社団法人 情報処理学会　研究報告
IPSJ SIG Technical Report

2004－ICS－138　(27)
2004／12／6

QC Chart Mining

Masanori Inada[†,††] and Takao Terano[††,†††]

This paper presents a novel method:“ QC Chart Mining ”, which aims at extracting systematic error patterns from quality control charts at a medical laboratory. In this paper we describe the basic principle of a time decomposition mechanism for QC Chart Mining in order to detect substantial systematic errors, which might deteriorate clinical test data in their analytical processes. QC Chart Mining is used to recognize quality problems such as long-term trends and/or daily cyclic variations in analytical processes of clinical tests, then to improve the quality level over clinical laboratory medicine. Intensive experiments from both actual quality-control data and artificial data have revealed the validity of the proposed method. Our results have shown that the proposed method is useful and effective for quality managements in a medical laboratory.

1. Introduction

This paper describes a quality management tool on basis of a time decomposition method for a medical laboratory. QC Chart Mining is a novel quality management methodology to uncover the abnormalities in analytical processes and to resolve quality problems, based on the viewpoint of long-term technical evaluation through a time decomposition method, which extracts patterns from time series of control specimens stored in a medical laboratory. The purpose of the QC Chart Mining is to recognize quality problems like long-term trends and daily cyclic variations within analytical processes of clinical tests. We are aiming at finding solutions for these problems, and to improve the quality level over clinical laboratory medicine finally.

”Control chart” is a well-known method for statistical process control[1)]. It is frequently used in numerous clinical laboratories. To use the control chart, they assume that only random errors will occur without systematic biases. Actually, the control chart detects vital changes from normal states and ignores trivial noises within the stationary condition in an analytical process. However, when there would exist systematic errors in the analytical process, the statistical decision using the control chart would be collapsed. Because it is difficult to establish the state of statistical control in real world, it is necessary to develop novel quality management methods, which are effective in the cases with systematic errors.

Cleveland et al. developed “ STL[2)] ”, which is a time decomposition method based on nonparametric regression[3)~5)]. It is often used in economic time series analysis as a seasonal adjustment technique. We will apply this method to the quality management tool for a medical laboratory.

We will validate the usefulness of the proposed tool with intensive experiments about actual quality-control data measured 10 times a day constantly for 20 days from an automatic analyzer. We will also show the performance of the tool through artificial simulation data, which contain Gaussian random noises, a trigonometrical function data, and a linear decreasing function data.

This paper organizes as follows. Section 2 describes issues of quality management in a medical laboratory and explains the drawback of the control chart. Section 3 describes the basic principles of QC Chart Mining. Section 4 applies the proposed tool to actual quality-control data in order to validate the method in practical use. Section 5 evaluates the performance of the tool using several composite functions. Sec-

† Department of Clinical Laboratory, Toranomon Hospital
†† Graduate School of Systems Management, Tsukuba University
††† Department of Computational Intelligence and Systems Science,Tokyo Institute of Technology

