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English edition

Premier Issue

MESSAGES FROM THE EDITORIAL BOARD

There has been a wide gap between science and society. The last three hundred years of the history of modern science indicates to us that many research results disappeared or took a long time to become useful to society. Due to the difficulties of bridging this gap, it has been recently called the valley of death or the nightmare stage [(Note 1)]. Rather than passively waiting, therefore, researchers and engineers who understand the potential of the research should be active.

To bridge the gap, technology integration [(i.e. Type 2 Basic Research – Note 2)] of scientific findings for utilizing them in society, in addition to analytical research, has been one of the wheels of progress [(i.e. Full Research – Note 3)]. Traditional journals, have been collecting much analytical type knowledge that is factual knowledge and establishing many scientific disciplines [(i.e. Type 1 Basic Research – Note 4)]. Technology integration research activities, on the other hand, have been kept as personal know-how. They have not been formalized as universal knowledge of what ought to be done.

As there must be common theories, principles, and practices in the methodologies of technology integration, we regard it as basic research. This is the reason why we have decided to publish "*Synthesiology*", a new academic journal. *Synthesiology* is a coined word combining "synthesis" and "ology". Synthesis which has its origin in Greek means integration. Ology is a suffix attached to scientific disciplines.

Each paper in this journal will present scenarios selected for their societal value, identify elemental knowledge and/or technologies to be integrated, and describe the procedures and processes to achieve this goal. Through the publishing of papers in this journal, researchers and engineers can enhance the transformation of scientific outputs into the societal prosperity and make technical contributions to sustainable development. Efforts such as this will serve to increase the significance of research activities to society.

We look forward to your active contributions of papers on technology integration to the journal.

Addendum to Synthesiology-English edition,

"*Synthesiology-English edition*" *is a translated version of* "*Synthesiology*" *which is published quarterly, ISSN 1882-6229, by AIST.*

Papers or articles published in "*Synthesiology-English edition*" *appear approximately four months after the publication of the original* "*Synthesiology*"*. The views expressed in translated version are exclusively those of the Japanese authors and editors. The Japanese authors are generally consulted regarding the translation of their papers, but are not responsible for the published English version.*

Papers or articles in the "*Synthesiology*" *originally submitted in English are also reproduced just as they were published in* "*Synthesiology*"*. Some papers or articles in* "*Synthesiology*" *are not translated due to the authors' or editors' judgement.*

Synthesiology Editorial Board

Note 1 : The period was named "nightmare stage" by Hiroyuki Yoshikawa, President of AIST, and historical scientist Joseph Hatvany. The "valley of death" was by Vernon Ehlers in 1998 when he was Vice Chairman of US Congress, Science and Technology Committee. Lewis Branscomb, Professor emeritus of Harvard University, called this gap as "Darwinian sea" where natural selection takes place.

Note 2 : Type 2 Basic Research

This is a research type where various known and new knowledge is combined and integrated in order to achieve the specific goal that has social value. It also includes research activities that develop common theories or principles in technology integration.

Note 3 : Full Research

This is a type of research where the theme is placed within a scenario of future society, and where a framework is developed in which researchers from a wide range of research fields can participate in studying actual issues. This research is done continuously and concurrently from Type 1 Basic Research (Note 3) to Product Realization Research (Note 5), centered by Type 2 Basic Research (Note 4).

Note 4 : Type 1 Basic Research

This is an analytical research type where unknown phenomena are analyzed, by observation, experimentation, and theoretical calculation, to establish universal principles and theories.

Note 5 : Product Realization Research

This is a type of research where the results and knowledge from Type 1 Basic Research and Type 2 Basic Research are applied to embody the use of a new technology in society.

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Contents

A journal of original papers of *Type Two Basic Research*

Hiroyuki Yoshikawa

[Translation from *Synthesiology*, Vol.1, No.1, p.1-6 (2008)]

A new journal entitled *Synthesiology* is now being published by the National Institute of Advanced Industrial Science and Technology (AIST). The path to the publication of this journal was not easy. Long hours of discussions were held among the members of the editorial board concerning the nature of the journal, and I believe its general direction and philosophy are gradually taking shape. Here, I would like to express my thoughts on this new journal.

Synthesiology is a collection of papers on the results of Full Research, especially Type 2 Basic Research. Full Research is a term used at AIST to indicate a research method that can effectively make contributions to industry. This research approach, however, has always been plagued by a fundamental problem. Although many important and original studies have been done, there has been no place where such researchers could exhibit their originality in the form of research papers. As a consequence, their original thoughts failed to become public property, and this has been a serious loss for society. Although this journal was born from the efforts of AIST researchers, I hope it will become a place of presentation for all similar research conducted around the world.

