

MATHYS 
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X-Ray by courtesy of Dr. K. Auerbach

**20 YEARS
CLINICAL
EXPERIENCE**

balanSys UNI

Results you can rely on

CLINICAL RESULTS



PROVEN

for more than 20 years

From the **patients' perspective**,
the balanSys UNI knee system offers
high satisfaction and leads to
clinically relevant pain reduction.¹

Significantly better function

In a multicentric study conducted in 2021, 116 patients who had received a unicondylar balanSys UNI were compared with 116 patients with a different knee endoprosthesis (TKA) 12 months after surgery. The balanSys UNI patients achieved a significantly better Knee Society Function Score, namely an excellent 95 out of a maximum of 100 points, than the TKA patients did (80 points, $p < 0.001$).²

Knee Society Score for **function**²



High satisfaction

In the study by Tille et al., the balanSys UNI patients reported a satisfaction of 9 (median) out of a maximum of 10 points on the visual analogue scale (VAS).²

Visual analogue scale (VAS) for **satisfaction**²



Proven

Swiss Implant Registry (SIRIS)³

In the Swiss implant registry SIRIS, the balanSys UNI knee system has proven its worth. The safety of balanSys UNI is confirmed with a revision rate of 11.2 % after 10 years. The benchmark of all cemented unicondylar knee systems documented in SIRIS amounts to 13.0 %.

Revision rate up to the relevant time after implantation of the balanSys UNI knee system;
revision rate in % incl. 95 % confidence interval in brackets³

	1 year	3 years	5 years	7 years	10 years
Benchmark	2.5 (2.3–2.7)	6.0 (5.7–6.3)	8.1 (7.8–8.5)	9.9 (9.5–10.4)	13.0 (12.4–13.8)
balanSys UNI	2.2 (1.7–2.7)	5.2 (4.4–6.1)	6.5 (5.6–7.6)	7.5 (6.5–8.7)	11.2 (9.3–13.5)

Significantly better

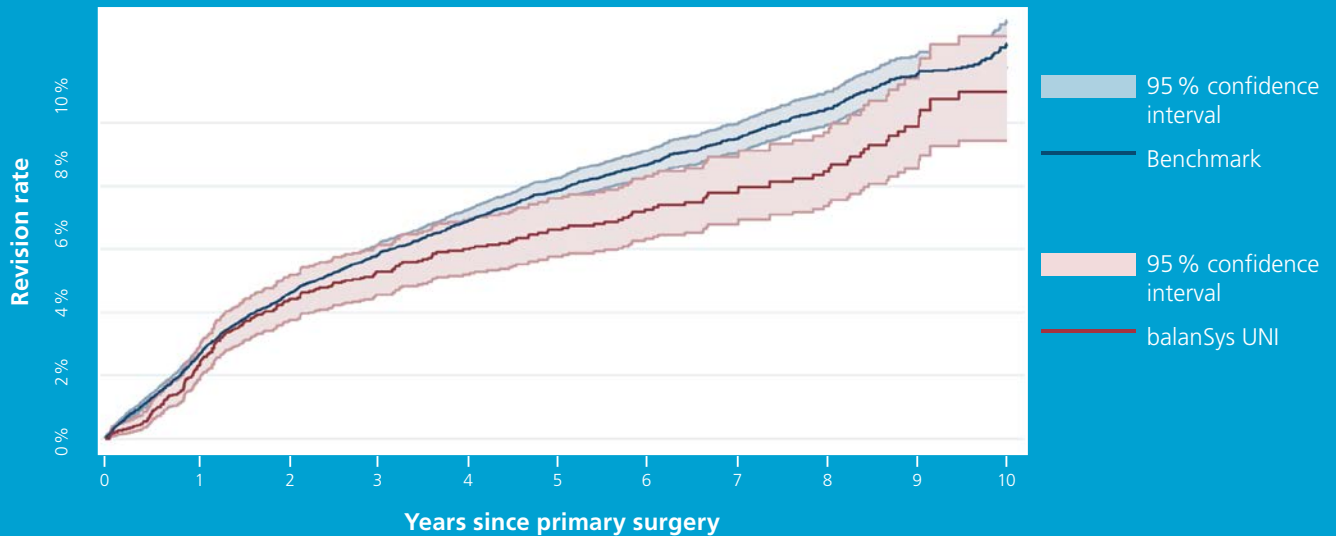
Within the benchmark

Above benchmark

Good survival results

Swiss Implant Registry (SIRIS)⁴

Revision rate of balanSys UNI versus the benchmark (all other unicondylar knee prostheses)



Reliable

German Arthroplasty Registry (EPRD)⁵

In the German endoprosthesis registry, the balanSys UNI convinces with a revision rate of 8.2 % after 6 years and is thus within the benchmark.

Revision rate up to the relevant time after implantation of the balanSys UNI knee system; revision rate in % incl. 95 % confidence interval in brackets. Only time points with at least 40 implants under surveillance are listed.⁵

	1 year	3 years	6 years
Benchmark	2.8 (2.6–2.9)	5.7 (5.5–5.9)	8.0 (7.7–8.4)
balanSys UNI	3.1 (2.0–5.0)	6.8 (4.8–9.5)	8.2 (5.8–11.5)

Significantly better

Within the benchmark

Above benchmark

Superior results

Australian Joint Replacement Registry (AOANJRR) ⁶

In the Australian Joint Replacement Registry, the long-term safety of balanSys UNI is clinically confirmed with superior 15-year results. With a revision rate of 12.4% after 15 years, the balanSys UNI achieves a significantly lower revision rate than the average of all documented unicondylar knee replacement systems. The average revision rate for all unicondylar knee prostheses after 15 years is 18.8%.

