CLINICAL ORTHOPAEDICS AND RELATED RESEARCH
Number 425, pp. 180–188

Use of the Cusum Technique for Evaluation of a CT-based Navigation System for Total Knee Replacement

Remy S. Nizard, MD, PhD; Raphael Porcher, PhD†; Philippe Ravaud, MD, PhD‡;
Edouard Vangaver, MD*; Didier Hannouche, MD*; Pascal Bizot, MD*; and
Laurent Sedel, MD**

Most of the early failures of total knee replacements are related to technical flaws. Conventional ancillary devices achieve good alignment in the frontal plane in only an average of 75% of total knee replacements. Computer-assisted surgery may improve the technical quality of implantation surgery. The aim of our study was to evaluate the use of computer-assisted surgery using a quality control process. Seventy-eight total knee arthroplasties were done with a CT-based computer-assisted surgery system. The outcomes studied were alignment of the lower limb, implant positioning, and operative time. The target for alignment was 180° ± 3°. Cusum analysis showed that the three outcomes were controlled during the study. The cusum test identified any existing outliers. Because few data were available at the beginning of this study regarding computer-assisted surgery for total knee replacement, a randomized study was not relevant. However, a control of the procedure was mandatory. The cusum technique allowed continuous evaluation of the performance of the new procedure, and is a useful tool in assessing new technology. The results of this study showed that it is possible to do a randomized study to determine if computer-assisted surgery can improve the technical result of total knee replacement.

Praemer et al[30] reported that in 1996, 245,000 total knee replacements (TKRs) were done in the United States. They estimated that the projected increase in TKRs in the United States will be 209,000 between 1996 and 2030 . Most of the early failures of TKRs are related to technical flaws. Experimental and clinical data indicate that to achieve optimal midterm and long-term results of a TKR, good alignment in the frontal plane of the lower limb is mandatory. In an experimental study, Hsu et al[14] showed that a femoral component in 7° valgus, with the tibial component placed at 90° to the long axis of the tibia, was the best position for the total condylar knee and produced equal force distribution between the medial and lateral plateaus. For the Kinematic knee, the best position was 9° valgus for the femoral component with 2° varus of the tibial component. A clinical association between failure of TKR and malalignment seems likely. Ritter et al[32] reported that varus knees had a lower survival at 10 years than aligned or valgus knees. Jeffery et al,[16] with the first design of the Denham prosthesis, reported that at 12 years the incidence of loosening was 3% when, on long-leg standing radiographs, the line joining the center of the femoral head to the center of the body of the talus passed through the middle ⅓ of the knee prosthesis. The incidence of loosening was 24% when the line was not in this range. Alignment in a narrow range around the neutral axis is a major objective of TKR even if the exact range is not clearly identified. To achieve this goal, different systems are available based on intramedullary or extramedullary rods that allow targeting. From experimental data[18,26,31] and clinical studies,[4,7,13,21] it has been shown that these systems have to be improved. A series that evaluated 673 knees showed that only 75.3% of the knees were in the 4° to 10° valgus range.[22]

To appraise the potential contribution of a new ancillary device to TKRs, one should check the technical quality of the procedure.[23] Methods for continuous quality control, such as cusum or Shewhart's charts, which initially were

---

Received: September 18, 2003
Revised: January 14, 2004; February 21, 2004
Accepted: April 7, 2004
From the *Lariboisière Hospital; †Department of Biostatistics and Medical Informatics, Saint-Louis Hospital, Paris, France; and ‡Department of Epidemiology, Biostatistics and Clinical Research, Bichat Hospital Paris, France.
The authors' institution has received funding from the Ministry of Public Health.
Each author certifies that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.
Each author certifies that his or her institution has approved the reporting of this case report, that all investigations were conducted in conformity with ethical principles of research, and that informed consent was obtained.
Correspondence to: R. S. Nizard, MD, PhD, Lariboisière Hospital, 2 rue A. Paré 75010 Paris, France. Phone: 33-149-959-136; Fax: 33-149-959-132; E-mail: remy.nizard@lrb.ap-hop-paris.fr.
DOI: 10.1097/01.blo.0000136902.01368.69

developed for industrial quality control, have proven to be valuable in medical research[39,40] but have not been used, to our knowledge, in orthopaedic surgery. Sequential outcome measures are considered measurements of a process, and cusum analysis aims to determine if the process is in control, that is, if some characteristics of the process (such as the mean) deviate from a prespecified target value.

Computer-assisted surgery has been considered a possible tool to improve reliability and reproducibility of implant positioning in TKR.[9] To evaluate the quality standards of this technique, we did a pilot study. The hypothesis of this study was that cusum analysis allows control of a new technology, such as computer-assisted surgery, on the main technical parameters (limb alignment, implant positioning, and operating time) and determines the potential learning curve. Placement of the tibial component in the sagittal plane, patellar alignment, and immediate postoperative complications also were evaluated as secondary outcomes.