1 Foundation of the National Institute of Advanced Industrial Science and Technology (AIST) — Background of the Journal

The National Institute of Advanced Industrial Science and Technology (AIST) was founded in 2001 by the integration of 15 research institutes under the Agency of Industrial Science and Technology (the former AIST), including some member organizations that date back to 1882. Harboring 3,000 researchers, it is one of the largest independent administrative research institution in Japan. Moreover, it is a multidisciplinary institute covering wide-ranging fields including mechanical engineering, electricity, electronics, materials, chemistry, life science, information science, energy, environment, geology, and metrology. Its objective is to promote industrial progress through basic research and developmental research. The mission of the Geological Survey of Japan, the oldest research organization, was to explore the natural resources that were essential for Japan to develop in the Meiji Period. Not only did it carry out exploration, but it also carried out the necessary basic research in geophysics and chemistry, and applied the knowledge gained to actual resource exploration. The Central Inspection Institute of Weights and Measures also has a long history and has conducted research on physical standards and units, the most basis of scientific research, while at the same time carrying out practical tasks such as the calibration of measuring instruments. Looking back at the history of the research institutes of AIST that were established one after another, it is clear that all pursued basic scientific research while also providing the knowledge needed for industrial development required by Japan at the time.

Immediately before the foundation of AIST, there were 15 separate research institutes under the auspices of the Agency of Industrial Science and Technology, which was an affiliated agency of the Ministry of International Trade and Industry (the present Ministry of Economy, Trade and Industry, METI); eight research institutes dedicated to individual research fields situated in Tsukuba and seven regional research institutes. Each institute was devoted to a specific field with specialized researchers conducting basic research in their respective fields. At the same time, each institute was engaged in national projects with industry involvement. This system has contributed greatly to the industrial development from the founding of Japan in the Meiji Period to the industrial revival after World War Ⅱ, as well as to the increased competitiveness of the manufacturing industry which has lead to strong economic growth. After achieving strong economic growth in the latter half of the 1980s, the export volume of Japanese industrial products increased and Japan occupied a significant position in the world market. Many countries saw Japan as a country, however, that created products by applying basic technology developed in other countries, mass-produced highly competitive, high-quality, low-cost products using mass production technology, and conquered international markets while expanding its economy. This perspective aroused criticism from countries that were disadvantaged by the competition. This viewpoint, which has been sometimes referred to as a “free ride on basic research”, claimed that Japan never conducted basic research on its own, but borrowed basic scientific results obtained by other countries with great investment, applied them, and made a profit. This emotional condemnation became the

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basis of trade conflicts and put Japan in a difficult situation. Japan has made tremendous efforts both internationally and commercially to solve this conflict, and this also affected Japanese research policy. It has resulted in an emphasis on basic research, and greatly influenced research activities as a whole. The phenomenon is referred to as the "shift to basic research" at the institutes under the Agency of Industrial Science and Technology.

The shift to basic research was a major event in the history of scientific research in Japan, and detailed analysis and interpretation are due, although it is perhaps too early to reach a conclusion. Here, I shall discuss what can be said as of now. First of all, the "free ride" viewpoint is too extreme and diverts attention away from Japan's achievements. Furthermore, it neglects the application of scientific knowledge to societal needs. Basic research is essential as source of new industry. Yet, basic research alone is insufficient to benefit mankind. It must be developed into something to benefit people to have value to society. As exemplified by textile production using weaving machines invented during the Industrial Revolution, and by further mass production of motor vehicles in the United States, affluence is spawned from the use of scientific knowledge. Thus, production technology, which was the most important factor in increasing Japan's competitiveness during its period of high economic growth, should be understood as a process of progress. For example, along with the improved performance of manufacturing processes the environment in which workers can make full use of their intellectual, emotional, and technical potential enabled the production of high-quality, high-reliability, low-cost products. This production format has not only been adopted by developing countries, but is employed by the advanced countries of Europe and the United States as the primary method of increasing affluence today. Therefore, Japan should be proud as the inventor of this production format and not be ashamed of taking a "free-ride". Yet in reality, Japan has not been commended. Japan's contribution to the evolution of production technology did not occur by accident, but was an inevitable result of scientific and educational policies set forth by our forerunners at the beginning of the Showa Period. However, I shall not elaborate on this matter here. The first problem is misevaluation or the neglect of our production technology achievements by us as well as others.

