MATHYS
European Orthopaedics

20 YEARS CLINICAL EXPERIENCE

balanSys BICONDYLAR
Results you can rely on

97.0%
survival at 12.4 years

In a 2017 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 superior clinical results over the long term.[1]

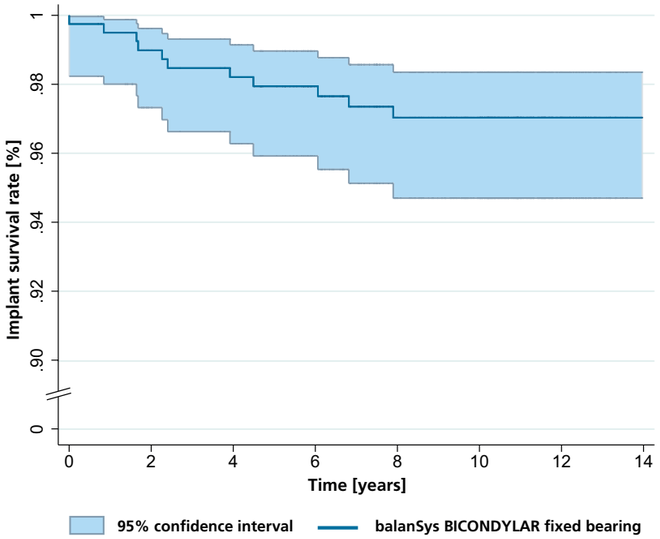

Fig. 1: Implant survival rate for the balanSys BICONDYLAR fixed bearing CR knee system after 12.4 years. Table adapted from Heesterbeek, P et al. 2017.[1]

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

Satisfaction

Mean patient pain with balanSys BICONDYLAR

Pain

Superior clinical results

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

AOANJRR[3]
The balanSys BICONDYLAR system delivered above average results for cemented systems, with a low cumulative revision rate of 4.2 % after 10 years. By comparison, the mean cumulative rate for Primary Total Knee Replacement is 5.3 %.

SIRIS[4]
The balanSys BICONDYLAR system has an overall revision rate of 0.778 revisions per 100 observed component years (ocy). The average rate for all other implants is 1.233 revisions per 100 ocy.

ODEP 7A*
balanSys
BICONDYLAR CR
cruciate-retaining

ODEP 3A*
balanSys
BICONDYLAR PS
posterior-stabilized

ODEP 3A*
balanSys
BICONDYLAR UC
ultra-congruent

ODEP 3A*
balanSys
BICONDYLAR RP
rotating platform

AOANJRR

balanSys BICONDYLAR cemented cumulative revision rate (Fig. 2a)

Femoral Component	Tibial Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	16 Yrs
balanSys	balanSys	27	1'636	0.3 (0.1, 0.7)	1.6 (1.0, 2.5)	2.1 (1.3, 3.2)	**4.2 (2.5, 7.0)**		

Mean cumulative revision rate of Primary Total Knee Replacement (Fig. 2b)

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	16 Yrs
Total Knee	19'627	534'202	1.0 (1.0, 1.1)	2.7 (2.7, 2.8)	3.6 (3.6, 3.7)	**5.3 (5.2, 5.4)**	7.4 (7.2, 7.6)	8.0 (7.7, 8.3)

Fig. 2a: Australian Orthopaedic Association National Joint Replacement Registry, Annual Report 2017. Extracted from Table KT7 Cumulative Percent Revision of Cemented Primary Total Knee Replacement by Prosthesis Combination.[3]

Fig. 2b: Australian Orthopaedic Association National Joint Replacement Registry, Annual Report 2017. Extracted from Table KT10 Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA).[3]

SIRIS

Revisions per 100 component years

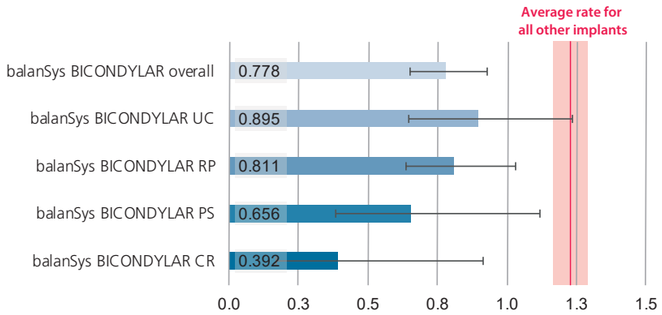

Fig. 3: Revisions per 100 component years for the balanSys BICONDYLAR knee system based on Swiss Implant Registry (SIRIS) Company-individual report for the balanSys Bicondylar, Jan. 2017.[4]

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] http://www.odep.org.uk/products.aspx, last access 16.10.2017
[3] Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, Knee & Shoulder Arthroplasty: 2017 Annual Report. Adelaide: AOA, 2017, Tables KT7 and KT10
[4] Swiss Implant Registry (SIRIS) Company individual report for the balanSys Bicondylar, Jan. 2017

Table KT7 Cumulative Percent Revision of Cemented Primary Total Knee Replacement by Prosthesis Combination[3]

Femoral Component	Tibial Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	16 Yrs
BalanSys	BalanSys	27	1636	0.3 (0.1, 0.7)	1.6 (1.0, 2.5)	2.1 (1.3, 3.2)	4.2 (2.5, 7.0)		

Table KT10 Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)[3]

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	16 Yrs
Total Knee	19627	534202	1.0 (1.0, 1.1)	2.7 (2.7, 2.8)	3.6 (3.6, 3.7)	5.3 (5.2, 5.4)	7.4 (7.2, 7.6)	8.0 (7.7, 8.3)
TOTAL	**19627**	**534202**						

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