PERSONA®
THE PERSONALIZED KNEE

CLINICAL SUMMARY
The Persona Knee exhibits strong short-term clinical performance for total knee arthroplasty, providing patients personalized implants designed for optimal fit and function.

The following summary highlights its performance to date.
Executive Summary........................................................................................................................................... 2

Clinical Evidence Summary ........................................................................................................................... 6
A. Published Literature Survivorship .............................................................................................................. 9
B. Patient Reported Outcome Measures (PROMs) ....................................................................................... 9
C. Medial Congruent Bearing .........................................................................................................................
D. Orthopaedic Data Evaluation Panel (ODEP) Ratings .............................................................................. 11
E. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) ............................ 11
F. UK National Joint Registry (NJR) ........................................................................................................... 11
Appendix - Definition of terms/metrics ........................................................................................................ 11
The Persona Knee is our most comprehensive system, including more anatomically accurate components with finer increments to help surgeons personalize the fit for each patient and restore the unique identity of every knee.

**Anatomic Tibia:** Helps prevent mal-rotation while facilitating proper rotation and optimal bone coverage. Mal-rotation of implants leads to over 50 percent of painful TKA cases.2

**Bearing:** Reproduces more natural ligament balance with five levels of constraint in 1 mm increments. The medial congruent bearing provides surgeons another option to treat patients and can be used with and without the PCL. In fact, initial publications show that patients with an MC bearing reported significantly higher forgotten joint scores and mid-flexion AP stability was greater with the MC bearing than with the CR bearing.3,4

**Femur:** There are 21 distinct profiles, with 2 mm increments available in standard and narrow, providing the most comprehensive femoral sizing scheme on the market. Eliminates overhang and associated pain observed in 54% of patients with a full offering of standard and narrow shaped implants5

**Legacy**

The introduction of the Persona Medial Congruent Bearing is an evolutionary step forward in Zimmer Biomet’s long history with differential rollback. In 1985, the Natural-Knee® System was launched with a UC bearing and introduced the concept of constraint through conformity. In 1986, the M/G® I CR Femur was released with asymmetric femoral condyles designed to simulate the motion of a healthy knee. The NexGen Knee System and the Natural-Knee II have continued to evolve these design attributes. The addition of the Medial Congruent Bearing to the Persona System combines these two philosophies to create the most natural feeling, kinematically driven bearing Zimmer Biomet has designed.

**Today**

The Persona Knee has exceptional worldwide registry results compared to all other total primary knees.6,7,8 Persona patient reported outcomes measures (PROMs) outperform NexGen, which is the most widely used and clinically proven knee system in the world.9–16 Notably, there are now initial clinical results with the Persona Medial Congruent bearing demonstrating better mid-flexion AP stability compared to CR inserts.3
## A. Published Literature – Survivorship

### The Takeaway

Persona has demonstrated excellent early survivorship results, as shown in the summary table below. This is highlighted by the recent 5 year and 4 year publications positive results.

<table>
<thead>
<tr>
<th>Publication</th>
<th>Variant</th>
<th>Total Number of Cases</th>
<th>Survivorship*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENAZZO, F., JANNELLI, E., IVONE, A., FORMAGNANA, M., ROSSI, S. M., GHIARA, M., DANESINO, G. &amp; MOSCONI, M. Knee arthroplasty system with medialized keel: Seven-year follow-up of a pioneer cohort. Knee, 27, 624-632 2020.⁴</td>
<td>PS</td>
<td>56</td>
<td>98% at 5 years</td>
</tr>
<tr>
<td>BENAZZO, F., GHIARA, M., ROSSI, S. M. P., PRUNERI, E., TIWARI, V. &amp; PERELLI, S. Clinical and radiological analysis of a personalized total knee arthroplasty system design. International Orthopaedics, 43, 1113-1121 2020.¹⁷</td>
<td>PS</td>
<td>100</td>
<td>100% at 4 years</td>
</tr>
<tr>
<td>MATHIJSENN, N. M. C., VERBURG, H., LONDON, N. J., LANDSIELD, M. &amp; DOMINKUS, M. Patient reported outcomes and implant survivorship after Total knee arthroplasty with the persona knee implant system: Two year follow up. BMC Musculoskeletal Disorders 2019.¹³</td>
<td>PS, CR</td>
<td>123, 23</td>
<td>99% at 2 years</td>
</tr>
</tbody>
</table>
### B. Patient Reported Outcome Measures (PROMs)

**The Takeaway**

PROMs provide the patients’ perception of how beneficial a knee replacement is in regards to their health, quality of life and functional status. Until now, NexGen has been considered the ‘benchmark’ TKR for PROMs. Here we present emerging evidence that Persona provides superior PROMs when compared to the benchmark NexGen Knee.

