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Application of a Cumulative Summation test (CUSUM) in the Lumbar Spine

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Study design: Retrospective analysis
Objectives: The aim of this study was to monitor the quality control of pedicle screw fixation using a cumulative summation test (CUSUM).
Overview of Literature: CUSUM test has already been used in several different surgical settings including the assessment of outcomes in transplant, laparoscopic, and total hip replacement surgeries. However, there has been no data regarding CUSUM analysis for spine surgery.
Methods: Patients with lumbar spinal stenosis who underwent lumbar fusion surgery were included in this study. The primary outcome was the CUSUM analysis for monitoring the quality control of the accuracy of pedicle screw insertion.
Results: Seven screws of the 100 pedicle screw insertions were considered to have failed in the lumbar fusion surgery, respectively. Throughout the monitoring period, there was no indication by the CUSUM test that the quality of performance of the pedicle screw fixation procedure was inadequate.
Conclusions: Thisstudy demonstrates the CUSUM test can be a useful tool for monitoring of the quality of procedures related with spine surgery.

Key Words: Cumulative summation, Free hand technique, Posterior lumbar interbody fusion

Introduction

For monitoring of quality control and/or the learning curve for surgical and interventional procedures, the Cumulative Summation (CUSUM) test has already been used in several different surgical settings including the assessment of outcomes in transplant, laparoscopic, and total hip replacement surgeries.[1-7)] This statistical analysis can be applied to monitor any process with a binary outcome, allowing researchers to judge whether the initial or continued performance of a task is acceptable.[8)] Furthermore, it has also been used to control new technologies as they are initiated.[9)]

Therefore, the hypothesis of the current study was that the CUSUM would be a useful tool to monitor the quality control of pedicle screw fixation. The purpose of this study was to monitor the quality control of pedicle screw fixation using a cumulative summation test (CUSUM).

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Materials and Methods

Study design and participants

The data of pedicle screw fixation for fusion surgery between November 2013 and April 2014 were retrospectively analyzed. Our inclusion criteria were age 40 to 85 years, diagnosis of LSS, and patients who were scheduled to undergo spinal surgery. A diagnosis of LSS required one or more of the following symptoms: leg pain, numbness, or motor deficits in the lower extremities and buttocks,[10, 11] with confirmation of a stenotic lesion in the lumbar spine on magnetic resonance imaging (MRI). Exclusion criteria included a history of peripheral vascular disease, any concurrent serious medical condition causing disability, general poor health status including sepsis or cancer, and the inability to complete the questionnaires on pain and disability. All participants were admitted to the spinal center of a tertiary care teaching institution.

Intervention

A conventional open pedicle screw fixation was performed through a midline skin incision. The corresponding facet joints with preserving intact facet joint capsule and transverse processes were exposed as the anatomical landmark.

Outcome measures

The primary outcome was the CUSUM analysis for monitoring of quality control of pedicle screw insertion accuracy. The accuracy of the pedicle screw insertion was evaluated by using postoperative computed tomography (CT) scans in axial, sagittal, and coronal views. The pedicle screw positions were classified into five grades as described by previous studies[12,13]: grade A, a screw in the pedicle without cortical breach; grade B, pedicle cortical breach <2 mm; grade C, pedicle cortical breach 2–4 mm; grade D, pedicle cortical breach 4–6 mm; and grade E, pedicle cortical breach of >6 mm.

CUSUM analysis

The CUSUM analysis scores performance outcome (the accuracy of pedicle screw placement) as a quantitative measurement. CUSUM scores of consecutive performance of an individual operator are displayed as a line chart, with the x-axis representing the consecutive series of procedures and the y-axis representing the CUSUM score. The CUSUM score is determined using the formula:

$$\text{CUSUM } C_n = \max(0, C_{n-1} + X_n - k)$$

where C=case; n=number of procedures (in chronological, consecutive order); X=outcome measure for the n^{th} procedure. For binary outcome, X_n=0(success), X_n=1(failure). K=reference value (a pre-specified standard of performance defined in terms of acceptable and unacceptable failure rate), which was calculated based on π_1 and π_2 using methods described by Hawkins and Olwell.[14] At the start, CUSUM C_0=0. At the n^{th} procedure, Xn is the outcome measure for the nth procedure. Performance with an acceptable standard has a negative score, and the chart is either flat or slopes downwards. Performance with an unacceptable standard has a positive score, and the CUSUM chart slopes upwards. When consecutive procedures performed by the same operator are at an unacceptable standard, the chart will continue to slope upward until it crosses a line drawn across the chart called the decision interval (*h*). When this occurs, the CUSUM chart is said to signal an unsatisfactory performance, thus providing early warning for corrective actions to prevent subsequent patients being harmed by adverse outcome resulting from deteriorating or substandard performance. The decision interval or h is determined by specifying the in-control (IC) and out-of control average run length (ARL). IC-ARL is the average number of consecutive performance required for a CUSUM chart to cross a decision interval or signal during the period when the operator is performing at an acceptable level. This is akin to Type I error in hypothesis testing. On the other hand, OC-ARL is the average number of procedures performed before the CUSUM chart signals, during the period when an individual is performing at an unacceptable level. It is a measure of sensitivity and is akin to power (1-Type II error) or false-negative error in hypothesis testing.

In this study, the CUSUM analysis was applied to pedicle screw placement by a single surgeon (HJ Kim), that is, in 100 cases of pedicle screw fixation by the free hand technique. The success of pedicle screw insertion was defined as a grade A state only, the other grades were considered a failure of pedicle screw insertion. The pre-specified standard of

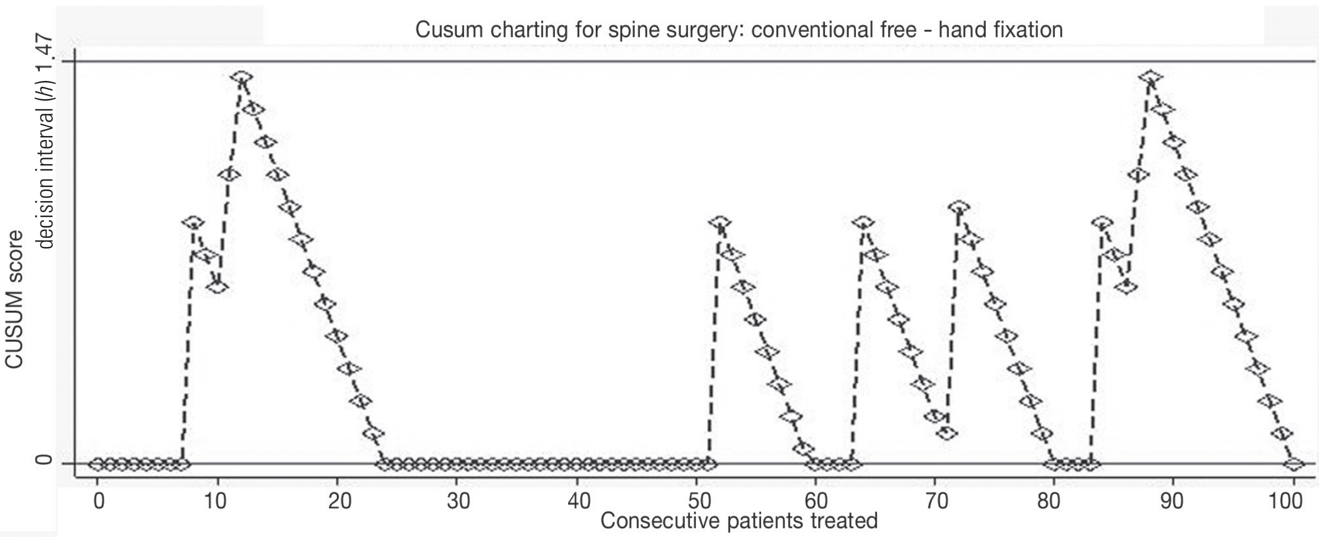

Fig. 1. Cumulative summation (CUSUM) charts for pedicle screw fixation in lumbar fusion surgery.

