.7 (96.0–97.3)
Unilateral	2,7440	5.5 (0–16)	955 (3.5%)	94.8 (94.4–95.2)

Results are significantly different ($p = 0.0001$, Log-Rank test).

Survival curves of both the first and the second knees of bilateral cases were plotted against, with a log rank test close to significance (Fig. 3, $p = 0.0606$). Hazard ratio on the influence of implant order was also not significant. As the populations were comparable, the only difference between them being the bilaterality, we looked at differences within the bilateral group that could have ponderated the difference.

To search only for the influence of the time between both surgeries on implant survival, survival curves of the 3 sub-groups (shorter than a year, between one and three years, and over three years between both surgeries) were plotted against second side survival curve (Fig. 4). All curves were found statistically different ($p = 0.0001$). Differences in favor of the first sub-group versus the

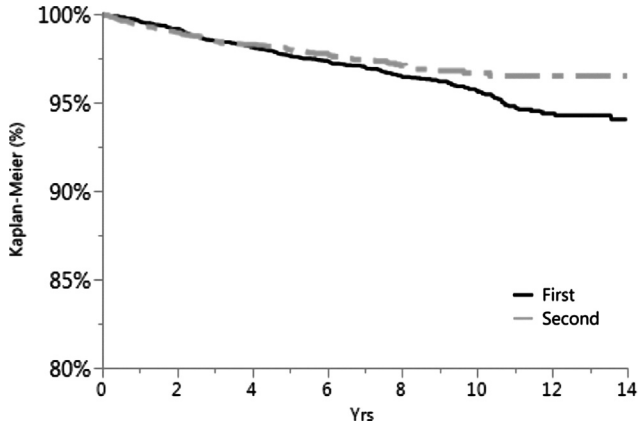

Fig. 3. Kaplan Meier survival analyses of first and second knees of bilateral total knee arthroplasties were compared via a log rank test.

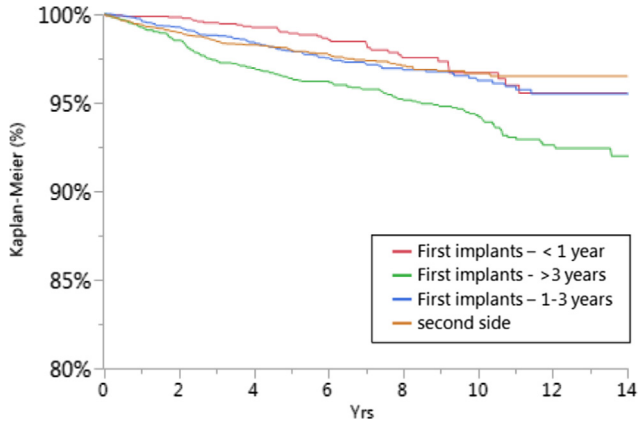

Fig. 4. Kaplan-Meier survival of the first TKA, according to the duration between both arthroplasties, was compared with survival of the second TKA via a log-rank test.

Table 4
Hazard ratios extracted from the Cox model to look for influencing factors on the survival of bilateral total knees.

	HR	95% LB	95% UB	*p*
Insert type (reference: fixed)	1.529	1.240	1.885	0.001
Age (years)	0.948	0.936	0.961	0.001
Time between first and second side (reference: second implant)				
< 1 year	0.644	0.432	0.961	0.031
Between 1 and 3 years	0.899	0.670	1.206	NS
> 3 years	1.518	1.175	1.960	0.001
Weight (reference: > 80 kg)	0.893	0.718	1.11	NS
Revision risk of the second side if the first side is revised	3.364	2.070	5.468	0.001

NS: non-significant; HR: hazard ratio; 95%LB & UB = 95% confidence interval.

second knee and in favor of the second knee versus the third sub-group, while no difference between the second sub-group and the second knee, were found when looking at hazard ratios.

Groups were also confronted pairwise using a Wilcoxon test and it could be concluded that all groups had significant differences, except when comparing second sub-group and second knee ($p = 0.753$). It is worth noting than the knees from first sub-group of under a year of duration between both knees were mostly staged bilateral knees,

Hazard ratios were extracted from the Cox model to look for influencing factors on the survival of bilateral total knees (Table 4). Insert type had a strong influence on survival, with a hazard ratio of 1.5 (95% confidence interval, IC95 1.24–1.885) unfavoring mobile liners versus fixed liners. Sex did not influence the results. A young age was also a revision factor, with a hazard ratio of 0.95 (IC95 0.936–0.961) for age at implantation. Weight did not influence survival, with a HR of 0.9 (IC95 0.718–1.11). The implant order played a significant role, as shown previously. Provided the first implant was revised, the influence of the first knee revision on the second knee survival was calculated. A hazard ratio of 3.4 on the second knee (IC95 2.07–5.468) could be extracted from these findings ($p = 0.001$).