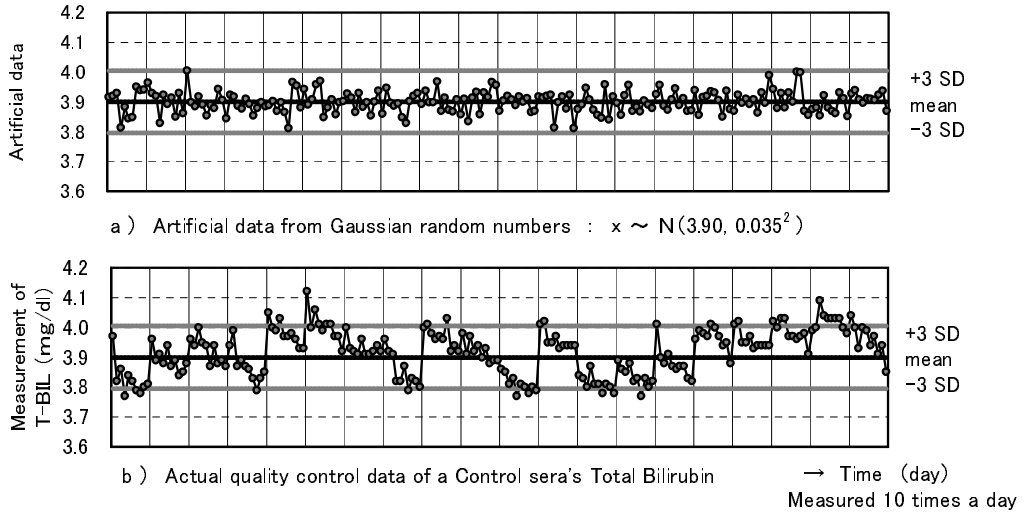

Fig. 1 Ideal Control Chart and Actual Control Chart

tion 6 discusses the experiment results. Final section describes conclusions and future work.

2. Quality Management in Medical Laboratory

Conventionally medical laboratories manage the quality of clinical test data with statistical process control. They throw some control specimens known concentration/activity into analytical processes in automatic analyzers and then compare the output values to predetermined values. They employ "Control chart" for this management[6),7)].

The control chart is an important management tool for manufacturing process control in the field of Statistical Quality Control[1)]. Shewhart translated statistics to the quality control and organized the methodology[8)]. When a target process is stable, its variation is random within a constant range. Based on statistical theory, if a normal distribution can be assumed for the random variation, the frequency exceeding the mean $\pm$ 3 $\times$ standard deviations is less than 0.3%. Employing the both ends of this range as lower and upper control limits, we become aware of the essential change deviated from a stable state to unexpected one in the process rather than the rare occurrence in the stable process.

The control chart can detect crucial changes in a target process under the state of statistical control where there are only random errors like normal distributions without systematic errors like trends and cyclic variations. In general, because it is difficult to establish the state of statistical control, we have to use the control chart with systematic errors. Systematic errors confuse statistical logic in the control chart and mislead us.

For example, Figure 1 shows two control charts. While the upper chart indicates most data plots generated with Gaussian random numbers are inside the mean $\pm$ 3 $\times$ standard deviations as the control limits, the lower chart indicates 32 plots among 200 points of real quality-control data are outside the control limits. At first glance it is clear that there are systematic errors in real data. In fact, since no fatal problems have occurred in the analytical process, users have allowed this behavior in the chart without regard to statistical control limits. It is not enough to manage processes with control charts. We need a tool to systematically manage measurement errors including systematic errors and random noises.

3. QC Chart Mining

The outline of QC Chart Mining is depicted in Figure 2. QC Chart Mining consists of the time decomposition phase and the problem discovery phase.