MATERIALS AND METHODS

After obtaining approval of the ethics committee and informed consent from patients, a clinical trial was initiated using the CT-based Navitrack navigation system (Sulzermedica, Winterthur, Switzerland). Inclusion criteria were patients with osteoarthritis or rheumatoid arthritis who needed a TKR. Patients needing revision TKRs were excluded as were patients who could not be followed up. Because the presence of unicompartmental arthroplasties did not prevent 3-D reconstruction, revisions of unicompartmental arthroplasties were included in the study. All the data were prospectively recorded. Seventy-eight knee prostheses were implanted in 72 patients with the Navitrack system. Fifty-five were women (76.4%) and 17 were men (23.6%). The average age of the patients was 72.2 years ± 9.8 years (range, 28.9–88.3 years). The right knee was affected in 40 patients and the left knee was affected in 38 patients. All operations were done by or under the supervision of the senior author (RSN).

Seventy-one knees (66 patients) had surgery because of osteoarthritis, three of which (three patients) were revisions of unicompartmental arthroplasties. Seven knees (six patients) had surgery for rheumatoid arthritis. The preoperative deviation was measured on preoperative full-length weightbearing radiographs. The knees were in varus deviation with an average of 9.4° ± 6.0° for 56 knees in 53 patients (range, 1°–32°) and in valgus deviation with an average of 8.1° ± 7.0° for 21 knees in 18 patients (range, 1°–34°). One knee (in one patient) was aligned. The preoperative International Knee Society score was 32.8 ± 15.1 for the knee score and 30.0 ± 17.4 for the function score.

The computer-assisted system was based on 3-D reconstruction of the lower limb from a CT scan. The thickness of the slices varied from 1 mm at the knee level, 3 mm at the hip and ankle levels, to 1 cm at the diaphysis levels. The data acquisition took an average of 20 minutes. After recording the data on a CD-ROM, the senior author always did the segmentation process that allowed selection of the relevant part of each slice that was useful for reconstruction of the 3-D model. The software provided determination of a gray threshold that allowed semiautomatic selection first, and then allowed fine tuning by the surgeon. Because it was considered a pilot and initial study, time taken for the reconstruction was not considered in this first step as a cause of concern and was not evaluated.

A magnetic detection system was used during surgery. Sensors were rigidly fixed to the bones by two 3.5-mm bicortical screws and to two instruments (a positioning block and a pointer); these sensors were detected in an 80-cm long, 80-cm diameter area created by an emitter. The displacement of the sensors, and then of the fixed bone or instruments, was shown on the screen of the computer if they were in the area created by the emitter. The positioning block was attached alternatively on the distal part of the femur and on the proximal part of the tibia with a 40- to 50-mm long conical screw; fine-tuning of this instrument was easy in the frontal, sagittal, and horizontal planes. The computer showed the lines targeting the center of the femoral head on the femur (Fig 1) and the center of the ankle to allow a theoretically ideal position of the cuts in the frontal and sagittal planes. Rotation of the femoral cut was based on analysis of the epicondylar line and the posterior condyle, and on the AP line as described by Arima et al.[1] The distance between the anterior cortex of the distal femur and the posterior condyles was evaluated by the system and assisted with the choice of an adequately sized femoral component. In the axial plane, rotation of the tibial cut was based on a line joining anteriorly the medial part of the tibial tubercle and posteriorly the zone of insertion of the posterior cruciate ligament (PCL). Once the ideal position was determined, the positioning block was fixed by pins and then replaced by conventional cutting guides. Once the cuts were made, the positioning block was used to check the bone cuts and the position of the implants. No systematic preoperative radiographs were obtained; the surgeon asked for preoperative radiographs only when he felt uncomfortable with the system.

The Wallaby prosthetic system (Sulzermedica) was used for all knees. This system includes three models for primary arthroplasties that share the same ancillary device. The Wallaby I preserves the PCL, and includes an anatomic asymmetric femoral component with an anatomic trochlear groove. The patella is an anatomically designed and inserted inlay. The Wallaby IUC has the same design but sacrifices the PCL; the ultracongruency of the tibial plateau and the heightened anterior lip compensate for the absence of the PCL. The Wallaby II has a posterior stabilized design with a symmetric femoral component. The patellar implant in the Wallaby II is a dome-shaped resurfacing component. Depending on initial disease, anatomic conditions, knee stability, and surgeon preference, a Wallaby I was used for 25 knees (23 patients), a Wallaby IUC for 30 knees (28 patients), and a Wallaby II for 23 knees (21 patients). The components were cemented and the patella was replaced in all patients with a congruent inlay polyethylene patellar button for the 25 knees treated with the Wallaby I and the 30 knees treated with the Wallaby IUC, and with a resurfacing dome-shaped patellar button for the 23 knees treated with the Wallaby II.

Fig 1. A screen capture during the procedure shows placement of the positioning block, which targets the center of the femoral head.

A synovectomy was done three times for three patients with rheumatoid arthritis and major synovitis. A lateral retinacular release was done for eight knees (eight patients). Four knees initially were in valgus and four knees were in varus. The patella initially was dislocated in one of these knees; the other knees were preoperatively aligned.

