

For healthcare professional use only. The illustrated image does not represent a connection between the use of the medical device described, nor its performance.

MATHYS 
European Orthopaedics

**20 YEARS
CLINICAL
EXPERIENCE**

balanSys BICONDYLAR
Results you can rely on

PROVEN

20 YEARS
CLINICAL
EXPERIENCE

Proven prosthesis

In a 2017 published multi-centre study with 433 patients available for implant survival analysis, the balanSys BICONDYLAR fixed bearing cruciate-retaining knee system achieved a cumulative implant survival rate of 97 % after 12.4 years*. This result shows that the system is safe to use and delivers reliable clinical results over the long term.¹

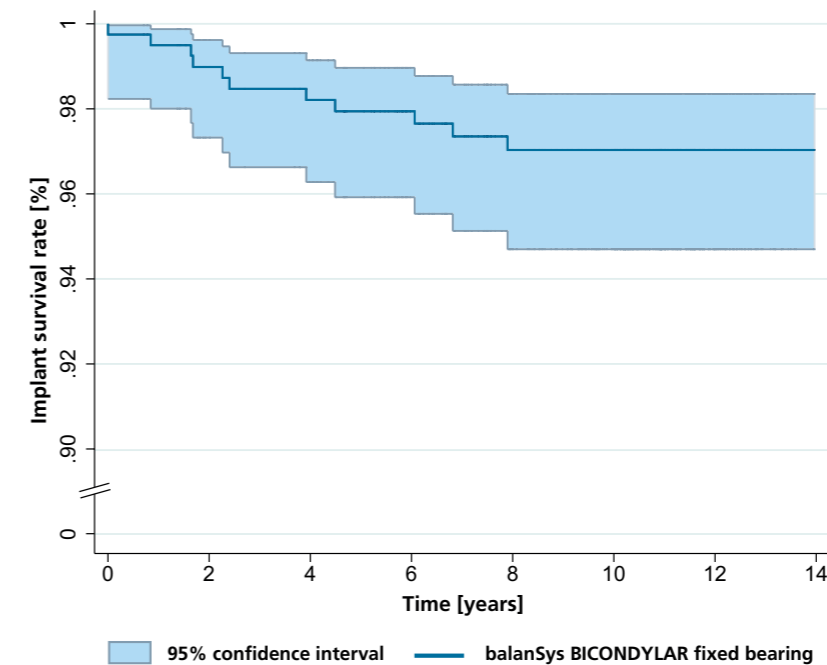


Fig. 1: Implant survival rate for the balanSys BICONDYLAR fixed bearing CR knee system after 12.4 years. Table adapted from Heesterbeek, P et al. 2017.¹

* The overall drop-out rate including death and lost-to-follow-up was 36.9 % for survival analysis

From a **patient** perspective, the balanSys BICONDYLAR knee system provides **high satisfaction** and results in **low pain**.¹

balanSys BICONDYLAR

Mean patient satisfaction with balanSys BICONDYLAR

Visual Analog Scale (VAS) for **Satisfaction**



Mean patient pain with balanSys BICONDYLAR

Visual Analog Scale (VAS) for **Pain**



Reliable clinical results

Reliable clinical results are additionally confirmed by registry data in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)² and in the Swiss Implant Registry (SIRIS)³. Furthermore, in the Orthopaedic Data Evaluation Panel (ODEP)⁴ the balanSys BICONDYLAR ultra-congruent knee system is listed with 3 years of very strong evidence, the posterior stabilized with 5 years of strong evidence, the rotating platform with 5 years of very strong evidence and the cruciate retaining knee system even with 7 years of strong evidence.

Australian Registry (AOANJRR)²

The balanSys BICONDYLAR system delivered above average results, with a low cumulative revision rate of 5.9% after 15 years. By comparison, the mean cumulative rate for Primary Total Knee Replacement is 7.3%.

Swiss Implant Registry (SIRIS)³

With 0.73 revisions per 100 observed component years (ocy) the uncoated balanSys BICONDYLAR system has a significantly lower revision rate compared to all other documented total knee replacements. The average revision rate per 100 ocy for all other prostheses is 0.97.



balanSys
BICONDYLAR UC
ultra-congruent



balanSys
BICONDYLAR PS
posterior-stabilized



balanSys
BICONDYLAR RP
rotating platform



balanSys
BICONDYLAR CR
cruciate-retaining

Australian Registry (AOANJRR)

balanSys BICONDYLAR cumulative revision rate

Femoral Component	Tibial Component	N Revised	N Total	5 Yrs	10 Yrs	15 Yrs
balanSys	balanSys	60	3'235	2.2 (1.6, 2.9)	4.7 (3.2, 6.7)	5.9 (3.9, 8.9)