The second problem is the way in which Japan has dealt with the confusion that arose from the trade conflict, although it should, in fact, be proud of its achievements. Individual companies have made efforts to shift to locally based production in foreign countries, and various policies and administrative directives have been undertaken. These policies included the removal of import restrictions and the implementation of procurement restrictions. These policies have also affected the scientific world. This meant a shift away from application and development, and a move toward the basics of scientific research. The same policies also promoted the import of research instruments. These changes did not necessarily mean an emphasis on basic research or prioritization of specific research disciplines, but simply meant a statistically significant increase in funds for basic research within the total research budget. In terms of total research funding, the capital investment by the private sector has always much greater than government expenditure. This tendency is still strong in Japan, although it has been stronger in the past, and this was the basis of argument that Japan neglected basic research. Therefore, it became necessary to assert that all state-funded research was basic research. As a result, all institutes under the Agency of Industrial Science and Technology were obliged to engage in basic research. This move was called the "shift to basics", and the emphasis on basic research gradually increased. For the sake of scientific development, basic research is important regardless of the time or circumstances. Therefore, this shift has raised the level of the institutes under the Agency of Industrial Science and Technology in terms of their ability to produce basic research results, and the knowledge accumulated remains valuable to this day. On the other hand, considering the historical mission of the institutes in promoting industrial development, this shift undeniably obscured the role of the institutes today. At the same time, other countries began seeking ways to use new scientific knowledge to develop industry in the 1990s, and set policies that systematically accelerated the use of scientific knowledge through academic-industrial collaboration and public projects. Thus, while Japan made efforts to avert criticism originating from trade conflicts that Japan was too good in using knowledge, the situation in the world has changed completely and there is now competition in the ways of using knowledge. This is a serious issue. The second problem is the fact that while Japan made the correct policy of emphasizing basic research, it unnecessarily put aside its skilled use of knowledge, which in itself does not contradict the need to carry out basic research on a national level. AIST was founded to solve this problem.

2 Full Research — Need for the journal

The integration of the various institutes of the Ministry of International Trade and Industry into AIST was a change made in response to the aforementioned problems. Simply stated, it was a realization of an institute that conducts basic research at international standards of excellence and contributes to actual industrial development. This has, in fact, always been the objective of the institutes of the Agency of Industrial Science and Technology since the Meiji Period, so the change was actually a return to its roots. However, considering the colossal changes in the situation that surrounded the institutes, rather than a simple return

to its origins, a new viewpoint was needed. For example, enterprises throughout the world are required to enhance their competitiveness by using original knowledge acquired through basic research. In the age of mega-competition, however, industry can no longer spare time for basic research. Instead, universities and public institutions are expected to conduct basic research to serve the needs of industry. This has become the style not only in Europe and the United States, but also in many developing countries. Japan needed its own agenda for change, and the integration of the institutes under the Agency of Industrial Science and Technology was part of this effort. This integration was a change in a true sense because it involved the integration of individual researchers rather than that of the organizations. Fifteen research institutes were dissolved, and 3,000 researchers were distributed into 60 new research units with specific purposes to make contributions to industrial technology. Researchers selected their affiliation by their industrial contribution rather than selecting institutes to which they formerly belonged. As a result, each research unit consisted of researchers from diverse fields. Researchers thus have been organized according to objective rather than field of study.

The research units are autonomous in conducting research and are operated under leadership of their unit directors. They are free to do any type of research but are required to have clear goals to make contributions to industry. They are expected to carry out basic research and to contribute to industry at the same time. Therefore, some researchers of the unit engage in basic research while others engage in industrial applications of the research (since 3,000 researchers were divided into 60 research units, the average number of researchers per unit is 50, but in practice there are units of various sizes ranging from 10 to 250 researchers.).

Traditionally, these two tasks are handled by researchers of different disciplines in separate organizations. Basic research is conducted by universities while product realization is done by private companies. Basic research is further divided into specialized fields, such as natural sciences and engineering at universities. There must be an effective relationship between basic research and product realization so that industry can reap the benefit of basic research. This is often accomplished by industry-academia cooperation, intellectual property licensing, and ventures, but it is commonly recognized worldwide that such attempts are not always successful. Basic research and commercialization may not be continuous. Cooperation between researchers of industry and academia is often difficult, and this has been long regarded as a problem, but has never been solved. The new research units at AIST are, however, required to simultaneously realize both basic research and industrial contributions. Here, general basic research is called Type 1 Basic Research. It is necessary to have a new group of researchers who merge the contents of Type 1 Basic Research to Product Realization Research. This new category is referred to as Type 2 Basic Research. Therefore in a research unit, there are three kinds of researchers: researchers of Type 1 Basic Research, researchers of Type 2 Basic Research, and researchers of Product Realization Research. The research collectively conducted by these groups of researchers is called Full Research.