Ligament balance was evaluated by introduction of a spacer sequentially in flexion and in extension. To achieve ligament balance, lateral, medial, and posterior release were done when necessary after adequate bone cuts were done. Lateral release was done for five knees (five patients), lateral and posterior release for two knees (two patients), medial release for seven knees (six patients), and medial and posterior release for three knees (three patients).

The main outcome studied was overall alignment measured on full-length weightbearing radiographs. Care was taken to avoid major rotational misplacement of the knee when taking radiographs. Radiographs were taken when postoperative flexion deformity was resolved as much as possible (2–12 weeks after surgery). An independent observer who did not participate in the surgeries did the measurements (EV). Individual placement of the femur and the tibia was evaluated on the full-length weightbearing radiographs with respect to the mechanical axis of the femur and the tibia. Sagittal placement of the tibial component, alignment of the patella on 30° skyline views, operating time, and preoperative bleeding recorded by an independent observer were the other outcomes studied. Sagittal alignment of the tibia was considered acceptable if there was a posterior slope ranging between 0° and 5°; an anterior slope or a slope superior to 5° was considered a failure. Preoperative and postoperative complications were recorded.

Cusum Analysis

Cusum[25,38] is a method that is helpful in monitoring a process. It focuses on cumulative sums of the deviations of the process measurements (denoted as $x_1, \ldots, x_n$) from a target value x^*. This yields the cusum S_i for the i^{th} measurement:

$$S_i = \Sigma\,(x_j - x^*),\ j \leq i$$

The S_i values of the cusum then are plotted against the rank of the observation i. On such graphs, a trend in the process results in a change in the slope of the cusum, whereas the values are expected to fluctuate around a horizontal line if the process is in control. An example of use of the cusum was provided by Wohl.[41] A technique called V-mask was proposed to determine graphically whether the process is out of control. It was shown that this technique was equivalent to drawing two modified cusums simultaneously[38]; a proper definition of this is given in the Appendix of the current study. These two cusums (one positive, S^+, and one negative, S^-) are drawn simultaneously. It then is possible to conclude that the process is out of control if S^+ crosses a predefined level h or if S^- crosses –h, where h is called the decision interval. We refer to this procedure as a cusum test. The use of a cusum test requires determination of the decision interval h and of another quantity, the reference value k. Both can be set using usual definitions for Type I and Type II error rates, with the choice of an alternative hypothesis that corresponds to the bias of an out of control process to be detected with fair probability. Detailed formulas linking the cusum test theory to sequential test procedures also are given in the Appendix. The decision interval h depends on deviation from the target to be detected (the alternative hypothesis) and on the statistical error rates, whereas the reference value k only depends on the alternative hypothesis.

In the current study, the cusum parameters were defined for the main end point as overall alignment of the femorotibial axis; the target was 180°. Three degrees deviation from the target in either way was to be detected (alternative hypothesis). For femoral and tibial components, the target value was 90°, and a 2° deviation was to be detected. For operating time, the target was set to the sample mean and the deviation to be detected was twice the standard deviation. The Type I error rate was set to 0.01, which is an acceptable value for cusum analyses,[38] and the Type II error rate was negligible (Appendix).

RESULTS

Results of the cusum analysis for the femorotibial axis (Fig 1) show that control of the process was obtained during the entire study and the learning curve lasted through 27 TKRs. The cusum plot shows that, for the first 19 first knees treated, a constant systematic varus deviation was observed, followed by eight knees with symmetric valgus deviations (Fig 2A). After these 27 knees, the process seemed to stabilize at the 180° target, with a slight trend toward varus knees. Figure 2B shows the results of the cusum test; both modified cusums are plotted together with the decision intervals. Results showed that the cusums S^+ and S^- never reached the out of control bounds. Postoperatively, 41 knees (39 patients) were in varus deviation, 31 knees (29 patients) were in valgus, and six knees (six patients) were aligned. The average deviation of varus knees was 182.1° ± 0.9° (range, 181.0° – 183.0°). The average deviation of valgus knees was 177.6° ± 1.1° (range, 175.0°–179.0°). Seventy-one knees (91%) in 67 patients were classified as acceptable (91.0%; 95% confidence interval, 82.6–95.6%) and eight knees in eight patients (9.0%; 95% confidence interval, 4.4–17.3%) were out of the 3° valgus, 3° varus range (Table 1).

After treatment of 17 knees, a positive trend was observed for the femoral component (angle slightly above the target), counterbalanced by a negative trend for the tibial axis (Figs 3, 4). Despite the evident deviations from respective targets, the cusum tests showed that both processes were globally under control. However, for the femoral axis, the cusum components crossed the upper control limit at the fifty-seventh and the fifty-eighth knees operated on and for the tibial axis, the lower (negative) limit was crossed at the twenty-second, twenty-third, twenty-seventh, and seventy-sixth knees operated on, meaning these cases were out of control. The femoral component was in the 2° valgus to 2° varus range for 58 knees (74.4%) in 56 patients, and the tibial component was in that range for 65 knees (83.3%) in 61 patients. The difference was not significant ($p = 0.17$).