**Five-Year Comparative Functional and Clinical Evaluation of Two Contemporary Cruciate Retaining Knee Implants**

- At 5 years follow-up KSS, KSSF, OKS, FJS and Kujala AKP scores were all significantly greater for Persona than for NexGen. Range of motion was also significantly higher for Persona.
- The Kujala AKP score is a recognized measure used within the field of orthopaedics to assess patellofemoral pain.
- The authors acknowledged that anterior knee pain is one of the common factors leading to patient dissatisfaction and revision knee surgeries, and concluded that the lower percentage of patients with residual anterior knee pain in the Persona group could possibly be attributed to the design modifications of anatomical knee implants.
## Clinical Summary

<table>
<thead>
<tr>
<th>PROMs Score</th>
<th>NexGen CR at 5 year follow-up [Mean ± SD]</th>
<th>Persona CR at 5 year follow-up [Mean ± SD]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee Society Score (KSS)</td>
<td>91.20 ± 5.70</td>
<td>93.03 ± 5.06</td>
<td>0.036</td>
</tr>
<tr>
<td>Knee Society Function Score (KSSF)</td>
<td>87.52 ± 6.16</td>
<td>90.25 ± 5.64</td>
<td>0.001</td>
</tr>
<tr>
<td>Oxford Knee Score (OKS)</td>
<td>39.90 ± 4.13</td>
<td>41.96 ± 3.58</td>
<td>0.001</td>
</tr>
<tr>
<td>Forgotten Joint Score (FJS)</td>
<td>81.12 ± 5.17</td>
<td>85.67 ± 5.68</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Kujala Score</td>
<td>57.6 ± 2.0</td>
<td>68.1 ± 2.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Range of Motion (ROM)</td>
<td>120.76 ± 5.01</td>
<td>126.14 ± 5.12</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

This data allows a direct comparison of NexGen with Persona and demonstrates statistically better PROMs for Persona.

### Morphometric Tibial Implant Decreases Posterior Overhang Rate and Improves Clinical Outcomes

- At 3 year follow-up the Persona Knee demonstrated superior results for all components of the KSS than the NexGen Knee
- This was associated with significantly lower rates of posterolateral tibial overhang of >3mm observed in the Persona anatomic tibial tray compared to the NexGen symmetrical tibial tray (2 of 33/6% Vs 13 of 33/39%: p = 0.001)
- The pain component of the IKS was 11 points higher in the Persona group than the NexGen group
- The authors recognized that pain after TKR has been attributed to conflicts between prosthetic components and soft tissues, and suggested that superior pain scores for Persona might be explained by the small number of prostheses with posterolateral overhang compared to NexGen
- The authors concluded that in this matched controlled study, the use of an anatomic tibial tray improved implant positioning, reducing prosthetic overhang. Compared with the use of a symmetrical tray, at midterm follow-up, an anatomic tibial tray allows better clinical results

<table>
<thead>
<tr>
<th>Score</th>
<th>NexGen LPS at 3 year follow-up [Mean ± SD]</th>
<th>Persona 3 year follow-up [Mean ± SD]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee Society Objective Score</td>
<td>80 ± 18.2</td>
<td>94 ± 6.2</td>
<td>0.0002</td>
</tr>
<tr>
<td>Knee Society Function Score</td>
<td>87 ± 12.6</td>
<td>93 ± 10.6</td>
<td>0.047</td>
</tr>
<tr>
<td>Pain (sub-score of the AKS)</td>
<td>36 ± 15.7</td>
<td>47 ± 4.2</td>
<td>0.0002</td>
</tr>
<tr>
<td>Knee Injury and Osteoarthritis Outcome Score (KOOS)</td>
<td>21 ± 10.5</td>
<td>16 ± 10.9</td>
<td>0.12</td>
</tr>
<tr>
<td>Flexion</td>
<td>124 ± 7.8</td>
<td>123 ± 10.8</td>
<td>0.45</td>
</tr>
</tbody>
</table>

