

DOES RISK OF REVISION FOR INFECTION FOLLOWING PRIMARY TOTAL KNEE ARTHROPLASTY VARY BETWEEN OPEN AND CLOSED BONE CEMENT MIXING SYSTEMS?

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Background

- Various bone cement products are used in total knee arthroplasty (TKA). In Norway, Palacos R+G with an open mixing system has long been the standard.
- However, since 2014 it has increasingly been replaced by Palacos R+G Pro, which uses a closed mixing system.

Aims

- to compare revision rates due to deep infection, aseptic loosening, and all causes after primary TKA using Palacos R+G versus Palacos R+G Pro at 1-, 5-, and 10- years follow-up.

Materials og Metode

- This register-based study included 28,944 fully cemented primary TKAs performed for osteoarthritis and recorded in the Norwegian Arthroplasty Register between 2015 and 2025 (Fig. 1).
- A directed acyclic graph (DAG) was applied to identify variables influencing revision risk (Fig. 2).
- Revision due to all causes, deep infection, and aseptic tibial loosening was assessed at 1, 5, and 10 years using Kaplan–Meier survival analysis and adjusted Cox regression with Palacos R+G as the reference.

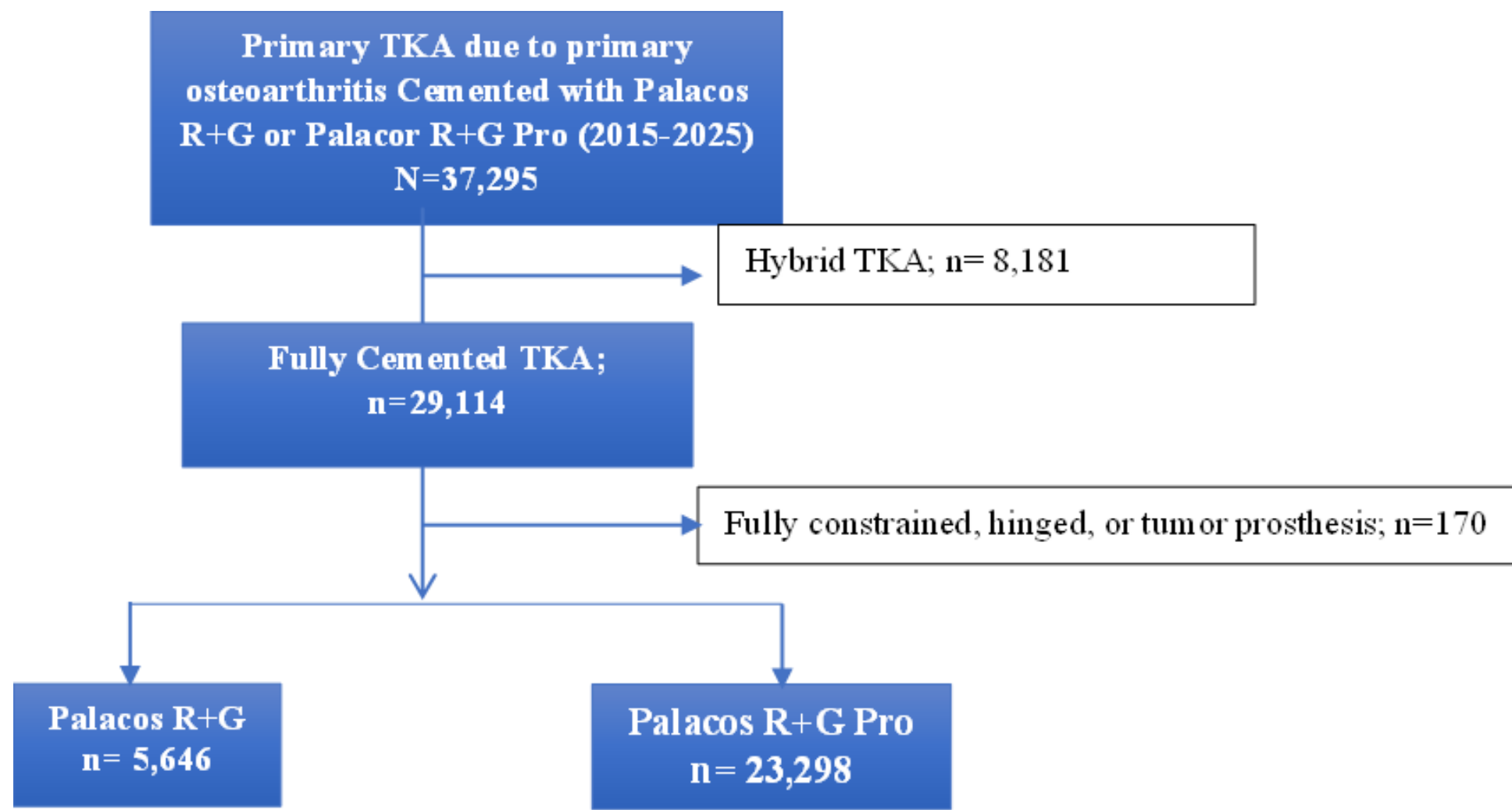
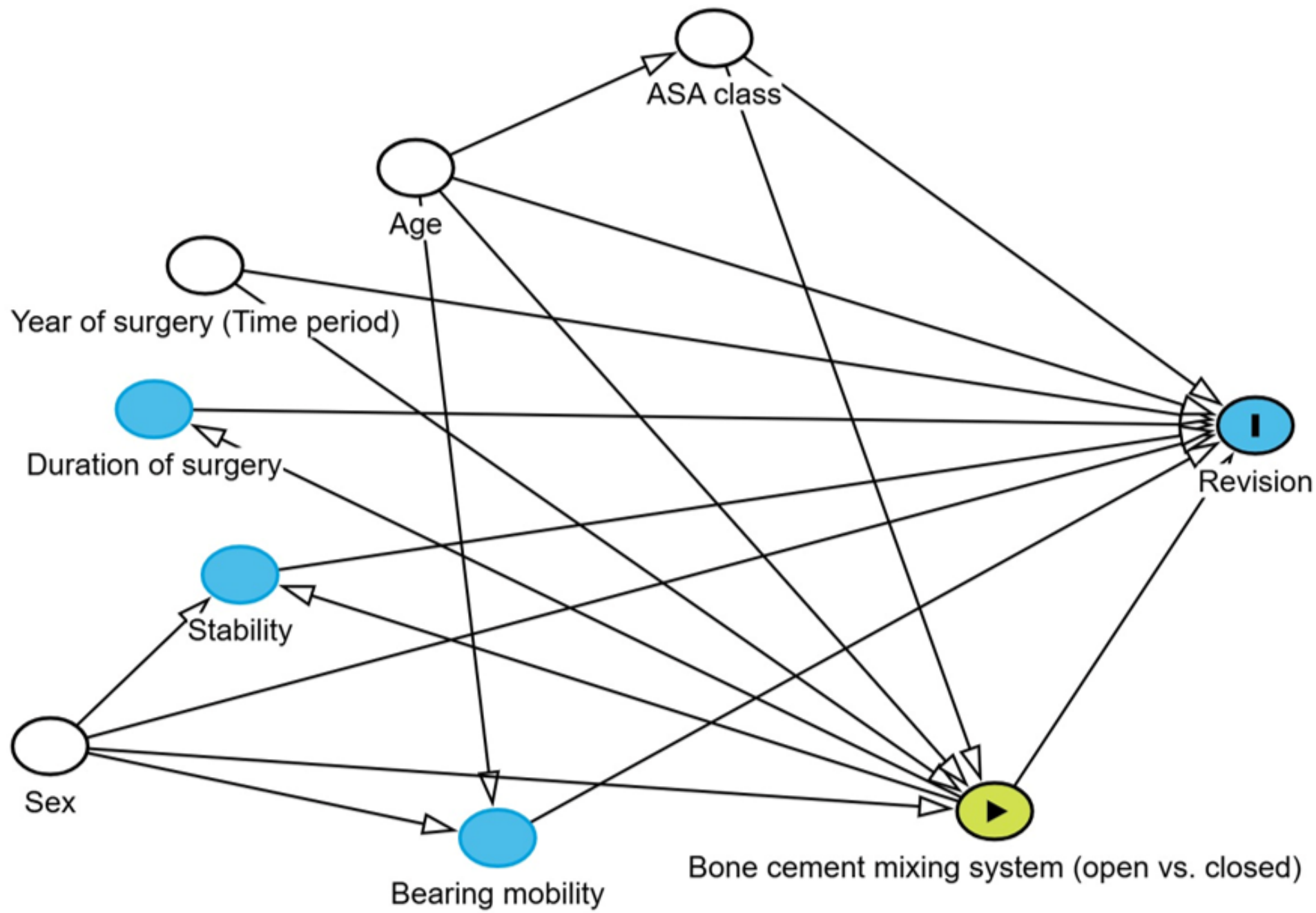


Fig. 1: Flow chart- primary TKA due to primary osteoarthritis Cemented with Palacos R+G or Pro.