The time decomposition method decomposes

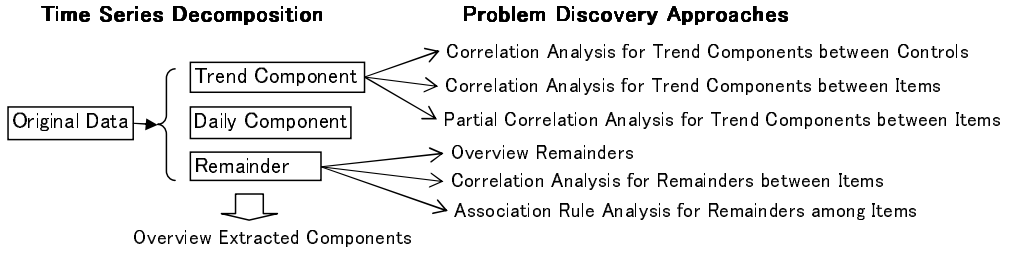

Fig. 2 Outline of QC Chart Mining

a time series into seasonal, trend and irregular components using" loess[3] ", acronym STL[2], by the following. The seasonal component is found by " loess " smoothing the seasonal sub-series (the series of all January values,$\cdots$); smoothing can be effectively replaced by taking the mean. The seasonal values are removed, and the remainder smoothed to find the trend. The overall level is removed from the seasonal component and added to the trend component. This process is iterated a few times. The remainder component is the residuals from the seasonal plus trend fit. For a medical laboratory, a quality-control data set is a time series with daily period, and then extracted components correspond as follows : the trend component is a long-term trend, the daily component is a cyclic pattern within day, and the remainder is a series of random error. This time decomposition method can be used to evaluate systematic errors.

After decomposing of a time series, extracted component patterns are visually distinguished. The proportion of each component contributing to original data is calculated.

In the problem discovery phase, extracted components are compared across other test items or other control specimens. Parallelisms/relationships of trend components among test items related on analytical mechanism are assessed with correlation analysis. Coincidences of outliers in remainders are also evaluated with apriori algorithm[9]. Focusing the background of systematic errors, these analyses would provide hints to solve quality problems.

4. Case Study

In this case study we would like to validate the usefulness of QC Chart Mining, applying the tool to actual quality-control data in a medical laboratory. We mainly deal here with the time decomposition phase and are not concerned here with the problem discovery phase intimately.

4.1 Data Set

We prepared the actual quality-control data; the both of Total and Direct bilirubin of a control serum have been measured 10 times a day constantly for 20 days on Hitachi 7600 analyzer at the Department of clinical laboratory in Toranomon hospital, Tokyo.

4.2 Method

First we decompose each time series. Second we calculate each variance of components and the proportion of each component to the original data. Third we compare the long-term trend of Total bilirubin to that of Direct bilirubin.

4.3 Result

Figure 3 depicts the result of time decomposition of Total bilirubin. There were systematic errors in the analytic process of Total bilirubin. The long-term trend accounts for 54% of the original data variation. The daily component represents that measurement values are decreased gradually from the morning to the afternoon within a day. Meanwhile, the remainder shows that random measurement errors are stable within the range of its mean $\pm$ 3 standard deviations. Figure 4 indicates the parallelism between Total bilirubin and Direct bilirubin. In addition, although the result is not shown, the daily component of Direct bilirubin is relatively small.

5. Simulation Study

In this simulation study we would like to evaluate the performance of the time decomposition of QC Chart Mining, applying the tool to arti-