Figure 5 shows that for operating time, the procedure was globally under control. After an initial period of 32 knees with an increasing slope and one knee that was out of control (Fig 4A), the slope declined, with one knee being out of control after this period. The two knees out of control were identified and were attributed to difficult reconstruction of the lateral condyle completely destroyed by rheumatoid arthritis in one knee, and to an associated Judet quadricepsplasty that was done for a preoperative permanent dislocation of the patella in the other knee. The average operation time was 120.7 minutes ± 34.4 minutes (range, 70–250 minutes). This time included placement of

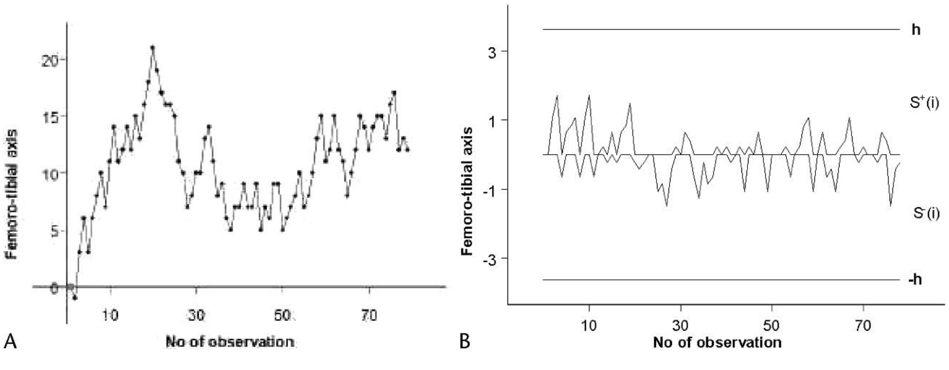

Fig 2A–B. The (A) cusum plot and the (B) cusum test for the femorotibial axis show that after 27 TKRs, the process stabilized around the 180° target.

TABLE 1. Frequency Distribution of Hip-Knee-Ankle Angle

Deviation	Angle (°)	Number of Knees	Percent
Varus	175.0	1	1.3
	176.0	4	5.1
	177.0	10	12.8
	178.0	7	9.0
	179.0	9	11.5
Aligned	180.0	6	7.7
Valgus	181.0	12	15.4
	182.0	15	19.2
	183.0	12	15.4
	184.0	3	2.6
	185.0	0	0
Total		78	100.0

the sensors, registration of bones and of instruments, implantation of the prosthesis, and additional actions when necessary. All the procedures were done without a tourniquet; bleeding during surgery averaged 510 mL ± 290 mL (range, 60–1450 mL).

The rate of acceptable placement of the tibial component in the sagittal plane was 88.5% and the rate of unacceptable placement was 11.5%. Sixty-five knees (60 patients) had a posterior slope, eight knees (eight patients) had no slope, and five knees (five patients) had an anterior slope. The posterior slope was more than 5° for four knees (four patients; 6° for two knees, 7° and 8° for one knee, respectively).

On the skyline view, 71 knees (91.0%) in 66 patients showed an aligned patellar component, and in seven knees (seven patients, 9.0%) components were tilted. None of the patellar components was subluxated or dislocated. At this early stage, no correlation was found between the position of the patellar component and the clinical status.

Immediate postoperative complications occurred in three knees. Two patients (two knees) needed reoperation for drainage of a hematoma and one patient had the wound open after falling 3 days after the operation. This patient had a skin closure. These complications resolved favorably. One patient had mobilization under general anesthesia 4 weeks after surgery for 60° flexion; 3 months after mobilization the patient had 90° flexion. No complication that was directly attributable to the computer-assisted surgery system was recorded.

DISCUSSION

In this series, alignment was considered the primary outcome measure because it plays a fundamental role in the long-term success of TKA.[16,33] An alignment within the range of 3° around the neutral axis on long-leg standing radiographs was achieved in 91% of the knees in the current study. This result compares favorably with other published series that used or compared intramedullary or extramedullary devices (Table 2).[3,7,11,13,21,22] Nevertheless, only a randomized study could show superiority of the computer-assisted surgical system. Acceptable alignment has been assessed differently in other studies; Maestro et al[21] considered 5° around a 7° tibiofemoral valgus as an optimal range, whereas other studies considered 4°[15] or 3° as the optimal range.[13,22,29] In the current study, the measurements were done by an independent surgeon who did not participate in surgery to reduce biases, however radiologic measurement of tibiofemoral axis or mechanical axis has several limitations. The long-leg standing radiograph, taken with care to avoid major rotational displacement, was chosen because Wright et al[42] showed in an experimental study that the measurement of the tibiofemoral axis was not influenced if the rotational misplacement was less than 10°; this observation was confirmed by Oswald et al.[27] However, reliability and reproducibility of this measurement have not been adequately evaluated. The use of long-leg radiographs was preferred because short-leg radiographs have several major disadvantages. Short-leg