This DAG graph (using Dagitty 3.1 software) is describing the hypothesized direct causal and association pathways of the selected possible confounders, mediator or collider. The green circle with a central triangle represents type of bone cement mixing system (open= Palacos R+G vs closed= Palacos R+G pro) used as the exposure (E), and the blue circle with the central vertical line represents implant failure (revision due to all-cause, deep infection, or aseptic tibia loosening) as the outcome (O). The green arrow between the 'E' and 'O' represents the relation under investigation. All the black arrows represent possible biasing pathways. The black-lined circles are possible confounders which we had adjusted for in the Cox regression analysis. The blue circle represents factors/variables which are a mediator or collider not adjusted for.

Fig. 2: Direct Acyclic Graph (DAG)

Results

Trend

The use of Palacos R+G pro in TKA in Norway increased sharply from around 250 in 2017 to slightly over 3,000 in 2025, whereas Palacos R+G usage decreased from around 1000 in 2017 to < 200 in 2025 (Fig. 3).

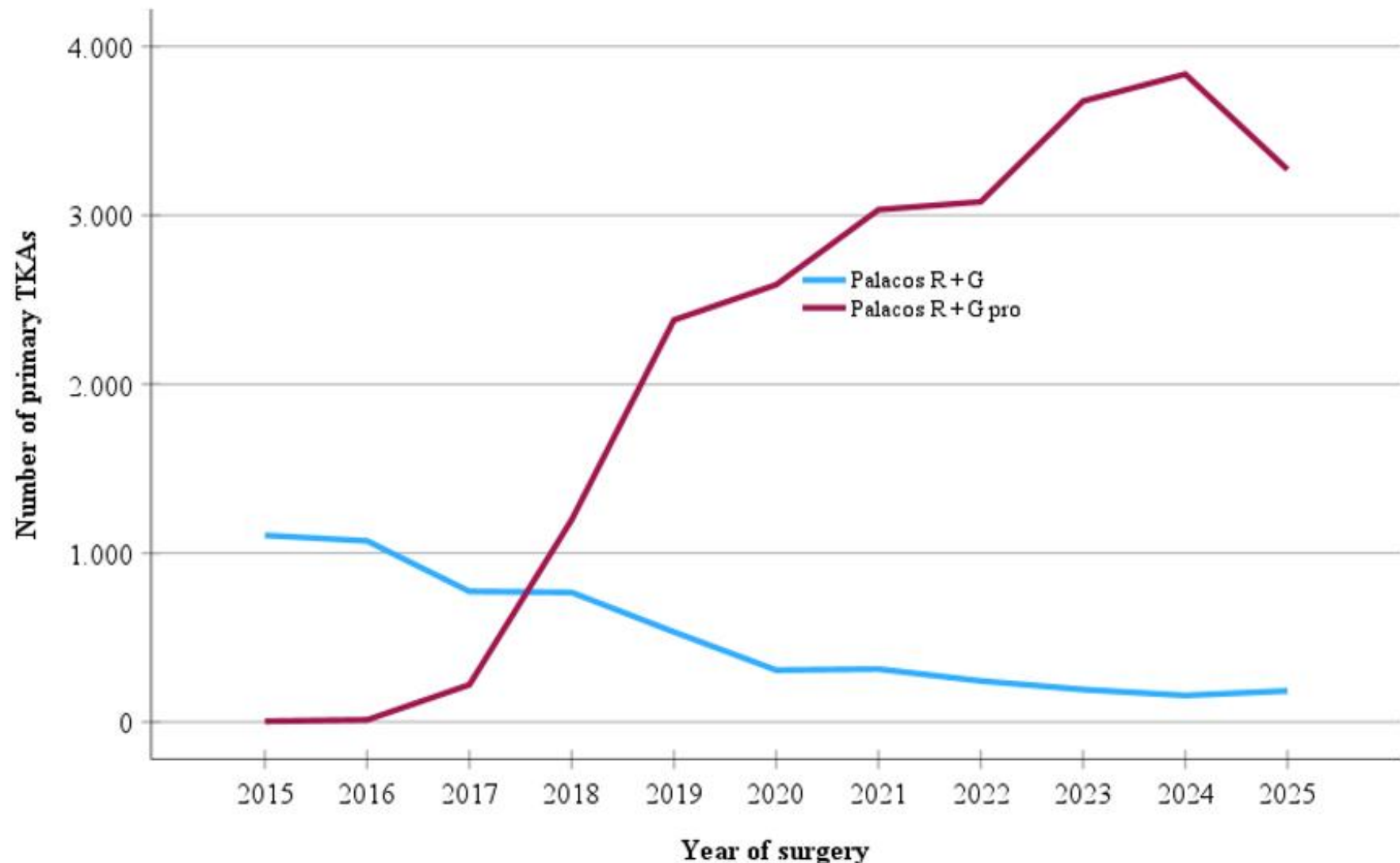


Fig. 3: Change in the use of Palacos R+G vs. Palacos R+G Pro in primary TKAs over time (2015–2025).

Results...

Revision rate

- Overall revision rates for Palacos R+G and Palacos R+G Pro respectively were 4.0% and 2.6% for all causes, 1.2% and 0.9% for deep infection, and 0.6% and 0.3% for aseptic tibial loosening (Table 1).

Time/ Reason for revision	Palacos R+G (n=5,646)	Palacos R+G Pro (n=23,298)
	n (% of primary)	n (% of primary)
1-Year		
All-causes	86 (1.5)	295 (1.3)
Deep infection	47 (0.8)	168 (0.7)
Tibial loosening	11 (0.2)	17 (0.1)
5-Years		
All-causes	201 (3.5)	602 (2.6)
Deep infection	61 (1.1)	208 (0.9)
Tibial loosening	28 (0.5)	56 (0.2)
10-Years		
All-causes	229 (4.0)	614 (2.6)
Deep infection	67 (1.2)	213 (0.9)
Tibial loosening	35 (0.6)	59 (0.3)

Table 1: Reason and number (%) of revision following primary TKAs with Palacos R+G vs. Palacos R+G Pro (2015-2025)

Survival probabilities (Kaplan-Meier)