4. Discussion

Bilateral knees had a better survival than unilateral knees, with a strong influence of the time between both surgeries on survival of the first knee. If the time between surgeries was below a year, first knee survival was superior to the survival of the second knee; a duration of more than three years between both arthroplasties significantly decreased survival of the first implant. If the first knee was revised, the hazard ratio for revision of the second implant was 3.5. Mobile liners had a worst survival rate than fixed liners. Our hypothesis is confirmed.

This series demonstrated our hypothesis, with a difference in favor of bilateral vs unilateral knees with regard to total knee survival. These results follow the findings from the study of Namba et al. [13], who studied risk factors for total knee revisions and found bilaterality as being protective, and the study of Bohm et al. [14] which focused on revision rates (1.4% vs 2.3% for the unilateral knees at 3 years). Our study allowed further explaining the reasons of this behavior. These conclusions were not present in hip arthroplasty for Lie et al. [9], who found no incidence of bilaterality on survival. Robertsson et al. [10] or Hooper et al. [15] also found no differences in knees. But Robertsson's study focused on the effect of bilaterality in unicompartimental versus tricompartimental results, and Hooper's study only had a 5 year follow-up period which could have tampered with significance.

No other series focused on the differences between the first and the second knee in bilaterals. Only in hip could we find the previously cited study from Lie et al. [9] with a difference found when time between surgeries reached two years. It is worth noting they also found a higher hazard ratio for second side revision when the first side was revised. When both sides were performed simultaneously, Seo et al. [16] showed similar revision rates of both sides.

One major revision risk factor found in our study was the time between surgeries. As it could be extracted from these findings that a threshold of a year should be set to avoid an incidence on revision, we couldn't go further into investigating the zero-to-one year period. The total amount of simultaneous bilateral knees was too small to compare them with staged bilateral knees. This issue of simultaneous versus staged is however still debated, with studies in favor of a staged procedure due to lower complication rates [17–21], in favor of the cost-effectiveness of simultaneous bilateral knees[20], or the absence of difference[15,21,22]. Ahn et al. showed a superiority for simultaneous knees [23]. Bohm et al. [14] in a significant-size registry study, showed that the populations involved in both groups were different. They found fewer infections in the simultaneous group but with more post-operative complications and no difference in revision rates.

We found an incidence of the type of insert in the survival of bilateral knees, in favor of fixed inserts. These results concurred with results from others like Gøthesen[24] or Namba et al. [25]. The multi-registry study from Namba et al. should allow modifying surgeon practice, as the objective of the introduction of mobile inserts was to prevent wear and so increase survival rates.

A limitation of our study was the absence of clinical findings, a limitation specific to registries that only focus on revision as an endpoint. Patients unwilling to suffer a third knee surgery, or challenged due to health issues could not have been investigated. It seems nevertheless that these findings could only increase the differences shown in this study.

The most important limitation of not having clinical results could be the absence of satisfaction scores. There could be a selection bias, as patients recovering better from the first arthroplasty could be more eager to undergo another arthroplasty, thus resulting in shorter duration between surgeries, ultimately explaining the difference in survival of the sub-groups. But as the three subgroups shared the same characteristics (age, sex, weight, BMI, implants and, more importantly, complications and causes for revision) and so found comparable, the effect of patient satisfaction cannot account for the total of the difference found between subgroups, as it would mean that patient satisfaction is not related to complications or survival.

Another limit was the absence of clinical value of the 2 thresholds (below a year and over 3 years). These thresholds were data-driven, to separate the population into three comparable groups in terms of group size. While they allowed conducting an appropriate statistical analysis, they can't be considered as precise landmarks in the clinical follow-up. A last limit also has to be mentioned, as the registry does not include history of arthroplasties before the start of the inclusion period. There is no possibility to know how many "unilateral" knees were in fact bilateral knees, especially at the start of the inclusion period. This bias mechanically had lowered its effect the longer the registry lived on. With our study's results in mind, finding a better survival of bilaterals versus unilaterals, it would seem this bias did not affect the results from reaching a statistically significant difference but the difference might be higher than presented.

5. Conclusion

Bilateral total knee arthroplasties showed a better survival rate than unilateral total knees. Total knee arthroplasty series should include a separate evaluation of bilateral cases to prevent the dependency bias, as well as to measure its effect on the series results; or at least use a statistical technique to account for bilaterality.

Time between both surgeries could have an effect on implant survival in bilateral cases. Surgeons could include this finding in their planning strategy and keep in mind that a period of more than 3 years between both knees significantly decreased the survival of the first knee arthroplasty.

Disclosure of interest

Bertrand Boyer and Thomas Neri are consultants for SERF (Décines, France). Aldo Toni receives royalties from Adler (Milan, Italy). The other authors declare that they have no competing interest.

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Contributions

Susanna Stea and Aldo Toni were responsible for data collect, loss of follow-up reduction strategies and manuscript overseeing; Barbara Bordini and Dalila Caputo were responsible for the statistical analysis and survival modeling; Thomas Neri was responsible for manuscript building and redaction, especially material and methods and results; Bertrand Boyer organized the study, built the manuscript and was responsible for introduction and discussion parts of the manuscript.

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