STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	*(a)* Indicate the study's design with a commonly used term in the title or the abstract **Single center experience**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **30 patients underwent primary unilateral TKA with the Knee+™ AR navigation system. Preoperative and postoperative radiographic exams were conducted to assess limb alignment. Measurements of femoral and tibial varus, femoral flexion, and tibial posterior slope were recorded at different stages.** **Results: Significant differences were observed only in femoral flexion measurements between expected values and radiographic measurements (Z score = 2.67, p = 0.01). Tibial varus values showed a significant difference between expected and controlled measurements (Z score = -2.33, p = 0.02). However, these differences were less than 1 degree, in terms of clinical significance.**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **Computer-assisted systems obtained an increased interest in orthopaedic surgery over the last years, as they enhance precision compared to conventional hardware. The expansion of computer assistance is evolving with the employment of augmented reality.**
Objectives	3	State specific objectives, including any prespecified hypotheses **The accuracy of augmented reality navigation systems has not been determined. This study aims to examine the accuracy of component alignment and restoration of the affected limb's mechanical axis in primary TKA, utilizing an augmented reality navigation system and to assess whether such systems are conspicuously fruitful for an accomplished knee surgeon.**
Methods		
Study design	4	Present key elements of study design early in the paper **Revision cases were excluded. A preoperative radiographic procedure was performed to evaluate the limb's axial alignment. All patients were operated on by the same team, without a tourniquet, utilizing three distinct prostheses with the assistance of the Knee+™ augmented reality navigation system in every operation. Postoperatively, the same radiographic exam protocol was executed to evaluate the implants' position, orientation and coronal plane alignment. Measurements in 3 stages regarding femoral varus and flexion, tibial varus and posterior slope were recorded. For the abovementioned, differences between expected values and radiographic measurements were recorded.**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **From May 2021 to December 2021, 30 patients, 25 women and five men, underwent a primary unilateral total knee arthroplasty**. **Measurements were obtaines pre and postoperatively.** **We recorded measurements in three steps during the entire procedure for the femoral varus and flexion, for the tibial varus and posterior slope. At**

		first, we documented the expected values preoperatively after the evaluation of joint deformity and the mechanical axis from the AR system. Afterwards, we recorded the same measurements after each cut intraoperatively, and ultimately, we also measured these values radiologically after the operation.
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants **In our study, 30 patients underwent a primary unilateral TKA for osteoarthritis with AR guidance from May 2021 to December 2021. The average age of patients was 71.6 years, with five men and 25 women. Patients were included irrespective of age, diagnosis, deformity and body mass index (BMI). Revision surgery cases were excluded.**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case **30 patients, 25 women and five men, underwent a primary unilateral total knee arthroplasty. Revision cases were excluded.**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **A statistically significant difference was observed regarding mean expected values and radiographic measurements for femoral flexion measurements only (Z score = 2.67, p-value = 0.01). Nonetheless, this difference was statistically significantly lower than 1 degree (Z score = -4.21, p-value < 0.01). In terms of discrepancies in the calculations of expected values and controlled measurements, a statistically significant difference between tibial varus values was detected (Z score = -2.33, p-value = 0.02), which was also statistically significantly lower than 1 degree (Z score = -4.99, p-value < 0.01).**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias **small sample size, the lack of a control group, and that only radiographic, rather than patient-reported or observed, outcomes were analyzed. More extensive comparative studies are required to further evaluate the exactness and fruitfulness of the system.**
Study size	10	Explain how the study size was arrived at **Series of 30 cases including the specific AR system**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why