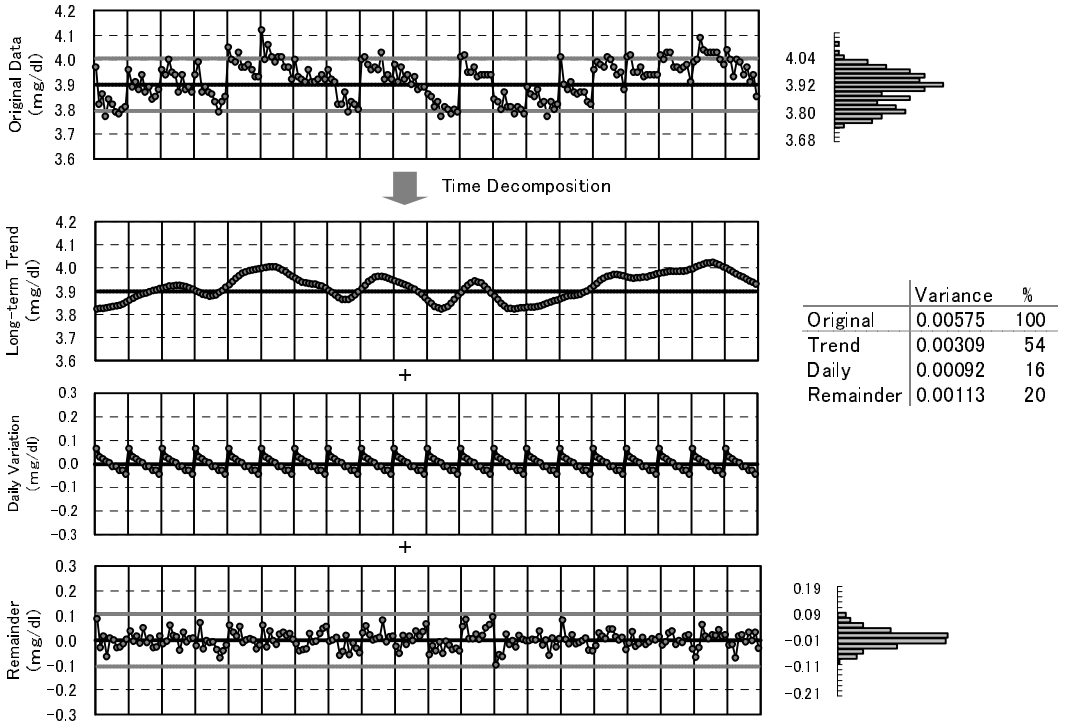

Fig. 3 Time Decompositon of Actual Control Chart Data

ficial data generated from a few functions and Gaussian random numbers. We observe the behavior of the tool on an ideal control chart created from Gaussian random numbers and a constant. Furthermore we evaluate the agreement between the origin and the recovery.

5.1 Data Set

We prepared two composite functions with 200 data points to evaluate the tool ; One is composed from the constant 3.9 and the Gaussian random numbers determined by the mean 0 and the standard variation 0.035 to reproduce the state of statistical control. Another is composed from 3 components: the trigonometrical function f(t)=0.1sin(t)+3.90, the linear decreasing function from 0.05 to -0.04 every piece of 10 points , and the Gaussian random numbers determined by the mean 0 and the standard variation 0.035.

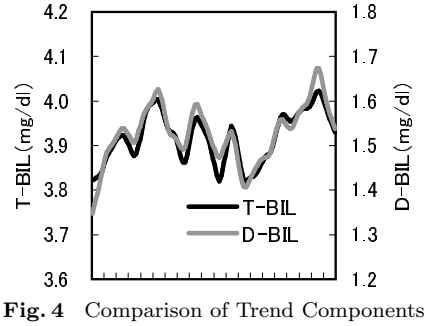

Fig. 4 Comparison of Trend Components

5.2 Method

First we decompose each composite function. Second, for the former function, we calculate the variance of extracted components and the proportion of each component to the composite function data. To grasp the reproductivity of this simulation about the ideal state, we replicate this study 10 times. Third we compare corresponding components between origin and recovery for the latter composite function.

5.3 Result

Figure 5 shows the result of time decomposition of the composite function reflected the ideal state in which there are only random noises without systematic errors. The extracted long-term trend and the daily component suggest that there are no systematic errors. The results of the reproductivity of this study appear in Table 1. Whereas the total variations of extracted trends and daily components are below 20% approximately, remainders account for the variations of the composite data mainly.