This data allows a direct comparison of NexGen with Persona and demonstrates less posterior lateral overhang and associated pain with Persona.
Promising early outcomes of a novel anatomic knee system

- At two year follow-up patients treated with the Persona knee system reported higher KOOS symptom and KOOS QOL scores than patients with the NexGen knee system. All other PROMs outcomes were similar.
- The authors stated that “the KOOS symptom and QOL sub-scores are the most appropriate gauge of how well an artificial knee replicates the feel of a native knee”; and that “the increased sizing options yield accurate intraoperative component placement, which in turn yields more favorable PRO[M] scores”.
- Based on these data, the authors suggested there may be “the potential to improve subjective PROMs and decrease the number of unsatisfied TKA patients by making TKA devices more anatomic and increasing the intraoperative sizing options.”

<table>
<thead>
<tr>
<th>Score</th>
<th>Persona 2 year follow up</th>
<th>p-value compared to NexGen</th>
</tr>
</thead>
<tbody>
<tr>
<td>KOOS pain</td>
<td>85.7 (range 42–100)</td>
<td>Not Significant</td>
</tr>
<tr>
<td>KOOS Activity of Daily Living</td>
<td>70.0 (range 22–100)</td>
<td>n.s.</td>
</tr>
<tr>
<td>KOOS sports and recreation</td>
<td>55.0 (range 27–100)</td>
<td>n.s.</td>
</tr>
<tr>
<td>KOOS Quality of Life</td>
<td>78.2 (range 30–90)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>KOOS Symptom</td>
<td>82.2 (range 24–96)</td>
<td>0.037</td>
</tr>
<tr>
<td>EQ-5D VAS</td>
<td>78.9 (range 60–94)</td>
<td>n.s.</td>
</tr>
<tr>
<td>EQ-5D index</td>
<td>0.79 (range 0.41–1.00)</td>
<td>n.s.</td>
</tr>
<tr>
<td>UCLA activity score</td>
<td>6.7 (range 2–10)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

This knee design demonstrates excellent clinical outcomes, similar to the NexGen Knee System, at early follow-up.
C. Medial Congruent Bearing

Medial Congruent Polyethylene Offers Satisfactory Early Outcomes and Patient Satisfaction in Total Knee Arthroplasty

- Patients with an MC bearing reported significantly higher forgotten joint scores than patients with a CR bearing. This is important because a patient’s ability to forget their joint replacement during everyday activities is an important expectation and goal of the surgery, as it reflects patient satisfaction.
- More patients with an MC bearing were "very satisfied" and fewer were “not at all satisfied” compared to patients with a CR bearing.
- 92.6% of patients with an MC bearing were “very satisfied” compared to just 81.5% of patients with a CR bearing.

<table>
<thead>
<tr>
<th>Score</th>
<th>Persona MC</th>
<th>Persona CR</th>
<th>Persona PS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FJS at 1 year (95% CI)</td>
<td>71.62 (65.44-77.81)</td>
<td>58.68 (51.9-65.46)</td>
<td>68.71 (64.07-73.34)</td>
</tr>
<tr>
<td>KOOS pain at 1 year (SD)</td>
<td>80.67 (18.29)</td>
<td>76.56 (22.56)</td>
<td>0.047 (22.40)</td>
</tr>
<tr>
<td>KOOS ADL at 1 year (SD)</td>
<td>82.01 (17.68)</td>
<td>76.56 (20.02)</td>
<td>86.69 (21.03)</td>
</tr>
<tr>
<td>KOOS QoL at 1 year (SD)</td>
<td>60.66 (26.49)</td>
<td>58.62 (22.79)</td>
<td>67.99 (28.29)</td>
</tr>
<tr>
<td>KOOS sport at 1 year (SD)</td>
<td>58.53 (33.46)</td>
<td>57.52 (28.95)</td>
<td>65.57 (32.96)</td>
</tr>
<tr>
<td>KOOS symptom at 1 year (SD)</td>
<td>80.55 (18.47)</td>
<td>76.05 (18.96)</td>
<td>82.58 (19.87)</td>
</tr>
<tr>
<td>PROMIS-10P 1 year (SD)</td>
<td>52.12 (8.75)</td>
<td>51.28 (7.45)</td>
<td>51.08 (8.84)</td>
</tr>
<tr>
<td>PROMIS-10M 1 year (SD)</td>
<td>52.12 (7.35)</td>
<td>51.28 (6.37)</td>
<td>51.08 (9.72)</td>
</tr>
</tbody>
</table>