Statistical methods	12	*(a)* Describe all statistical methods, including those used to control for confounding **Lin's concordance correlation coefficient (CCC) was estimated in terms of statistical analysis. Also, results for Bland and Altman's limits-of-agreement (LOA) procedure are provided as the mean of the two values, minus and plus 1.96 standard deviations. CCCs between 0.60 and 0.80 are considered substantial, while coefficients greater than 0.80 are considered excellent. As the discrepancies between the measurements could not be assumed to be normal, the Wilcoxon Signed Rank Test was also performed to examine whether there was a significant difference between the mean values of the expected values and the radiographic measures, as well as between the mean values of the expected and controlled values. If a statistically significant difference was detected, a Wilcoxon Signed Rank Test was carried out to test if the differences were significantly different from the 1 degree. The level of statistical significance was set to 0.05.**
		(*b*) Describe any methods used to examine subgroups and interactions
		(b) Explain how missing data were addressed **There were no missing data**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, andanalysed **30 patients primary TKA**
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **30 patients, both male and women who underwent primary TKA**
		(b) Indicate number of participants with missing data for each variable of interest **No missing data**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	***(a)* Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for andwhy they were included** **For patients' femur calculations, the difference between the controlled and the expected varus/valgus values ranged from -1 to 1 degree, whilst there was no discrepancy in terms of radiographic measurements. Regarding flexion values, the difference between expected and controlled values (which refer to the calculated varus/valgus values from the AR system after the osteotomies have been executed) ranged from -1 to 1 degree. The same was observed for the difference between expected values and radiographic measurements. The mean differences between all paired comparisons varied from 0 to 0.33 degrees. Concerning tibia calculations, the discrepancy between controlled and expected values for varus ranged from -1 to 1 degree with a medium value of zero degrees, while the difference between radiographic measurements and expected values for varus ranged from 0 to 1 degree with a medium value of zero degrees. Finally, the difference between controlled and expected values for the posterior slope ranged from -2 to 1 degree and between radiographic measurements and expected values from -1 to 1. The corresponding median values were equal to zero. The mean differences between all paired comparisons were narrow, varying from 0 to 0.23 degrees. Near-perfect CCCs were reckoned for comparisons only between estimated flexion values and controlled and radiographic measurements in the femur and between estimated posterior slope values and controlled and radiographic measurements in the tibia, varying from 0.66 to 0.89. Also, as mentioned before, no deviation was observed between expected varus values and radiographic measurements in the femur. The 95% limits of agreement were within -1.46 to 1.52 degrees, and most estimates lie within the indicating. Low CCC was estimated for expected and controlled values of varus in the femur and tibia. A graphical display of the data and their agreement are presented. A Wilcoxon Signed Rank Test was performed to determine whether there was a statistically significant difference regarding the expected values and radiographic calculations. The test revealed a statistically significant difference in mean expected values and radiographic measurements only for femoral flexion measurements (Z score = 2.67, p-value = 0.01). However, this difference was statistically significantly lower than 1 degree (Z score = -4.21, p-value < 0.01). Concerning discrepancies in the values of expected values and controlled measurements, a statistically significant difference between varus values measured in tibia was noted (Z score = -2.33, p-value = 0.02), which was also statistically**

		significantly lower than 1 degree (Z score = -4.99, p-value < 0.01). Finally, it is of utmost importance to mention that there was no difference between the different implants used.
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives **Significant differences were observed only in femoral flexion measurements between expected values and radiographic measurements (Z score = 2.67, p = 0.01). Tibial varus values showed a significant difference between expected and controlled measurements (Z score = -2.33, p = 0.02). However, these differences were less than 1 degree, in terms of clinical significance**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **The limitations of this study were its small sample size, the lack of a control group, and that only radiographic, rather than patient-reported or observed, outcomes were analyzed.**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **Present-day literature data propound that AR systems, such as Knee+™, are becoming comparable to conventional navigation techniques in terms of precision and safety for routine clinical practice. AR appears to be a robust contemporary digital tool capable of revolutionizing the field of orthopaedic surgery, providing substantive information regarding intraoperative guidance and decision-making. In the future, it will distinctly possibly serve as a transcendent human-computer interface, enabling dexterous surgeons to attain superior results.**
Generalisability	21	Discuss the generalisability (external validity) of the study results **further technological and medical research is requisite to achieve augmented reality technologies' maximum potential and cost-effectiveness.**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.