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A fully automated clinical laboratory

The history of the systemic and robotic automated clinical laboratory at the Kochi Medical School

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Abstract

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This paper chronicals the history behind the development and implementation of an automated, robotic clinical chemistry laboratory at the Kochi Medical School. A key stage in the automation of the laboratory was the development of a belt line system for sample distribution.

INTRODUCTION

We initiated the implementation of a fully automated clinical laboratory in 1981, when the medical laboratory at the Kochi Medical School was initially established. We have been able to reduce the number of laboratory technologists as well as improve laboratory safety through the use of an automated specimen distribution conveyor belt system.

The 'belt line system' provides rapid identification and delivery of bar-coded medical specimens directly to commercially available analytical instruments. Analytical results are returned via computer directly to each patient's physician.

The belt line system was constructed by our medical technologists in four years. We then focused our efforts on creating robotic analytical systems after the distribution system was complete. Since 1985 we have created a number of robotic workstations; for example for serology, blood transfusion tests, antibiotic sensitivity tests, hormone assay tests and protein electrophoresis.

This paper chronicals the history behind the building of an automated, robotic laboratory at the Kochi Medical School. This article will be a record of how we started, developed, and completed our clinical laboratory.

A RESOLUTE STEP TAKEN BY THE KOCHI MEDICAL SCHOOL

The Kochi Medical School was started in April 1978. It is only 15 years old, and therefore one of the newest national medical schools in Japan.

In the past, it was customary in Japan that a Professor in charge of the clinical laboratory in a newly founded medical school would be appointed immediately before, or even after, the hospital was opened. At the Kochi Medical School, however, the appointment of the Professor was exceptional as it occurred one year before the hospital was opened. This was due to the fact that the importance of the clinical laboratory was well recognized by Professor Kiyoshi Hiraki, the first President; Professor Masanori Morimoto, Vice President (later the second president); and Professor Jutaro Tawara, Vice President (later the third president). They agreed that a Professor should be appointed first and that the Professor should select a Chief Technologist as well as other technologists. I was informally appointed as the Professor of the Kochi Medical School from the Kawasaki Medical School, one of the new private medical schools in Okayama city in April