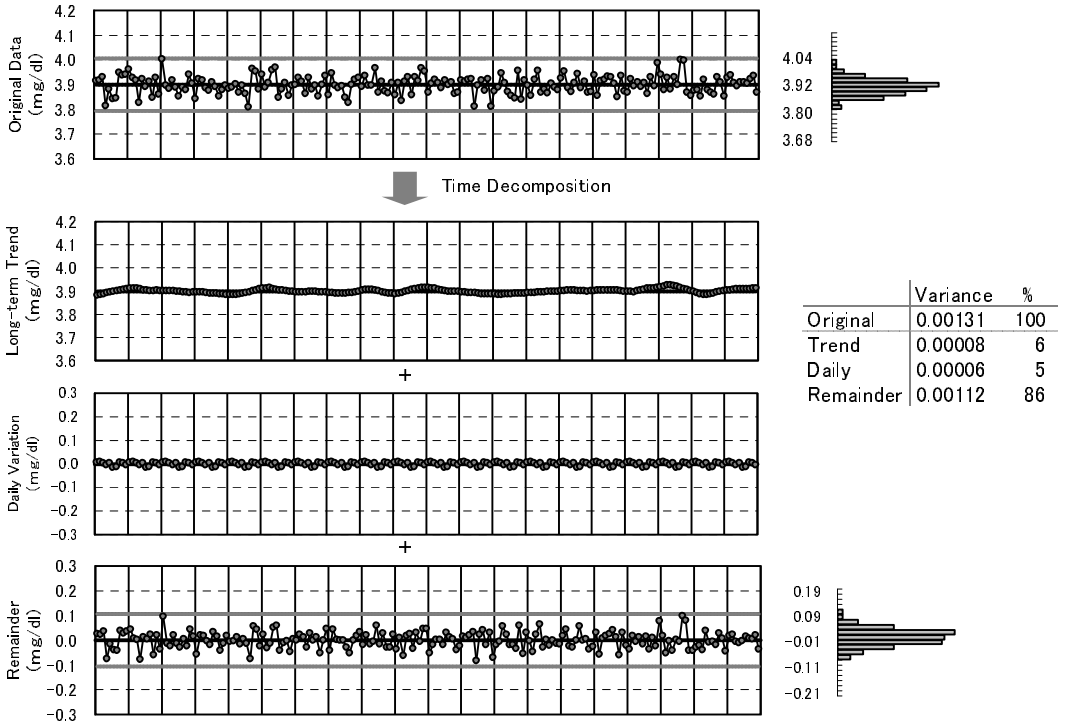

Fig. 5 Time Decompositon of Ideal Control Chart Data

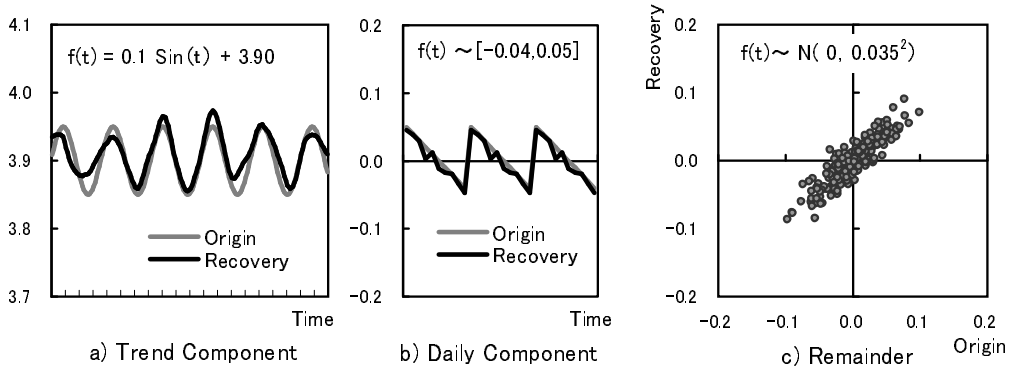

Fig. 6 Result of Simulation Study

Figure 6 indicates that the origins of the latter composite function are recovered by the core technique of QC Chart Mining namely the time decomposition.

6. Discussion

The result of the case study makes us recognize systematic errors visually. We can deduce from Figure 3 that much of the variation of the analytical process is made from the long-term trend and the daily cyclic variation. It becomes clear that the measurement values of Total bilirubin are decreasing gradually from the morning to the afternoon by the time decomposition, although it is not clear from the chart of the original data. The remainder suggests that random errors follow a normal distribution without extreme outliers. The parallelism in Figure 4 demonstrates that two analytical processes have a common factor of the fluctuation. Investigating the stability of the control specimen itself, we have solved this problem.