According to the authors, these results indicate that the MC bearing provided similar or improved early pain, ROM, KOOS, PROMIS-10, FJS-12, and patient satisfaction as compared with standard bearings in TKA. Additionally, the MC bearing scored higher in patient satisfaction as compared to CR.

Mid-flexion stability in the anteroposterior plane is achieved with a medial congruent insert in cruciate-retaining total knee arthroplasty for varus osteoarthritis.

- This study has shown that the Persona MC bearing restored physiologic AP kinematics more in mid-flexion than the Persona CR bearing under PCL-retaining conditions.
- Mid-flexion AP stability was greater with the MC bearing than with the CR bearing.
- The results for the CR bearing showed that the femoral position relative to the tibia was significantly anterior at 45°, 60°, and 90° flexion compared to the preoperative condition.
- The authors acknowledged that this paradoxical motion or mid-flexion instability is more common in CR knee designs, and can be one of the causes of dissatisfaction after CR-TKA.
- By comparison the femoral position in the MC group at 45°, 60°, and 90° flexion did not differ significantly from that of the preoperative condition.

According to the authors, these results indicate that the MC bearing could prevent mid-flexion instability in CR TKA.
D. ODEP Ratings

ODEP, the Orthopaedic Data Evaluation Panel, was set up in 2002 to implement NICE guidance on primary hip implants. Hip resurfacing followed in 2004. Since then Knees (2014) have been added to the list of joints that ODEP benchmark and early in 2017 ODEP commenced benchmarking Shoulders. The ODEP rating is now a commonly used benchmark used not only in the UK, but globally.

http://www.odep.org.uk/Home.aspx

Explanation to ODEP Ratings:

- An ODEP rating consists of a number, a letter, and an optional star:
- The number represents years of evidence that exist for a product.
- The letter represents the strength of evidence based on survival rate: quality, and number of cases: quantity.
- The star (*) represents the highest rating for a given benchmark.
- For new products just introduced to the UK market and launched under the Beyond Compliance program, a Pre-Entry A* rating is granted.

The Takeaway

Persona has performed well with its early ODEP ratings. All ratings are an A or an A*, which represents the strength of the evidence based on the survival rate.

<table>
<thead>
<tr>
<th>Persona Variant</th>
<th>ODEP Rating</th>
<th>Link to Homepage</th>
</tr>
</thead>
</table>

Latest ODEP ratings can be found at www.odep.org.uk
D. Registry Results:
The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

In 1998 the Commonwealth Department of Health agreed to fund the Australian Orthopaedic Association to establish the AOANJRR. The AOANJRR began data collection in South Australia on 1 September 1999. The purpose of the AOANJRR is to define, improve and maintain the quality of care of individuals receiving joint replacement surgery. It achieves this by collecting a defined minimum data set that enables outcomes to be determined on the basis of patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. The principal measure of outcome is revision surgery, with a key metric known as the CPR – cumulative percent revision.

The Takeaway

The takeaway below is that Persona CR Total Knee performed significantly better than all other total knees in cumulative percent revision out to six years.