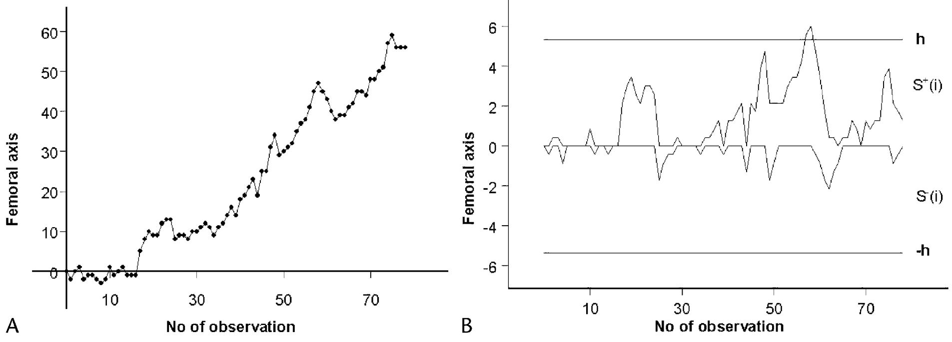

Fig 3A–B. The (A) cusum plot and the (B) cusum test for the femoral axis are shown.

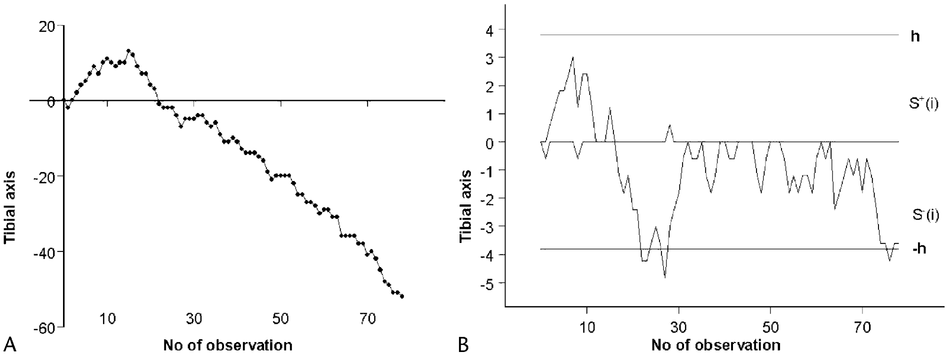

Fig 4A–B. The (A) cusum plot and the (B) cusum test for the tibial axis are shown.

radiographs overestimate tibiofemoral varus between 1.4° and 1.9° compared with long-leg radiographs[28,29]; this mean difference, with a standard deviation of 2.2°, may seem insignificant, however, as stated by Petersen and Engh,[29] this potentially could underestimate tibiofemoral valgus by 5.8° or overestimate it by 3°. Furthermore, bowing of the tibia or femur or both is not recognized on short-leg radiographs; this was responsible for significant error measurements in the study by Petersen and Engh,[29] for some difficulties in doing TKR for patients with tibial Paget's disease,[12,35] and for difficulties in treating Chinese patients.[20]

When we began our study, no data were available on CT-based computer-assisted surgery for TKR. Therefore, it was necessary to control the procedure, so as not to harm the patients. The cusum technique that was used to analyze this series is a quality control method that used sequential measurements as measurements of a process. Implantation of a prosthesis in a TKR was assimilated to an industrial process that needed to be under control during each step of the procedure. Our aim primarily was to draw reference values regarding what to expect in subsequent studies evaluating computer-assisted surgery for TKR. For that purpose, cusum techniques have several advantages. In addition to a more classic determination of means and standard deviations for axis angles, the cusum method, that was described for evaluating surgical trainees,[2,8,39] provides additional information. First, it allows detection of trends in the mean of the process, such as learning curves or periods of increased or decreased performance. Second, after each new case, it is possible to decide whether the process is still under control or to conclude that a significant change in the mean has occurred.

One potential drawback of the cusum method is the importance of determining target values and alternative hypotheses.[24] A common choice when no previous information is available is to use the observed mean as the target and to use two or three times the observed standard deviation as the acceptable failure rate to be detected with fair probability (alternative hypothesis). Such parameterization, however, has been criticized as defining a test rule depending on the observations. Therefore, agreed targets and decision intervals are preferred. In the current study, such requirements were verified, as target values and decisions intervals were fixed before the study for three parameters, independent of the observed results. Compared with other quality control charts, such as Shewhart's method, that only plot the last observation, the cusum has the advantage of considering the entire history of the process when drawing a result that corresponds to a new observation. This enables detection of smaller but consecutive biases.[38]

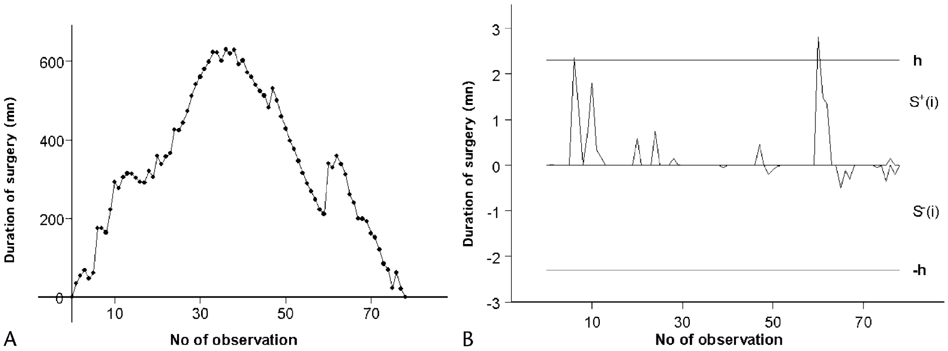

Fig 5A–B. The (A) cusum plot and the (B) cusum test for the operating time show that after an initial period of 32 knees with an increasing slope, the slope declined. Two knees were classified as out of control.