Table 1. Cumulative sum charting design for monitoring the performance of pedicle screw fixation

Specification	Parameter
Outcome measure for purpose of performance monitoring	Successful pedicle screw placement (grade A)
Acceptable failure rate of performance for the outcome measure, π_1	9%
Unacceptable failure rate of performance for the outcome measure, π_2	15%
Reference value k	0.118
Decision interval, h	1.47
IC-ARL	48.8
OC-ARL	40.9

performance was derived from previous literature.[13,15-17] The acceptable failure rate was less than 9%, and the unacceptable rate was more than 15% of procedure performed. Table 1 summarizes the specifications and parameter values used in CUSUM charting for monitoring pedicle screw fixation. The CUSUM charts were monitored closely.

Results

Overall, seven screws of the 100 pedicle screw insertion were considered to have failed in the lumbar fusion surgery, respectively. The six cases were grade B and one was grade C. Seventy and ten screws were 6.5 and 5.5 mm in diameter, respectively. One screw placement was revised because the patient had radicular pain caused by a misplaced screw.

Throughout the monitoring period, there was no alarm to indicate inadequacy in the quality of performance of the pedicle screw fixation by the CUSUM test in either group (Fig. 1). Failures can be seen as a jump on the graph; however, the limit h was never crossed in either group. Therefore, the performance of pedicle screw fixation using free hand technique was considered adequate quality control.

Discussion

As the primary endpoint, the CUSUM chart showed adequate quality control for the accuracy of pedicle screw fixation by the free hand technique. For the purpose of improving the accuracy of pedicle screw fixation, several methods have been introduced.[12,18,19] Historically, a C-arm has been used during pedicle screw fixation. Recently, CT navigation has provided the precise anatomy of the pedicle as well as reduced radiation exposure.[19] Intraoperative two-dimensional and three-dimensional fluoroscopy based navigation systems (O-arm) have also shown more accurate and reliable results.[19,20] However, our study showed that the free-hand technique for pedicle screw fixation system reaches an adequate level of performance without any image assistance.

As expected, the use of a process control chart and CUSUM could provide evaluation of the quality control with real-time information. In our study, the plot did not cross the limit h and no alarm was emitted, indicating that the free hand techniques maintained an adequate quality of performance. The CUSUM test presents a lot of advantages,[14] and the graph of CUSUM is easily and intuitively comprehensible. The unique feature of CUSUM is its ability to indicate the trend of deteriorating performance early, prompting preventive and corrective measures.[21] A retrospective review showed that the use of statistical process control would have detected the inadequate performance much earlier.[22] Therefore, CUSUM can be applied not only to monitor the quality control of a certain procedure, but also to accurately assess the learning curve in surgical procedures.[21,23,24]

Several A limitation should be acknowledged in our study. First, we did not consider operating times in the measurement of performance quality. Even though previous studies on learning curves have regarded this as a surrogate of performance quality,19,25,26) it is rarely related to clinical outcomes.

In conclusion, our study demonstrates the CUSUM can be a useful tool for monitoring the quality of procedures related with spine surgery.

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요추 수술에서 누적합(cumulative summation) 방법을 통한 정도 관리

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연구계획: 후향적 분석
목적: CUSUM (cumulative summation)을 이용한 척추경 나사못 삽입의 질 관리 및 감시를 하는 것이다.
문헌고찰: CUSUM (cumulative summation)은 이미 이식수술, 복강경, 인공고관절 치환술의 결과 평가 등 여러 수술 술기에 의료의 질을 관리 감독하기 위하여 사용되고 있다. 그러나 척수수술 분야에 관한 자료는 아직 없는 실정이다.
방법: 이번 연구는 요추부 척추협착증 환자중 척추 유합술을 받은 환자들을 대상으로 하였다. 척추경 나사 삽입의 정확도에 대한 감시를CUSUM (cumulative summation)으로 분석하였다.
결과: 각각의 척추 유합수술에서 100개의 척추경 나사 중 7개의 위치가 부적절 한 것으로 평가되었다. CUSUM (cumulative summation) 따르면 모니터링 기간 동안, 척추경 나사 삽입시술의 질이 부적절하다는 증거는 없었다.
결론: 이번 연구를 통해CUSUM (cumulative summation)이 척추수술의 정도 관리 감시에 유용한 도구가 될 수 있음을 알 수 있었다.

색인단어: 누적합, 프리핸드 기술, 후방 요추체 유합술