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Value of the cumulative sum test for the assessment of a learning curve: Application to the introduction of patient-specific instrumentation for total knee arthroplasty in an academic department

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ABSTRACT

Background: The purpose of the study was to use the cumulative summation (CUSUM) test to assess the learning curve during the introduction of a new surgical technique (patient-specific instrumentation) in total knee arthroplasty (TKA) in an academic department.
Methods: The first 50 TKAs operated on at an academic department using patient-specific templates (PSTs) were scheduled to enter the study. All patients had a preoperative computed tomography scan evaluation to plan bone resections. The PSTs were positioned intraoperatively according to the best-fit technique and their three-dimensional orientation was recorded by a navigation system. The position of the femur and tibia PST was compared to the planned position for four items for each component: coronal and sagittal orientation, medial and lateral height of resection. Items were summarized to obtain knee, femur and tibia PST scores, respectively. These scores were plotted according to chronological order and included in a CUSUM analysis. The tested hypothesis was that the PST process for TKA was immediately under control after its introduction.
Results: CUSUM test showed that positioning of the PST significantly differed from the target throughout the study. There was a significant difference between all scores and the maximal score. No case obtained the maximal score of eight points. The study was interrupted after 20 cases because of this negative evaluation.
Conclusion: The CUSUM test is effective in monitoring the learning curve when introducing a new surgical procedure. Introducing PST for TKA in an academic department may be associated with a long-lasting learning curve.
The study was registered on the clinical.gov website (Identifier NCT02429245).

1. Introduction

Introducing a new technique during a surgical procedure must be followed by evaluation of the technical quality of this change. Methods for quality control have been initially developed for industrial quality control, but may be adapted for medical research [1,2]. Sequential outcome measures are considered measurements of a process.

The Cumulative Summation (CUSUM) test allows a sequential quality process control and is well adapted to getting early feedback on surgical performance [3,4]. This test may determine whether the process is under control, and if some characteristics of

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the process (such as the mean) deviate from a pre-specified target value. Its use for total knee arthroplasty (TKA) quality control has been scarcely published [5].

The impact of limb and implant alignment after TKA remains the subject of debate [6]. However, it is generally accepted that excessive tibial varus or tibial and femoral malrotation may negatively influence clinical outcome [7]. Patient-specific templates (PSTs), in which the bone resections are performed with disposable guides fashioned for each individual patient, have been developed with the theoretical advantage of both an outlier rate reduction and a decreased operating time in comparison to conventional instruments [8]. However, there remains controversy about the accuracy of PSTs in comparison with either computed assisted or conventional instruments [9–15]. Furthermore, the learning curve after introducing PSTs has not been well defined. The goal of the present study was to evaluate the use of the CUSUM test for monitoring quality control during the introduction of the PST technique at an academic department.

The hypothesis tested with the CUSUM test was that there is no learning curve during the introduction of a new PST process for TKA in an academic department.

2. Materials and methods

The first 50 TKAs implanted with the use of PSTs at an academic department were scheduled to enter a prospective, observational study. Inclusion criteria were a patient with end-stage primary knee osteoarthritis (OA), scheduled for TKA, agreeing to undergo an additional preoperative computed tomography (CT) evaluation and agreeing to wait six weeks for surgery (the time required to manufacture the templates). There were no additional exclusion criteria.

The preoperative radiological assessment included weight-bearing standing anteroposterior (AP) and lateral knee radiographs and hip-to-ankle standing AP radiographs. On preoperative standard views, OA grading was carried out according to the Ahlbäck classification system [16]. The preoperative hip–knee–ankle (HKA) angle was measured on hip-to-ankle standing AP radiographs according to Siu et al. [17], with positive angle values denoting varus angle. Radiographic measurements were performed with a standard digital picture archiving and communication system (Centricity Enterprise Web 3.0.10, GE Healthcare, Strasbourg, France).

PSTs were developed by OneFit Medical (Besançon, France) after a preoperative CT scan of the hip, knee, and ankle. A three-dimensional (3D) model of the knee joint was uploaded to the manufacturer's software planner (OneFit Knee Planner) together with the digital templates of the TKA to be used (e.motion®, B. Braun Medical France, Boulogne-Billancourt, France) [18]. Implants were virtually placed by the operating surgeon (J.Y.J.) to obtain a 0° frontal alignment of both femoral and tibia components with respect to the coronal mechanical axes, a 0° sagittal alignment of the tibia component with respect to the sagittal mechanical axis of the tibia and a 0 to four degree sagittal alignment of the femoral component with respect to the sagittal mechanical axis of the femur. The height of resection was set at 8 mm (with an accepted variation of $\pm$ 1 mm) measured from the most distal point of the femoral condyles and the most proximal point of the tibia condyles, and the expected height of resection of the opposite side was calculated. The targets were recorded for each individual item and transferred to the database.

All TKAs were implanted by an experienced, high-volume senior consultant (J.Y.J.). Through an anteromedial trans-vastus approach, a complete exposure of the knee was performed. In order to fully match with the preoperative planning, no osteophyte removal was performed, as required by the PST manufacturer as the osteophytes were included in the PST manufacturing process. PSTs were used in accordance with the manufacturer's instructions and carefully positioned over the bone and articular surfaces to the best fit position, without any navigated information. No sterile model was provided because of the additional costs involved. The OrthoPilot® navigation system (Aesculap, Tuttlingen, Germany) [19] was used to register the 3D femoral and tibia PSTs positioning: coronal orientation, sagittal orientation, medial and lateral heights of resection. The surgical procedure was then completed following the routine navigated procedure with standard navigated templates [18,19]. Consequently, no postoperative data were collected, as the data would not relate to the use of the PST.

2.1. Data analysis

EXCEL 2016 (Microsoft, Redmond, WA, USA) and XLSTAT (Addinsoft, Paris, France) software were used for the database construction and the statistical analysis. A P value <0.05 was considered significant. The sample size was calculated to allow the detection of a two-point deviation of the knee score with $\alpha = 0.05$ and $\beta = 0.80$.

For each planned and PST item, median, minimal and maximal values were recorded. The difference between planned and PST positions was analyzed with a paired Wilcoxon test. For each PST item, the absolute value of the deviation from the planned position was recorded, and the measurement was considered as an outlier if it was outside the target if the absolute deviation was more than two degrees (for angles) or one millimeter (for heights of resection). The median, minimal and maximal values of the absolute deviation from the planned position of each individual PST item and the number of outliers were calculated. The absolute difference of each individual item and the target was compared to the null difference with a paired Wilcoxon test. The deviation of the outlier rate of each individual item from null rate was tested with a Fisher exact test.

To assess the 3D positioning of each template individually and of both templates together as a surrogate of the final TKA positioning [19], one point was given for each item inside the target, giving a maximal femur and tibia score of four points, and a maximal knee score of eight points, when all items were fulfilled.

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