TABLE 2. Studies on Ancillary Devices

Authors	Comparative/ Prospective/ Randomized	Number of Knees	Knee System	Outcome Measure	Result	Observations
Petersen and Engh[29]	N/N/N	50		Anatomic femorotibial alignment	26% out of the 4°–10° valgus	Comparison between long and short radiographs; average significant difference, 1.4°
Tillett et al[37]	Y/Y/N	50		6° ± 2° anatomic avalgus on radiograph of knee	IM versus EM = NS	Comparison only on the femoral side
Engh and Petersen[11]	Y/N/N	72	Synatomic Knee Femur: Comp EM/IM Tibia: EM	Anatomic axis	IM > EM ($p < 0.1$) 87.5% versus 68.8%, between 4° and 10° valgus	
				Tibial axis	82% at 90° ± 2°	
Brys et al[3]	Y/N/N	114	Femur: EM Tibia: IM or EM	Mechanical axis	NS	Tibial instrumentation was different
				Lateral tibial axis (90° ± 2°)	IM > EM ($p < 0.05$)	Extramedullary femoral instrumentation
				Medial femoral axis	NS	
				Mechanical and anatomic axis	NS	
Dennis et al[10]	Y/N/N	120		Lateral tibial axis	88% with EM versus 72% with IM at 90° ± 2°	Better positioning with extramedullary instruments
				Mechanical and anatomic axis	NS	
Harvey et al[13]	N/N/N	101	Johnson-Elloy IM	Anatomic axis	72% in ± 3°	
Cates et al[4]	Y/N/N	200		Mechanical axis	NS	Femoral instrumentation was different; extramedullary instrumentation for the tibia
				Lateral tibial axis	IM > EM ($p = 0.019$)	
				Medial femoral axis	IM > EM ($p = 0.052$)	
				Mechanical and anatomical axis	NS (11%–24% of the cuts were not satisfactory)	
Ishii et al[15]	Y/N/N	100		Mechanical axis	NS	Tibial instrumentation was different
				Lateral tibial axis	NS	
				Medial femoral axis	NS	Intramedullary femoral instrumentation
				Mechanical and anatomic axis	NS (88% to 92% of the cuts were satisfactory in the 90° ± 4° range)	
Maestro et al[21]	Y/Y/N	116		Anatomic axis	NS (90.1% versus 87.2% in 7° ± 5°)	Tibial instrumentation was different
				Lateral tibial axis	IM > EM $p <0.01$ (85.2% versus 87.2% in 90° ± 4°)	Intramedullary femoral instrumentation
				Medial femoral axis	NS (98.3% versus 94.5% in 90° ± 4°)	
Coull et al[7]	N/N/N	79	Tibia: EM Kinemax System	Medial tibial axis	Average: 86.88° ± 2.84° 48% were more than 3° varus	
Mahaluxmivala et al[22]	N/N/N	673	Fibia: IM Tibia: EM PFC System	Anatomic valgus seen on the radiograph of the knee	7° ± 3° in 75.3% of the cases	No difference attributable to surgeon experience

Y = yes; N = no; IM = intramedullary; EM = extramedullary; NS = not significant

To our knowledge, this is the first study of CT-based computer-assisted surgery for TKR. Despite its innovative character, CT-based computer-assisted surgery provided a high rate of acceptable alignment. The early problems were easily controlled and the absence of major outliers indicates that CT-based computer-assisted surgery could be a useful tool to implant knee prostheses. However, it still is impossible with the data of the current study to determine if CT-based computer-assisted surgery can replace conventional systems; this conclusion can be made only with data from well-designed comparative randomized studies. However, data are needed regarding the performance of computer-assisted systems. These data, as discussed by McCulloch et al,[23] are mandatory before designing a randomized study. When dealing with such innovative techniques in surgery, unlike the conventional drug development process, no previous Phase I and Phase II studies are available. Suitable end points and expected differences between the control and the experimental arms that allow sample size calculation cannot be determined as in a classic randomized trial. The results of cohort studies such as ours are critically important.

Several options are available for computer-assisted surgery for TKR. Most of them were studied with conventional statistical tools but without the continuous evaluation that is allowed by the cusum technique.[5,6,17,19,34,36] The first randomized study was done by Saragaglia et al,[34] but did not show any difference in limb alignment between conventional systems and computer-assisted surgery; this study included only 25 patients in each group, and no a priori calculation of the number of patients to be included was done that considered the potential result of each technique.