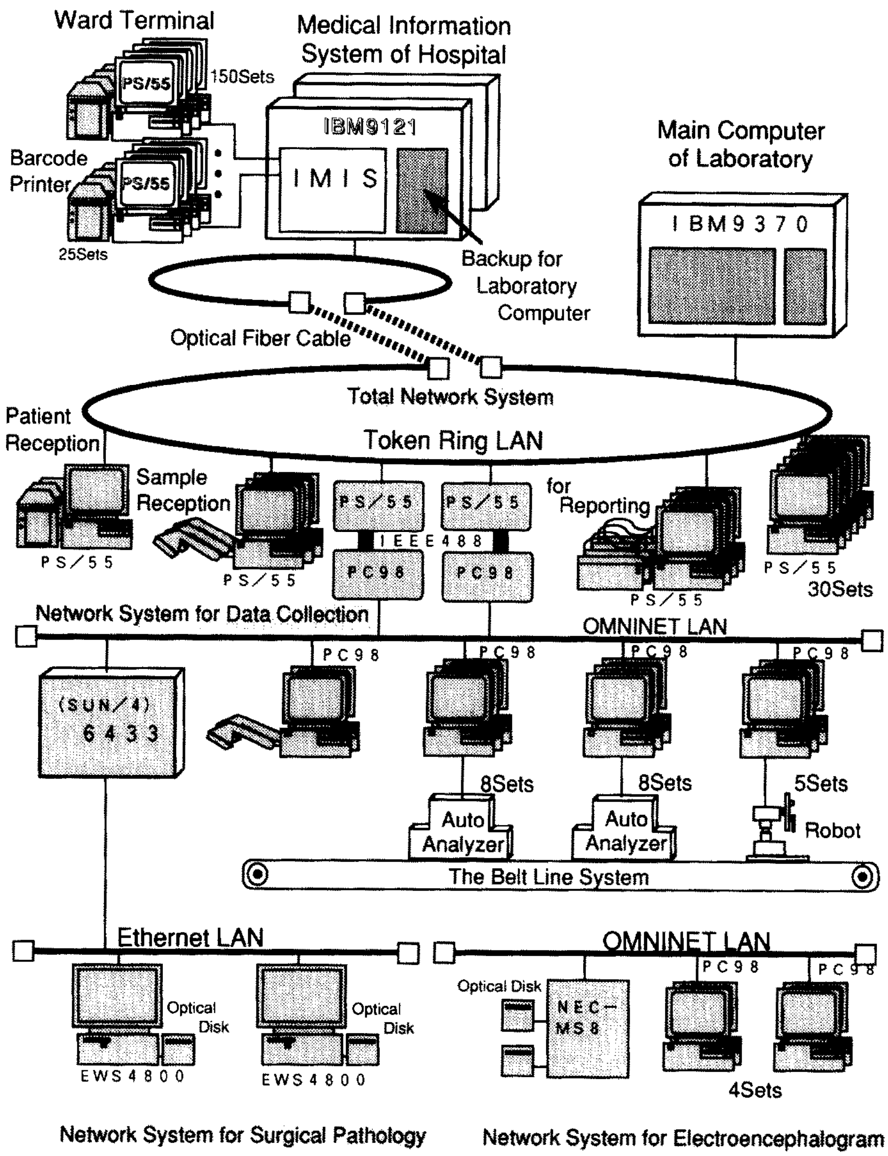

Fig. 1. Outline of the computer system composition of the Kochi Medical School Laboratory in 1992.

1980 and formally started my new post in April 1981. During this initial one-year period I was requested to come to Kochi once every other month, and to join in meetings which dealt with planning the new hospital. At the same time, we nominated a Chief Technologist, recruited technologists, designed a laboratory, and began selecting instruments. In addition, we were informed that the number of technologists to be assigned to our laboratory would be limited. This gave me great cause for concern.

Notwithstanding this early consternation, we today have a complete framework of the laboratory here by having incorporated and streamlined three main factors: (i) manpower, (ii) location and (iii) instruments. An outline of the automated laboratory is shown in Fig. 1 and describes both the computing and automation resources at the disposal of the staff.

The success we achieved is clearly due to the resolute step taken by the Kochi Medical School to informally appoint a Professor one year before the formal assignment.

HOW I GOT THE IDEA FOR A CONVEYOR BELT

The year before my formal assignment, I drove from Okayama, where the Kawasaki Medical School is located, down to Kochi. During the six-hour drive, I took a ferry boat from Mizushima, Kurashiki city to Marugame city, Kagawa prefecture. After leaving the port of Mizushima, the ferry passes the Mizushima Industrial Complex canal for 30 min, before reaching the Seto Inland Sea. One day, while looking at the west bank of the canal from the early morning ferry, a bright idea occurred to me. I happened to see a coal freighter moored at the pier of the Mizushima Thermal Power Station unloading coal. A crane installed at the pier was moving a gigantic shovel up and down. After the shovel scooped up coal from the freighter, it was pulled up with a rope, and then swung horizontally to unload the coal in small amounts onto a conveyor belt. The conveyor carried the coal as far as 1000 m or 2000 m. I was further surprised to realize that there were no men involved in the process. It was a completely unmanned operation.

I remember thinking, almost unconsciously, what a good idea that was. A conveyor would solve our manpower shortage problem. I was reminded of an inspection trip abroad in which six young doctors, including myself, went under the orders of Dr. Sukenobu Kawasaki, a founder of the Kawasaki Medical School. When we visited the Mayo Clinic in Minnesota, we saw how the conveyor belt transported patient charts. Conveyors are widely used in factory automation in the world too. I began to believe that it was strange that they were not used in clinical laboratories. Since then, the matter has been ever present in my mind, wondering how we could connect analyzers.