AOA Data - Persona CR - Cumulative Percent Revision (CPR)

![Cumulative Percent Revision of Primary Total Knee Replacement by Model](image)

Table 13: Yearly Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses)

<table>
<thead>
<tr>
<th>CPR</th>
<th>1 Yr</th>
<th>2 Yrs</th>
<th>3 Yrs</th>
<th>4 Yrs</th>
<th>5 Yrs</th>
<th>6 Yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persona/Persona</td>
<td>0.8 (0.7, 1.0)</td>
<td>1.4 (1.1, 1.7)</td>
<td>1.7 (1.4, 2.1)</td>
<td>2.2 (1.6, 3.1)</td>
<td>2.2 (1.6, 3.1)</td>
<td>2.2 (1.6, 3.1)</td>
</tr>
<tr>
<td>Other Total Knee</td>
<td>1.0 (1.0, 1.0)</td>
<td>2.0 (2.0, 2.0)</td>
<td>2.6 (2.6, 2.7)</td>
<td>3.1 (3.0, 3.1)</td>
<td>3.5 (3.4, 3.5)</td>
<td>3.8 (3.8, 3.9)</td>
</tr>
</tbody>
</table>


Disclaimer - AOANJRR is confident in the accuracy of the data included in this report, at the time it was provided.
The takeaway below is that Persona PS Total Knee performed significantly better than all other total knees in cumulative percent revision out to six years.

**AOA Data - Persona PS - Cumulative Percent Revision (CPR)**

Table 13: Yearly Cumulative Percent Revision of Primary Total Knee Replacement by Model (All Diagnoses)

<table>
<thead>
<tr>
<th>CPR</th>
<th>1 Yr</th>
<th>2 Yrs</th>
<th>3 Yrs</th>
<th>4 Yrs</th>
<th>5 Yrs</th>
<th>6 Yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persona/Persona</td>
<td>0.8 (0.7, 1.0)</td>
<td>1.4 (1.1, 1.7)</td>
<td>1.7 (1.4, 2.1)</td>
<td>2.2 (1.6, 3.1)</td>
<td>2.2 (1.6, 3.1)</td>
<td>2.2 (1.6, 3.1)</td>
</tr>
<tr>
<td>Other Total Knee</td>
<td>1.0 (1.0, 1.0)</td>
<td>2.0 (2.0, 2.0)</td>
<td>2.6 (2.6, 2.7)</td>
<td>3.1 (3.0, 3.1)</td>
<td>3.5 (3.4, 3.5)</td>
<td>3.8 (3.8, 3.9)</td>
</tr>
</tbody>
</table>


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The National Joint Registry (NJR), which covers England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey, collects information on hip, knee, ankle, elbow and shoulder joint replacement surgery and monitors the performance of joint replacement implants. The 17th annual report is now available online. It contains surgical data from 2003 through Dec. 31st, 2019.

**The Results**
The Persona Primary Knee System is performing well. The Persona Primary Knee System was listed in the most recent UK NJR and broken out by both Persona CR and Persona PS.

**The Takeaway**
The takeaway in the table below is that Persona CR and PS knees performed well in their respective categories.\textsuperscript{24,25}

- Persona CR at 3 years performs significantly better than all primary CR knees, known as the unconstrained, fixed category in the UK NJR.
- Persona PS at 3 years performs as well as all other primary PS (constrained fixed) TKA in the UK NJR

<table>
<thead>
<tr>
<th>TKA</th>
<th>3 Yrs</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>All CR Knees</td>
<td>1.41</td>
<td>(1.39–1.44)</td>
</tr>
<tr>
<td>Persona CR</td>
<td>.54</td>
<td>(.24–1.19)</td>
</tr>
<tr>
<td>All PS Knees</td>
<td>1.73</td>
<td>(1.68–1.79)</td>
</tr>
<tr>
<td>Persona PS</td>
<td>1.78</td>
<td>(1.08–2.92)</td>
</tr>
</tbody>
</table>
Frequently Asked Questions Related to Literature Terminology

Q: What does a 95% confidence interval mean?
A: A 95% confidence interval (95% CI) is a range of values that you can be 95% certain contains the true mean of the population.

Q: What do the confidence interval (CI) ranges mean and what if two sets of data do not overlap?
A: The confidence interval (CI) is a range of values that’s likely to include a population value with a certain degree of confidence.
A: If the two sets of CI ranges do not overlap, then the data is significant.
   • For example, in the Australian Registry the Persona CR cumulative percent revision confidence interval ranges do not overlap, thus the data is significant. Thus, Persona CR performs significantly better than other total knees.