Considering the cost-containment environment and the absolute necessity for surgeons to offer patients a safe procedure even when a new technology such as computer-assisted TKR is being studied, the cusum analysis provides information regarding the performance of the whole system, including the surgeon and the technique. From a methodologic viewpoint, the cusum technique was useful in evaluating this new technology. However the technical difference between computer-assisted surgery and conventional surgery needs to be evaluated with well-designed randomized studies. The clinical relevance of such systems also need long-term study.

APPENDIX

Cusum test

S^+ and S^-: $S^+_i = \max[S^+_{i-1} + (x_i - x^* - k)/\sigma, 0]$, where $S^+_0 = 0$ and $S^-_i = \min[S^-_{i-1} + (x_i - x^* + k)/\sigma, 0]$, in which $S^-_0 = 0$ σ denotes the standard deviation of the observed series (x_i), and k is called the reference value.

The cusum S^+ (respectively S^-) only increases (respectively decreases) if deviations from target value x^* exceed k positively (respectively negatively).

In quality control, several considerations have been taken into account to specify the values k and h. Most commonly, quality control concepts are used. However, Van Dobben de Bruyn[38] proposed a parallel between the cusum test and a sequential hypothesis test in reverse. Assume we wish to test the null hypothesis that the process is in control (the mean of the process is equal to the target), which is expressed as:

$$H_0 = \{\mu = x^*\},$$

where μ is the mean of x_i (in the sense of the mathematic expectancy), against the alternative hypotheses $H_1 = \{\mu = x^* + g\sigma\}$ and $H_{-1} = \{\mu = x^* - g\sigma\}$. A test of H_0 against the alternatives, with Type I error rate α and a high power (the Type II error rate is negligible), corresponds to a cusum test with parameters defined as: $k = g/2$ and $h = -1/g \log(\alpha)$.

For example, in the current study, given a standard deviation of 2.35° for the femorotibial axis and a 3° bias to be detected in either way, the parameter g was then $3/2.35 = 1.28$, yielding $k = 0.64$ and $h = 3.60$, as $\alpha = 0.01$.

References

1. Arima J, Whiteside LA, McCarthy DS, White SE: Femoral rotational alignment, based on the anteroposterior axis, in total knee arthroplasty in a valgus knee: A technical note. J Bone Joint Surg 77A:1331–1334, 1995.
2. Bolsin S, Colson M: The use of the cusum technique in the assessment of trainee competence in new procedures. Int J Qual Health Care 12:433–438, 2000.
3. Brys DA, Lombardi Jr AJ, Mallory TH, Vaughn BK: A comparison of intramedullary and extramedullary alignment systems for tibial component placement in total knee arthroplasty. Clin Orthop 263:175–179, 1991.
4. Cates HE, Ritter MA, Keating EM, et al: Intramedullary versus extramedullary femoral alignment systems in total knee replacement. Clin Orthop 286:32–39, 1993.
5. Clemens U, Miehlke R, Jens J: Computer Integrated Instrumentation in Knee Arthroplasty: The First 100 Cases With the Orthopilot Knee Navigation System. Computer Assisted Orthopaedic Surgery. Davos, Switzerland 71, 2001. Abstract.
6. Confalonieri N, Cerea P, Motavalli K: Comparison Study Orthopilot/Search Versus Intra and Extramedullary Alignment System in Total Knee Replacement. Computer Assisted Orthopaedic Surgery. Davos, Switzerland 52, 2001. Abstract.
7. Coull R, Bankes M, Rossouw D: Evaluation of tibial component angles in 79 consecutive total knee arthroplasties. Knee 6:235–237, 1999.
8. de Oliveira Filho GR: The construction of learning curves for basic skills in anesthetic procedures: An application for the cumulative sum method. Anesth Analg 95:411–416, 2002. table of contents
9. Delp SL, Stulberg SD, Davies B, Picard F, Leitner F: Computer assisted knee replacement. Clin Orthop 354:49–56, 1998.
10. Dennis D, Channer M, Susman M, et al: Intramedullary versus extramedullary tibial alignment systems in total knee arthroplasty. J Arthroplasty 8:43–47, 1993.
11. Engh GA, Petersen TL: Comparative experience with intramedul-

lary and extramedullary alignment in total knee arthroplasty. J Arthroplasty 5:1–8, 1990.