A BUILDING-BLOCK CONCEPT IN THE LAYOUT OF LABORATORY SPACE

When a new medical school is founded, everything from small pencils to large analyzers must be purchased. In other words, each laboratory's design could start from scratch. We drew our original plans on blank sheets of paper as even a minor mistake would result in grave consequences. With this determination, the newly appointed Chief Technologist, Mr. Masaaki Nishida, and I worked over our ideas for a new clinical laboratory. The seven basic concepts we came up with may be itemized as follows:

(1) *Prepare to undertake as many tests as possible.* Although the number of technologists was small, we did our best to undertake all necessary tests. Any overload was parcelled out to other laboratories until our department became fully staffed.

(2) *Never buy unnecessary instruments.* The purchase of instruments was funded by the taxpayer's money. As the clinical department began operations, it was necessary to buy instruments which were indispensable. When the department became fully staffed, we were able to make additional purchases.

(3) *Standardize the dimensions of the furniture.* A workbench measures $60 \times 80 \times 80$ cm; a side table, $80 \times 80 \times 40$ cm; and a small cabinet, $25 \times 25 \times 80$ cm. These three kinds of furniture were

considered the main building blocks which permitted a flexible layout of the furniture in the testing rooms. For example, you may place a centrifuge on a side table laid on its side. If you stack two side tables, they will be as high as a workbench (40 cm × 2). If you stack a few small cabinets, they will serve as shelves. Thus, it is easy to rearrange the layout utilizing these building blocks.

(4) *Connect two identical analyzers by a conveyor belt*. We made it a rule to buy analyzers in pairs and connected them by conveyor belts. If a certain model of equipment could not be connected by a conveyor belt, we selected models which permitted us to modify them for connection with conveyor belts.

(5) *Create a consistent flow from reception of samples to report of results*. We were laymen as far as automation was concerned, and we encountered some unexpected problems. Therefore, we employed the method of trial and error, and made replacements whenever we happened to find better ideas. We were willing to take such steps as the occasion demanded.

(6) *Harmonize the computer system of the clinical laboratory with the hospital computer system*. In our school, Professor Morimoto, Vice President, promoted a comprehensive computer system which covered the entire school. The clinical department was incorporated into this network to computerize all procedures, from receiving test requests to producing test results.

(7) *Leave the decision up to Professor Sasaki*. To achieve these goals, we should not let too many cooks spoil the broth. Autocratic rule shall be permitted for the next ten years.

Thus, we declared the guideline of the Seven Articles.

ON-LINE COMPUTER SYSTEM AS THE FIRST STEP FOR AUTOMATION

In the meantime, we felt that the project for comprehensively computerizing the entire school seemed to be limited. One day, I was present at a committee meeting relative to this project and asked how the system would incorporate the clinical laboratory department. The answer was that a request for a test would be printed out from the computer, but the report would be handwritten. I was quite shocked by this response, and even felt impatient because I was determined to do my best in Kochi.

The beginning would define what kind of completed hospital laboratory we would have. If we missed this opportunity which accompanied the opening of the new hospital, we would forever be without an on-line system. I consulted with the Chief Technologist and made up my mind to draw 50 million yen from our budget. We would build our system and manage to connect it with the host computer controlling the entire system.

We asked a few companies for estimates on how much software development for an automated system would cost. They replied that it would cost at least 100 million yen. We visited them to politely ask for a reduction in their quoted prices. They all were unable to do so. The only company who was convinced by us through the uniqueness of our system was Tachibana Electric Co. Ltd. (Tokyo). The company accepted our request and completed the system. This may have been the first time in the world that a company actually did something at the quoted price within the promised time of delivery.

At the same time, we persuaded the committee members to agree to our proposal. They had initially been reluctant and had insisted that it was still too early to think about building a computer system for the clinical laboratory. Fortunately, our host computer is an IBM 4341, a user-oriented system. Thanks to that feature, software development was accomplished by the entire staff of our department. The development included planning the process of accumulating test requests to finalizing result reports, as well as the design of screen displays for the registration of test items.