Revision rate of primary unicondylar knee replacement *

Table KP7: Revision rate of primary unicondylar knee replacement (primary diagnosis: osteoarthritis) ⁶

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs
Unicompartmental	4813	48544	1.9 (1.8–2.1)	4.5 (4.3–4.7)	6.3 (6.1–6.6)	11.7 (11.3–12.1)	18.8 (18.2–19.5)

Revision rate of balanSys UNI *

Table KP6: Revision rate of primary unicondylar knee replacement by prosthesis combination ⁶

Uni Femoral	Uni Tibial	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs
balanSys UNI	balanSys UNI Fixed	61	1211	1.9 (1.3–2.9)	3.8 (2.8–5.1)	4.4 (3.2–5.9)	8.0 (5.9–10.9)	12.4 (8.8–17.5)

* Revision rate in % incl. 95% confidence interval in brackets

 Significantly better

 Within the benchmark

 Above benchmark

Strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP)⁷

The Orthopaedic Data Evaluation Panel (ODEP) awards the balanSys UNI knee system the 10A ODEP rating. The 10A ODEP rating can be achieved with 10 years of clinical results, and is based on strong evidence of clinical performance including low revision rates.



balanSys UNI
fixed bearing

Glossary

Confidence interval

The confidence interval is a value range that describes the uncertainty surrounding a calculated parameter. A 95 % confidence interval is most commonly used. This means a probability of 95 % that an interval is obtained that comprises the unknown expected value. The minimum and maximum values of the confidence interval are called the lower and upper confidence limit, respectively.

Estimation of survival and revision rates

The survival and revision rates of implants in registries and scientific publications are often calculated by means of the Kaplan-Meier estimation. In the Kaplan-Meier estimation, the time to the first implant revision corresponds to the survival rate. The cumulative revision rate at a certain point in time, e. g. after 5 years, is the complement (in terms of probability) of the Kaplan-Meier survival calculation at that point in time. If a patient is deceased or the implant is in the patient at the time the database is closed (data export), the data will be censored at that time.

ODEP

ODEP is an acronym meaning «Orthopaedic Data Evaluation Panel». It is an independent panel of experts drawn mainly from British surgeons but also including some non-clinical experts with many years of industry experience.

The panel was established by the National Health Purchasing and Supply Agency (PASA, later replaced by SCCL – the Supply Chain Coordination Limited).

The numbers indicate the number of years of clinical evidence. The letter represents the clinical evidence of the data provided by the manufacturer.

Further information can be found at <http://www.odep.org.uk/ODEPExplained.aspx>

References

- ¹ Campbell D, Schuster A J, Pfluger D, Hoffmann F. Unicondylar knee replacement with a new tensioner device: clinical results of a multicentre study on 168 cases. Arch Orthop Trauma Surg. 2010;130(6):727-32.
- ² Tille E, Beyer F, Auerbach K, Tinius M, Lützner J. Better short-term function after unicompartmental compared to total knee arthroplasty. BMC Musculoskelet Disord. 2021;22(1):326.
- ³ Swiss National Joint Registry (SIRIS). SIRIS Report 2012 – 2022. Annual Report 2023.
- ⁴ Swiss Implant Registry (SIRIS), SIRIS Implant Report (Extended) for balanSys UNI partial knee system, October 2023.
- ⁵ EPRD. Endoprothesenregister Deutschland – Jahresbericht 2023, <https://www.eprd.de>
- ⁶ Smith PN, Gill DR, McAuliffe MJ, McDougall C, Stoney JD, Vertullo CJ, Wall CJ, Corfield S, Page R, Cuthbert AR, Du P, Harries D, Holder C, Lorimer MF, Cashman K, Lewis PL. Hip, Knee and Shoulder Arthroplasty: 2023 Annual Report, Australian Orthopaedic Association National Joint Replacement Registry, AOA: Adelaide, South Australia. 2023. <https://doi.org/10.25310/YWQZ9375>; Tables KP6 and KP7.
- ⁷ <http://www.odep.org.uk/products.aspx>, last access 02.02.2024.

Table KP6 Cumulative Percent Revision of Primary Unicompartmental Knee Replacement by Prosthesis Combination

Uni Femoral	Uni Tibial	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	20 Yrs
BalanSys Uni	BalanSys Uni Fixed	61	1211	1.9 (1.3, 2.9)	3.8 (2.8, 5.1)	4.4 (3.2, 5.9)	8.0 (5.9, 10.9)	12.4 (8.8, 17.5)	

Table KP7 Cumulative Percent Revision of Primary Unicompartmental Knee Replacement (Primary Diagnosis OA)

Knee Type	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	20 Yrs
Unicompartmental	4813	48544	1.9 (1.8, 2.1)	4.5 (4.3, 4.7)	6.3 (6.1, 6.6)	11.7 (11.3, 12.1)	18.8 (18.2, 19.5)	27.8 (26.7, 29.0)
TOTAL	4813	48544						

Note: Restricted to modern prostheses