12. Gabel GT, Rand JA, Sim FH: Total knee arthroplasty for osteoarthrosis in patients who have Paget disease of bone at the knee. J Bone Joint Surg 73A:739–744, 1991.
13. Harvey IA, Manning MP, Sampath SA, Johnson R, Elloy MA: Alignment of total knee arthroplasty: The relationship to radiolucency around the tibial component. Med Eng Phys 17:182–187, 1995.
14. Hsu HP, Garg A, Walker PS, Spector M, Ewald FC: Effect of knee component alignment on tibial load distribution with clinical correlation. Clin Orthop 248:135–144, 1989.
15. Ishii Y, Ohmori G, Bechtold JE, Gustilo RB: Extramedullary versus intramedullary alignment guides in total knee arthroplasty. Clin Orthop 318:167–175, 1995.
16. Jeffery RS, Morris RW, Denham RA: Coronal alignment after total knee replacement. J Bone Joint Surg 73B:709–714, 1991.
17. Jenny J, Boeri C: Image-free Computer-assisted Total Knee Prosthesis Implantation: A Radiological Matched-paired Comparison With Surgeon-controlled Instrumentation. 68th Annual Meeting Proceedings, American Academy of Orthopaedic Surgeons. February 28–March 4, San Francisco, CA 431, 2001. Abstract.
18. Jiang CC, Insall JN: Effect of rotation on the axial alignment of the femur. Pitfalls in the use of femoral intramedullary guides in total knee arthroplasty. Clin Orthop 248:50–56, 1989.
19. Kiefer H, Langemeyer D, Schmerwitz U, et al: Computer Aided Knee Arthroplasty Versus Conventional Technique: First Results. Computer Assisted Orthopaedic Surgery. Davos, Switzerland 132, 2001. Abstract.
20. Ko PS, Tio MK, Ban CM, et al: Radiologic analysis of the tibial intramedullary canal in Chinese varus knees: Implications in total knee arthroplasty. J Arthroplasty 16:212–215, 2001.
21. Maestro A, Harwin SF, Sandoval MG, Vaquero DH, Murcia A: Influence of intramedullary versus extramedullary alignment guides on final total knee arthroplasty component position: A radiographic analysis. J Arthroplasty 13:552–558, 1998.
22. Mahaluxmivala J, Bankes MJ, Nicolai P, Adlam CH, Allen PW: The effect of surgeon experience on component positioning in 673 Press Fit Condylar posterior cruciate-sacrificing total knee arthroplasties. J Arthroplasty 16:635–640, 2001.
23. McCulloch P, Taylor I, Sasako M, Lovett B, Griffin D: Randomised trials in surgery: Problems and possible solutions. BMJ 324:1448–1451, 2002.
24. Mohammed MA, Cheng KK, Rouse A, Marshall T: Bristol, Shipman, and clinical governance: Shewhart's forgotten lessons. Lancet 357:463–467, 2001.
25. Nix AB, Rowlands RJ, Kemp KW, Wilson DW, Griffiths K: Internal quality control in clinical chemistry: A teaching review. Stat Med 6:425–440, 1987.
26. Novotny J, Gonzalez MH, Amirouche FM, et al: Geometric analysis of potential error in using femoral intramedullary guides in total knee arthroplasty. J Arthroplasty 16:641–647, 2001.
27. Oswald M, Jakob R, Schneider E, Hoogewoud HM: Radiological analysis of normal axial alignment of femur and tibia in view of total knee arthroplasty. J Arthroplasty 8:419–426, 1993.
28. Patel D, Ferris B, Aichroth P: Radiological study of alignment after total knee replacement: Short radiographs or long radiographs? Int Orthop 15:209–210, 1991.
29. Petersen TL, Engh GA: Radiographic assessment of knee alignment after total knee arthroplasty. J Arthroplasty 3:67–72, 1988.
30. Praemer A, Furner S, Rice D: Musculoskeletal Conditions in the US. Rosemont, IL. American Academy of Orthopaedic Surgeons. 127-141, 1999.
31. Reed S, Gollish J: The accuracy of femoral intramedullary guides in total knee arthroplasty. J Arthroplasty 12:677–682, 1997.
32. Ritter MA, Faris PM, Keating EM, Meding JB: Postoperative alignment of total knee replacement: Its effect on survival. Clin Orthop 299:153–156, 1994.
33. Ritter MA, Herbst SA, Keating EM, Faris PM, Meding JB: Long-term survival analysis of a posterior cruciate-retaining total condylar total knee arthroplasty. Clin Orthop 309:136–145, 1994.
34. Saragaglia D, Picard F, Chaussard C, et al: Mise en place des prothèses totales du genou assistée par ordinateur: Comparaison avec la technique conventionnelle. Rev Chir Orthop Reparatrice Appar Mot 87:18–28, 2001.
35. Schai PA, Scott RD, Younger AS: Total knee arthroplasty in Paget's disease: Technical problems and results. Orthopedics 22:21–25, 1999.
36. Stulberg S, Loan P, Sarin V: Computer Assisted Total Knee Replacement Surgery: An Analysis of an Initial Experience With the Orthopilot System. Computer Assisted Orthopaedic Surgery. Davos, Switzerland 116, 2001. Abstract.
37. Tillett ED, Engh GA, Petersen T: A comparative study of extramedullary and intramedullary alignment systems in total knee arthroplasty. Clin Orthop 230:176–181, 1988.
38. Van Dobben de Bruyn C: Cumulative Sums Tests: Theory and Practice. London, Griffin 1968.
39. Van Rij AM, McDonald JR, Pettigrew RA, et al: Cusum as an aid to early assessment of the surgical trainee. Br J Surg 82:1500–1503, 1995.
40. Williams SM, Parry BR, Schlup MM: Quality control: An application of the cusum. BMJ 304:1359–1361, 1992.
41. Wohl H: The cusum plot: Its utility in the analysis of clinical data. N Engl J Med 296:1044–1045, 1977.
42. Wright JG, Treble N, Feinstein AR: Measurement of lower limb alignment using long radiographs. J Bone Joint Surg 73B:721–723, 1991.