FUND RAISING FOR THE CONVEYOR BELTS

Now that the computer system had acquired a firm footing at last, we found that we had no funds to procure conveyor belts. We had already used up all the allocated money. I consulted with an Accounting Manager of the school. He willingly accepted my proposal, and told me to submit a written proposal, which he would use to negotiate with the Ministry of Education. I was very much surprised to find such a sensible person on the staff of a national university. Encouraged by his reply, I promptly wrote a proposal including drawings and descriptions of conveyor belts, and handed it to the Accounting Manager. I received this reply from the Ministry of Education in three weeks:

(1) Who is this Dr. Sasaki? (Not enough time had passed since I had been assigned to a post in a national university for my career to be known to the Ministry.)

(2) Why had not anyone else thought of such a simple thing as connecting analyzers by conveyor belts before?

(3) Are you sure that you can complete the system with 30 million yen and within six months of the actual hospital opening date?

My reply was as follows:

(1) As to who I am, I can hardly venture to answer myself.

(2) As to why this had not been thought of before; sample containers and sampling methods, among other things, vary with manufacturers because they are not subject to the Japanese Industrial Standard or other standards. As a result, they are not interchangeable with one another. Our idea is 'unique' in that they will become interchangeable.

(3) As to the time restriction; it would be impossible to complete the system within six months. Since I am not known to the Ministry, I would be happy if you would grant me 5 million yen at first. We shall then build a system, to the utmost of our abilities, and show it to you when you come to the opening ceremony of our hospital. If what you see pleases you, then please be so kind as to grant me another 5 million yen by the end of this fiscal year. After that, grant me 10 million yen annually for the following two years, for a total of 30 million yen. If you will be so kind as to do so, I am confident in saying that this project will succeed.

To my surprise, they told me to proceed.

THE CHALLENGE IN THE FIRST PHASE OF CONSTRUCTION

Given the green light by the Ministry of Education, we started on the construction of the conveyor networks. Women worked until midnight, and men until two o'clock in the morning. I asked several times for additional money to provide for overtime wages but my appeal was flatly rejected. I was told that we were not doing any of the tests usually done as part of the preparation for opening a hospital. The necessity for overtime work itself thus was not deemed understandable.

Although we worked hard, we were laymen. We could not predict how the system would work out. For instance, we bought a belt and cut it right in two, and placed iron angles between the belts to increase the total length of the conveyor belt. This was done to save money. We also encountered problems when we asked the analyzer manufacturers for slight modifications. It was especially evident from the very beginning that our requests to foreign manufacturers would be rejected. As a result, we made the modifications by ourselves.

After struggling hard against seemingly insurmountable difficulties we finally completed the first phase of the system. In this system, a request for a test is transmitted through a computer by a clinician. Our technologists, or a nurse (working in our laboratory), takes blood from the outpatient. A blood container is placed in a rack, which is transported automatically on a conveyor to an analyzer. The blood is tested. The result is printed out on the analyzer, and then transmitted through an on-line computer back to the clinician. This is the first fully automatic system completed in the world. On 12 October 1981, officials of the Ministry of Education visited Kochi to attend the opening ceremony of the hospital and inspected our system. We tried to save as much money as possible, but costs totalled 5 500 000 yen, going into the red to the extent of 500 000 yen.

THE SECOND PHASE OF CONSTRUCTION SOON FOLLOWED

At the same time the hospital opened, the conveyor system was put into operation for routine tasks. The flow of samples was smooth, and the clinicians were satisfied with the speedy output of test results. However, we encountered some unexpected problems discovered only after the system had begun operating. The conveyor was 1 m high, and technologists found it difficult to traverse. We also found that the centrifuges required some modification. In the second phase of construction, the height of the conveyor was raised to 2 m. We developed an elevator to carry samples from the conveyor down to the analyzer. We had our routine work to do during the daytime, so we worked on the second phase of construction during the evening and in the night.