The results of the simulation show that the

Table 1 Proportion of Variation in Ideal State

	Trend	Daily	Remaindar
1	0.24	0.03	0.73
2	0.12	0.01	0.87
3	0.12	0.07	0.81
4	0.11	0.02	0.87
5	0.15	0.05	0.80
6	0.18	0.05	0.77
7	0.18	0.01	0.81
8	0.11	0.02	0.87
9	0.18	0.04	0.78
10	0.11	0.02	0.88

proposed tool seldom misleads us. If the analytical process is stable in an ideal state, most of the variation of original data is accounted by the remainder. When there are long-term trends and/or daily cyclic variations in the process, they are recovered respectably. Critics may argue that the performance depends on the smoothing parameter tuning in the local regression[3] as a non-parametric regresson[4]. It is sure. However, the default value recommended by Cleveland et al.[2] has been well-performing in our experiences.

QC Chart Mining would bring paradigm shift. Due to systematic errors, control charts make users insensitive to alarms and make them lose quality improvement opportunities. QC Char Mining makes us evaluate the state of process easily in the time decomposition phase, and recognize the structure of problems and the hint for solutions in the problem discovery phase. Ultimately QC Chart Mining will improve the quality level toward attaining the state of statistical control.

7. Conclusion and Future Work

In this paper, we have proposed QC Chart Mining: a quality management tool for a medical laboratory. QC Chart Mining decomposes a time series of quality-control data into long-term trend, daily variation and remainder components. Through the intensive case study, the tool is useful both to uncover substantial systematic errors visually and to evaluate random errors. The results of simulation study have also shown that the time decomposition method has good performance for the practical use. In the near future, QC Chart Mining will change quality managements in a medical laboratory from passive monitoring approach to active improvement of analytical processes of clinical tests. The future direction of this study is to develop a Case Based Reasoning[10] system, which would store cases of quality problems and their solutions.

Acknowledgments

We are grateful to MD. Akiko Yoneyama and MT. Kiyoko Kinpara of Toranomon Hospital for giving us valuable advice. This work was partially supported by the grant-in-aid for scientific research on priority area "Active Mining" funded by the Japanese Ministry of Education, Culture, Sport, Science and Technology.

References

1) NIST/SEMATECH : *e-Handbook of Statistical Methods*, http://www.itl.nist.gov/div898/handbook/ (2004).
2) Cleveland, R. B., Cleveland W. S., McRae, J. E. and Terpenning, I. :STL: A Seasonal-Trend Decomposition Procedure Based on Loess, *Journal of Office Statistics*, Vol. 6, No. 1, pp. 3–73 (1990).
3) Cleveland, W. S. and Devlin, S. J. :Locally-Weighted Regression: An Approach to Regression Analysis by Local Fitting, *Journal of the American Statistics Association*, Vol. 83, pp. 596–610 (1988).
4) Simonoff, J. S. : *Smoothing Methods in Statistics*, Springer-Verlag(1996).
5) Hastie, T., Tibshirani, R. and Friedman, J. : *The Elements of Statistical Learning*, Springer(2001).
6) Levey, S. and Jennings, E. R. : The use of control charts in the clinical laboratory, *American Journal of Clinical Pathology*, Vol. 20, pp. 1059–1066 (1950). (1991).
7) Westgard, J. O. and Barry, P. L. : *Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes*, , AACC Press (1986).
8) Shewhart, W. A.: *Statistical Method from the view point of Quality Control*, The Graduate Schol, The Department of Agriculture, Washington(1939).
9) Agrawal, R., Mannila, H., Srikant, R., Toivonen, H. and Verkamo, A. I. : *Fast Discovery of Association Rules*, Advances in Knowledge Discovery and Data Mining (Fayyad, U. M., Piatesky-Shapiro, G., Smyth, P. and Uthurusamy, R.(eds.)) , AAAI/MIT Press, chapter 12, pp. 307–328 (1996).
10) Pal, S. k., Dillon, T. S. and Yeung, D. S. (eds.) : *Soft Computing in Case Based Reasoning*, Springer (2000).