Table FY2 Cumulative Percent Revision of Primary Total Knee Replacement Combinations with 15 Year Data (Primary Diagnosis OA)²

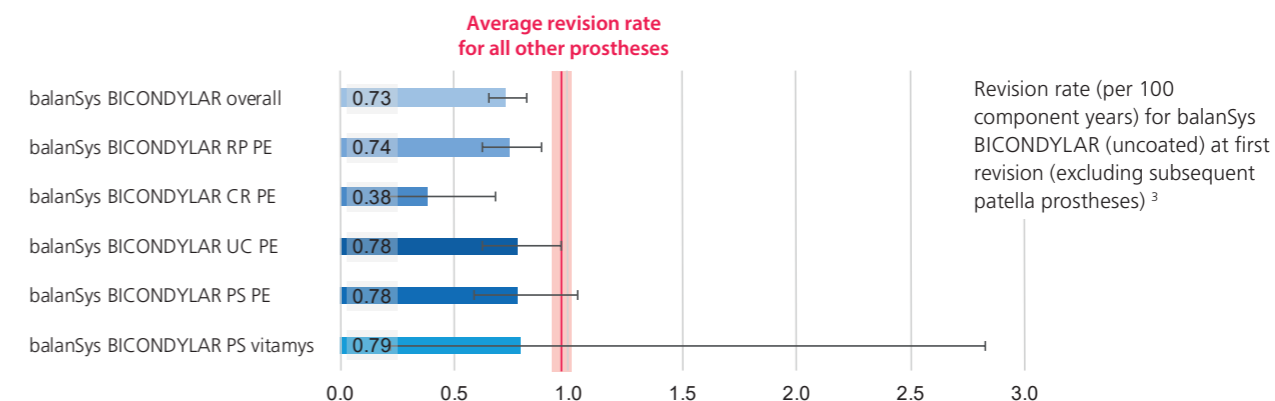
Mean cumulative revision rate of Primary Total Knee Replacement

Knee Class	N Revised	N Total	5 Yrs	10 Yrs	15 Yrs
Total Knee	24'722	643'201	3.5 (3.5, 3.6)	5.3 (5.2, 5.3)	7.3 (7.2, 7.5)

Table KT10 Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)²

Swiss Implant Registry (SIRIS)

Revision rate per 100 component years



The revisions per 100 component years are only presented if there are more than 500 cases in the follow-up for the corresponding category. Not shown are balanSys BICONDYLAR UC vitamys (N=199), CR vitamys (N=208) and RP vitamys (N=344).³

Glossary

Implant survival rate

The percentage of patients having the implant still in situ after a given time.

Observed component years

For the observed component years, each registered prosthesis contributes its number of years in situ to the overall total observed component years.

Revisions per 100 component years

The revisions per 100 component years is given by the number of prostheses revised, divided by the observed component years, multiplied by 100.

Confidence interval

The confidence interval is a range of values that describes the uncertainty surrounding a calculated parameter. A 95 % confidence interval is most commonly used. There is a probability of 95 % that the true value lies within this range. The minimum and maximum of the interval are called the lower and upper confidence limits.

- ¹ Heesterbeek, P. et al. Superior long term survival for fixed bearing compared with mobile bearing in ligament balanced total knee arthroplasty. KSSTA, 2017.
- ² Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2019 Annual Report. Adelaide: AOA, 2019, Tables FY2 and KT10
- ³ Swiss Implant Registry (SIRIS), balanSys BICONDYLAR SIRIS Implant Report (Extended), November 2019
- ⁴ <http://www.odep.org.uk/products.aspx>, last access 20.11.2019

Table FY2 Cumulative Percent Revision of Primary Total Knee Replacement Combinations with 15 Year Data (Primary Diagnosis OA)²

Femoral Component	Tibial Component	N Revised	N Total	Type of Revision				5 Yrs	10 Yrs	15 Yrs
				TKR	Femoral	Tibial	Other			
BalanSys	BalanSys	60	3235	11	3	6	40	2.2 (1.6, 2.9)	4.7 (3.2, 6.7)	5.9 (3.9, 8.9)

Table KT10 Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)²

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	18 Yrs
Total Knee	24722	643201	1.0 (1.0, 1.1)	2.7 (2.6, 2.7)	3.5 (3.5, 3.6)	5.3 (5.2, 5.3)	7.3 (7.2, 7.5)	8.6 (8.3, 8.8)