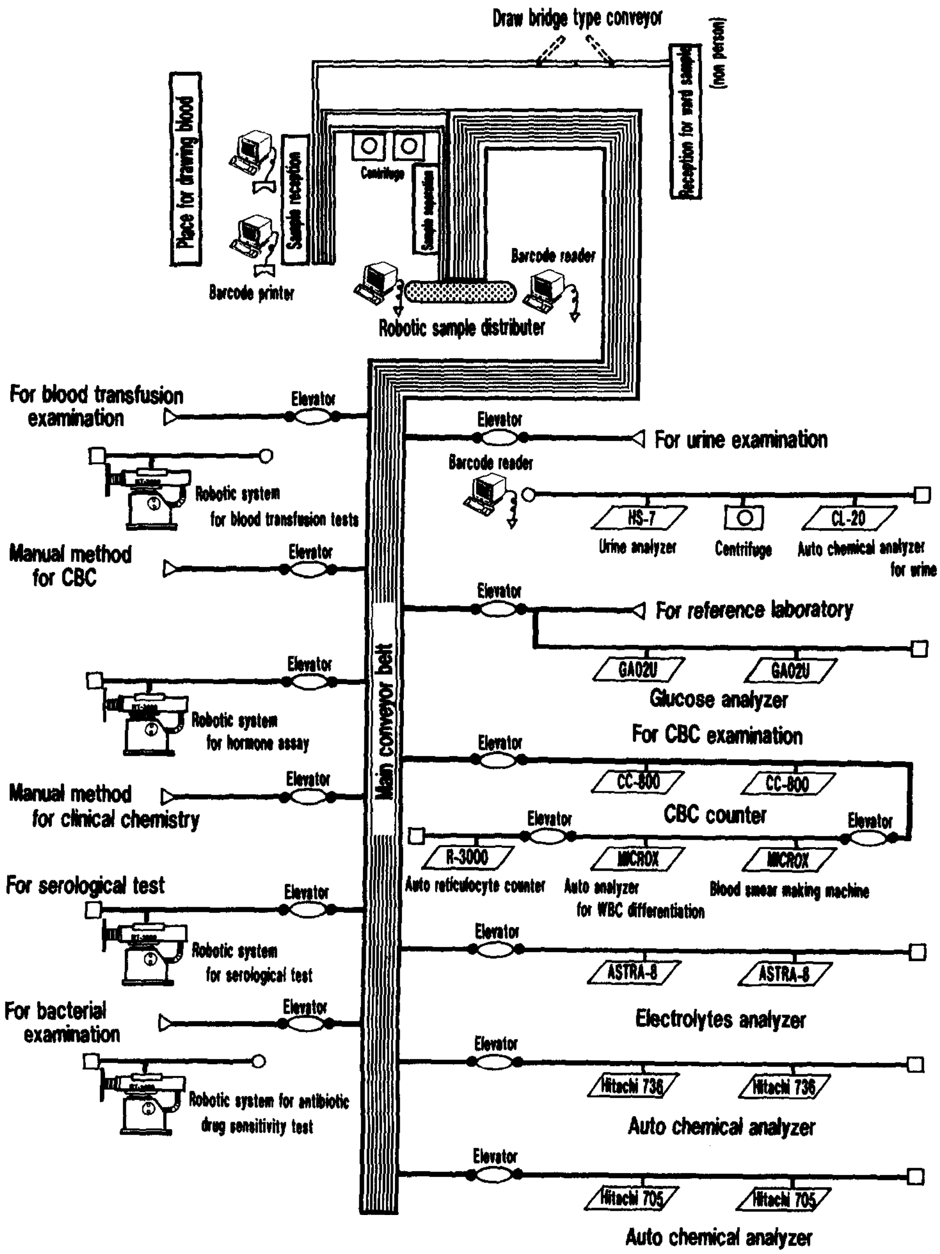

Fig. 2. Outline of the third phase of the belt line system.

Fortunately, first 3, and then 6, additional technologists joined us in the second and third year, respectively, bringing the total number to 19 including the Chief Technologist, as we had planned initially. All of the nineteen technologists worked days and nights to continue the construction work. However, progress was very slow, requiring a further two full years since its inception in April 1982.