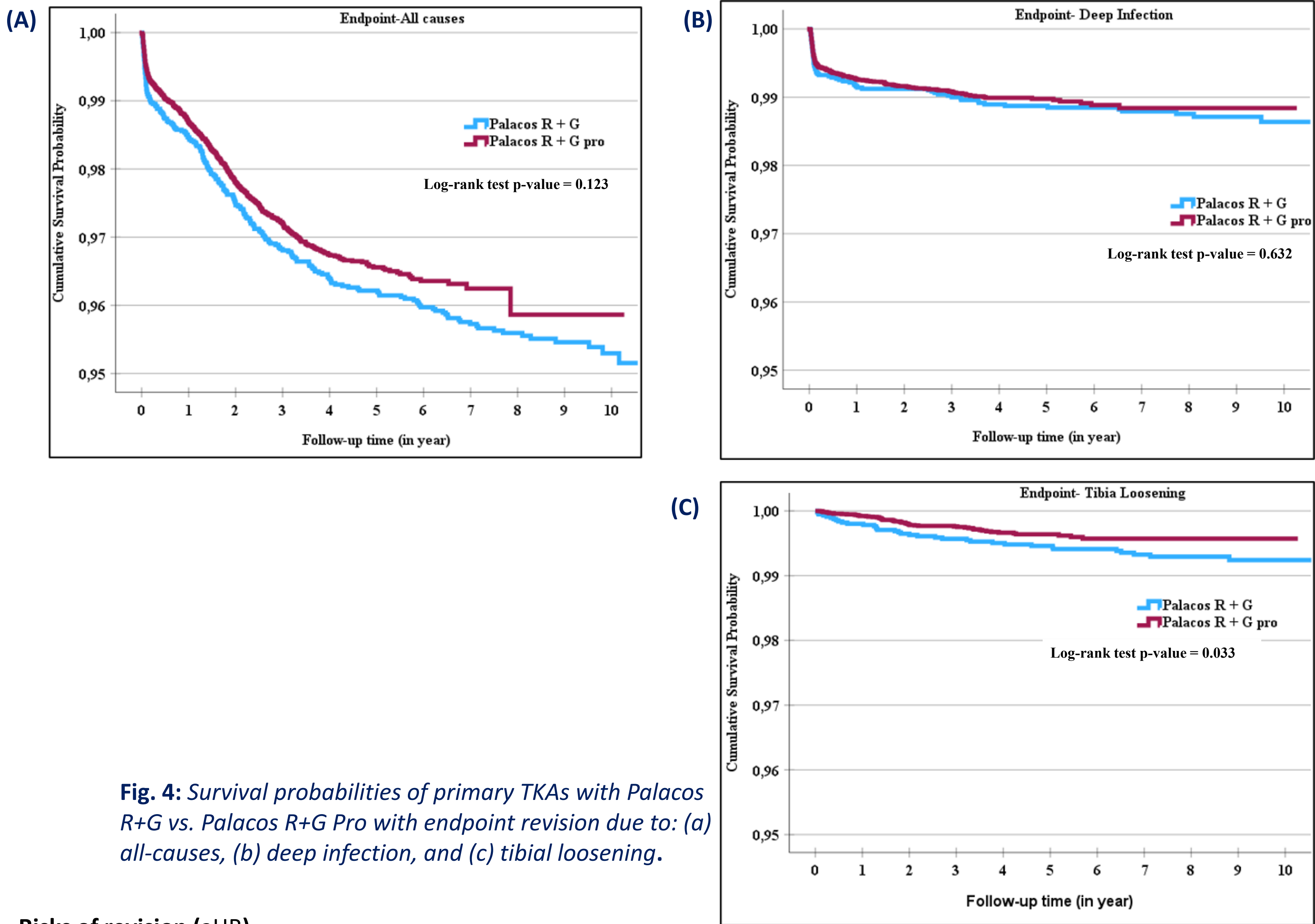


Fig. 4: Survival probabilities of primary TKAs with Palacos R+G vs. Palacos R+G Pro with endpoint revision due to: (a) all-causes, (b) deep infection, and (c) tibial loosening.

Risks of revision (aHR)

- Lower risk of revision due to aseptic tibia loosening (aHR= 0.40; 95%CI: 0.16-0.996) among Palacos R+G pro compared to the Palacos R+G group at 1-year follow-up, but these differences did not persist at 5- years (aHR= 0.90; CI: 0.53-1.52) and 10- years (aHR= 0.87; CI: 0.53–1.42) (Table 3).
- However, no statistically significant differences observed for risk of revision due to all causes or due to deep infection at 1-, 5- or 10-years (Table 3).

Endpoint/reason for revision/follow-up	Unadjusted Cox regression		Adjusted cox regression ^a	
	HRR (95% CI)	P-value	HRR (95% CI)	P-value
1-year follow-up				
All-causes	0.85 (0.67-1.08)	0.188	0.86 (0.65-1.14)	0.302
Deep infection	0.88 (0.64-1.22)	0.439	0.92 (0.626-1.34)	0.651
Tibia loosening	0.39 (0.18-0.83)	0.014	0.40 (0.16-0.996)	0.049
5-years follow-up				
All-causes	0.90 (0.76-1.05)	0.183	0.99 (0.82-1.19)	0.920
Deep infection	0.93 (0.70-1.24)	0.614	1.05 (0.75-1.46)	0.787
Tibia loosening	0.63 (0.40-1.00)	0.050	0.90 (0.53-1.52)	0.689
10-years follow-up				
All-causes	0.89 (0.76-1.034)	0.123	0.97 (0.81-1.16)	0.700
Deep infection	0.97 (0.73-1.29)	0.824	1.09 (0.79-1.51)	0.612
Tibia loosening	0.63 (0.41-0.97)	0.035	0.87 (0.53-1.42)	0.572

Table 3: Risk of revision using Cox regression following primary TKAs with Palacos R+G (n=5,646) vs. Palacos R+G Pro (n=23,298) with endpoint/reason for revision due to all-causes, deep infection, and tibia loosening at 1- and 5- years follow-up. Palacos R+G was used as a reference.

Clinical implications

- Overall, the absence of statistically significant differences in mid-term outcomes suggests that both Palacos R+G and Palacos R+G Pro provide effective fixation and comparable prophylaxis against periprosthetic joint infection and aseptic loosening after primary TKA.
- Although closed cement mixing systems may offer practical advantages—such as standardized preparation and reduced work-related exposure, these benefits do not appear to translate into substantial differences in clinically relevant endpoints.

Conclusion/relevance

- Palacos R+G Pro demonstrated comparable risks of revision for deep infection and all-cause revision to Palacos R+G.
- Although Palacos R+G Pro was associated with a lower risk of aseptic tibial loosening at 1 year, this advantage was not maintained with longer follow-up.
- It seems safe to use the Palacos R+G Pro version.
- Further comparative studies using data from multi-national arthroplasty registries is recommended to confirm our results.