Q: What is a Hazard Ratio (HR)?
A: The hazard ratio says how much more likely it is that a patient with a specific implant need to be revised than a patient with any other total knee. If the hazard ratio is lower than 1.0, this means that the risk of getting revised is lower compared to all other total knees.
   • For example, in the Australian Registry the Persona CR has a hazard ratio of .68, thus lower than 1.0 and thus has a lower risk of getting revised.

Knee Scoring:
• Knee Society Score
• KOOS Score
• Oxford Knee Score
• WOMAC Score
• Forgotten Joint Score
• Kujala Score
• EQ-5D
• VAS

Knee Society Score (KSS)\textsuperscript{26,27}
The KSS is a clinician-completed questionnaire and consists of 2 sub-scores: a knee rating (0–100 points) and function (0–100 points) worth a total of 200 points. Each sub-score can range from 0 to 100 points, with higher scores corresponding to better outcomes, classified as follows:

Excellent (80 – 100 points), Good (70 – 79 points), Fair (60 – 69 points), Poor (<60 points)
KOOS\textsuperscript{27,28}

The KOOS is a patient-completed questionnaire with 42 questions. There are 5 subscales, each measuring a specific outcome: pain (9 items), symptoms (5 items), activities of daily living (17 items), sports and recreation function (5 items), and knee-related quality of life (4 items). Scores for each subscale should be calculated separately and then transformed into a score between 0 and 100. A higher score indicates a better outcome.

Oxford Knee Score\textsuperscript{27,29}

The OKS is a patient-completed questionnaire and consists of 12 questions, 5 for assessing pain and 7 for assessing function. Each question is scored from 0 to 4 points (0 being the worst outcome and 4 being the best). The overall score is the sum of all items and can range from 0 to 48 points, with higher scores corresponding to better outcomes. The outcome categories for the OKS are classified as follows: excellent (> 41 points), good (34 – 41 points), fair (27 – 33 points), and poor (<27 points).

WOMAC Score\textsuperscript{27,29}

The WOMAC is a patient-completed 24-item questionnaire with 3 subscales measuring pain (5 items), stiffness (2 items), and physical function (17 items). A total WOMAC score is calculated by summing the items for all 3 subscales, for a total score between 0 and 96. A lower score indicates a better outcome.

Forgotten Joint Score (FJS)\textsuperscript{30}

The FJS-12 is a patient-completed questionnaire consisting of 12 questions about the awareness of the affected knee joint in everyday life. The raw score, ranging from 12 (best outcome) to 60 (worst outcome), is linearly transformed to a 0 to 100 scale and then reversed to obtain the final score with higher scores corresponding to better outcomes.

EQ 5D\textsuperscript{31}

EQ-5D is a standardized health-related quality of life questionnaire developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D is patient-completed and consists of either 3 or 5 items about quality of life as well as a VAS for the patient’s general health state. Depending on the version (EQ-5D-3L or EQ-5D-5L), there are three or five levels to choose an answer from. For the final score, 1 is the highest possible score, <0 (variable) is the worst possible score (EuroQol Group: EuroQol—a new facility for the measurement of health-related quality of life. Health Policy 16, 199–208 (1990)).

Kujala Score\textsuperscript{32}

The Kujala Score is a patient-completed questionnaire consisting of 13 questions evaluating subjective symptoms and functional limitations in patellofemoral disorders. The score ranges from 0 to 100, with higher scores corresponding to better outcomes.

Visual Analogue Scale (VAS)\textsuperscript{33}

The VAS is a patient-completed scale, most often used to assess pain. It consists of a straight line with the two extremes (e.g. “no pain” and “worst imaginable pain”) at one end each. Patients should mark the point on the line corresponding to the intensity of pain they experience. The distance from “no pain” until the point marked by the patient divided by the length of the line results in a score between 0 and 1 (or 0% and 100%) with lower scores corresponding to better outcomes (i.e. less pain).
References:

1. Global sales data on file at Zimmer Biomet.