FULL OF AMBITION FOR THE THIRD PHASE OF CONSTRUCTION

Even after the second phase was completed in March 1984, many problems still remained to be solved. One of them involved moving the receptionist's desk. Initially, only one receptionist was allotted by the Ministry of Education. The reception desk was far away from the room where blood samples were taken. The receptionist was very busy every day dealing with the rush of the many outpatients.

In October 1984, three years after the hospital opened, the School approved the move of the reception desk to the immediate area of the room where blood samples were taken. As a result, we found that the flow route of the samples would have to be changed and we were compelled to extend the route of the conveyor belt. Leaving the New Year's Party early on 4 January 1985, we began our work, and completed it by the end of March, the same year. The construction was fairly complicated, but due to our four-year experience in conveyor belt arrangements, we had become as skillful as professionals, and the construction was completed in only three months.

Fig. 3. The starting point of main conveyor belt and robotic sample distributor. The sample reception and the place for drawing blood from the outpatients can be seen (left upper corner).

Fig. 4. One of the scenes at the belt line system. A conveyor belt is connected to Hitachi 736 autoanalyzers by the elevator (on the left).

The main conveyor line, carrying 12 racks in a row, was extended up to 93 m. It was then branched off onto single-track conveyors which lead to each analyzer, which were provided with elevators. We used a 2.5-cm wide belt. The total length of the belt required was found to be as

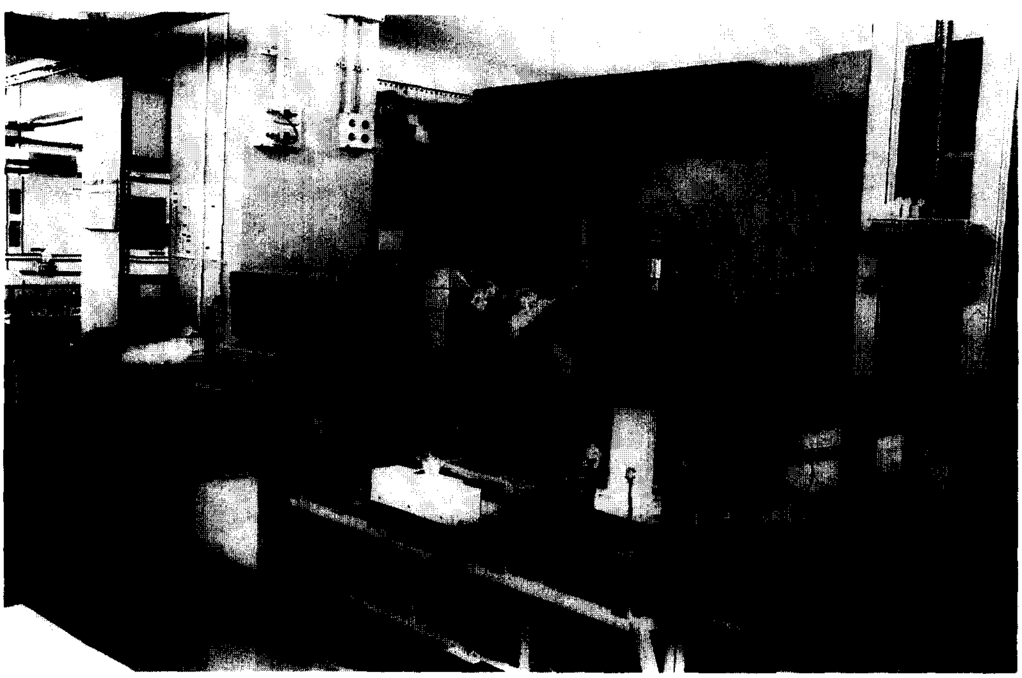

Fig. 5. Hormone assay robot and elevator. A sample rack is coming down to the robot by the elevator (on the right).

long as 2176.4 m. This is shown in Fig. 2. Figs. 3–5 show the starting point of the main conveyor belt and robotic sample distributor (Fig. 3), the belt line system connected to a Hitachi 736 autosampler via an elevator (Fig. 4) and a robotic assay connected to the belt line system, again via an elevator (Fig. 5).

THE ROBOTIC SYSTEM

A new idea occurred to me while I was engaged in the third phase of construction. The construction compelled us to move the reception desk to a temporary location. However, it was still 100–120 m away from the sample processing room and no one was available to carry the samples. A new medical school is commonly short of technologists. Fortunately, I had happened to see a hand-made robot carrying samples at Dr. Seligson's laboratory at Yale University which I visited in 1984. We wanted to make a prototype of this kind of robot, and found that that kind of robot is sold by Matsushita Electric Industrial Co. Ltd. We bought two of the robots, and modified them to suit our purposes. This kind of robot was found to be a suitable tool in the transportation of samples, having been introduced recently into several other clinical laboratories in Japan.

Subsequently, directors of the Seiko Electronic Industry Co., Ltd. visited us and told us that they were using four-axis robots in the assembly of wristwatches. I accompanied a technologist, Mr. Katsumi Ogura, who is familiar with mechanical engineering, and we went to Seiko to see how the robots worked. We were fascinated with the robot's smooth movements. After a few months of consideration, we decided to utilize one of these robots in the serological examination area. Mr. Ogura's prototype also demonstrated its suitability in serological testing. The following year, in January 1986, we started to develop the robotic system, and we were able to obtain satisfactory results by May. It was good enough for presentation of the system at the meeting of the Japanese Association of Clinical Laboratory Automation in the same year. We are proud of the fact that this is the first time robots have been successfully used in clinical laboratories in Japan.

In 1987 we succeeded in the development of a robotic system in blood transfusion testing. I devoted myself to the development of the next robot. At that time, clinicians were very strong in their request for antibiotic drug sensitivity tests through the MIC (minimal inhibitory concentration) method. We were not able to accept their requests due to a shortage of personnel. Therefore, we decided to utilize robots in this test. We completed 90% of the construction, but eventually had to give up due to technical difficulties. We then changed our plans to one which considered the simultaneous use of two robots, and prepared it for presentation at an academic meeting. The winter of the year 1988 was approaching. With great effort of our staff, now approximately 6600 tests are analyzed each day in our clinical laboratory using 17 medical technologists; 89% of the specimens are transported and analyzed in the automated laboratory with results being reported directly to the physician in less than 60 min. The use of a combination of a conveyor belt distribution system and advanced robotics has dramatically improved laboratory efficiency.

CONCLUSION

Four years were spent on conveyor belts, and another eight years on robotic systems. A Japanese proverb says, "Peach and chestnut trees bear fruit in three years, and persimmon trees in eight". It takes some time for everything to bear fruit. Our clinical laboratory has attracted attention because of its technological process. More than 6000 visitors have come to Kochi to see our laboratory. In 1988, Professor Kiyoshi Okuda of Osaka City University, was so kind as to introduce our laboratory to Dr. Carl A. Brutis of the Oak Ridge National Institute and Dr. Robin A. Felder of the University of Virginia. Since then, we have had an increasing number of visitors from the United States, Asia and Europe. I was invited to the AACC Symposium in Atlanta, GA, in July 1989, Oak Ridge Conference in Tampa, FL, in April 1990, and the ASCP Symposium in

New Orleans, LA, in September 1991, where I gave three presentations: 'The robotic system in Kochi', 'A fully robotic assay for human hormone analysis' and 'An attempt at making an automated systemic and robotic laboratory'.

ACKNOWLEDGEMENTS

Today, thanks to the favors and kindness of many people, our laboratory has achieved an automated, systematic, and robotic system. The bitter struggle over that twelve years is changing itself into a sweet memory. I find myself fortunate to be able to feel that way. However, much remains to be done. I am lucky to have good teachers, friends, and colleagues. I hope to continue to make the utmost effort in creating a more ideal system, which may always be advanced a step further. These days I spend every day convincing myself of my determination.

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