3 Type Two Basic Research and knowledge — Mission of the journal

The new journal provides a place to publish the papers of Type 2 Basic Research and to exhibit the original thinking of the researchers. It is necessary, therefore, to define Type 2 Basic Research, but this task is not simple, and not completely possible as of now due to its diversity. Let us study the significance of the original Type 2 Basic Research papers by referring to the following definition that I presented in an article in which I discussed the matter in detail [1]. The definition of Type 2 Basic Research is as follows:

“A form of research that integrates the knowledge of different disciplines or creates new knowledge when necessary, and transforms a concept into artifacts (product or service) that can be recognized by society”

Such activity is nothing new since it has been done widely with new inventions and industrial product creation. Yet it has not historically been called “research”. Furthermore, it has never been called basic research. It is necessary therefore to consider this as a form of basic research referred to here as Type 2 Basic Research.

First, it is necessary to ask, “What is basic research?” If it can be said that basic research without an adjective has no purpose, a new category of purposeful basic research can be defined . Limiting the discussion to basic research in natural sciences, such research enriches the body of knowledge of natural science by creating new knowledge. Strictly speaking, the value of scientific knowledge depends on the kind of “enrichment” pursued, but researchers may not necessarily be aware of this concept, and research may “lack purpose” in this sense.

In general, although individual research carried out by a researcher only aims to enrich the body of knowledge, or in other words, is basic research not intended to be immediately useful in society, the knowledge acquired may become extremely useful for societal activities regardless of the intentions of the researcher. This is self-evident from the fact that almost all contemporary technologies are grounded in scientific knowledge. Thus, it can be said that the “basic” of basic research is the “base” that underpins real societal

activities. Real societal activities are not just technology. Basic knowledge acquired through basic research is the basis of all societal activities including politics, public administration, economy, finance, management, medicine, education, industry, production, and media. At the same time, it is fundamental to regard scientific knowledge created through basic research as public knowledge i.e. the collective property of society. This is the premise for the public funding of basic research. Today, basic research result sometimes becomes privately owned intellectual property, but this is only temporary. In general, research results are published in various specialized journals as research papers that are publicly recognized as the original work of the researcher who conducted the research. At this point, the knowledge becomes public property.

It is necessary to consider whether Type 2 Basic Research fulfills the fundamental requirements of basic research. The fundamental requirements are as follows: research results should refine or add to specific knowledge regarded as the collective property of society, and it should be useful to actual societal needs although individual research does not necessarily have to have immediate purpose. With these considerations, if we were to distinguish Type 2 research from general basic research, the Type 2 body of knowledge should be different from existing scientific knowledge. Here, general basic research is referred to as Type 1 Basic Research, and the body of knowledge consists of the scientific knowledge accumulated over history. The argument that the body of knowledge of Type 2 Basic Research is different from that of Type 1 Basic research is the basis for claiming the existence of two types of basic research. Therefore, it is now necessary to clarify the difference between the bodies of knowledge of Type 1 and Type 2 research.

The body of knowledge created by Type 1 Basic Research is knowledge of the actual world. The driving motive of research is a researcher's intellectual curiosity. Physics, for example, historically began as a study of the properties of the world around us, and has been successful in consistently explaining the emergence of matter, the dispersion of matter and its historical transition in the universe, and the properties of matter both on earth and in space. Explanations were initially limited to nonliving matter, but now are being applied to life as well. Physics has achieved great success in creating a consistent body of knowledge concerning the existence and behavior of all matter on earth as well as in the universe. Being consistent means, for example, that the explanation for the light originating from a light bulb nearby is consistent with the explanation for the light emitted by distant celestial body.

Physics, however, has not explained everything. Traditionally, the academic study of nature has included chemistry, biology, geology, meteorology, oceanography, and archeology, and if human beings are included in nature as study subjects, then there are also the fields of linguistics, psychology, anthropology, sociology, economics, and cultural anthropology. These varied fields are commonly referred to academic disciplines. Individual disciplines do not necessarily use common concepts, and in general, unrelated, different explanation may be given for the same topic. Therefore, it is necessary to state precisely what "mutually consistent body of knowledge" means. This consistency is valid only within each academic discipline, and the explanations are unrelated or mutually non-interactive rather than consistent between disciplines. However, a larger movement is emerging within the field of science, where physics is expanding its scope to interactions between matter and life and the demarcations between other disciplines such as chemistry and biology are blurring. In a similar way the topic of neuroscience hints at merging with parts of linguistics. Unity, however, will not be easily attained because the situation is complex and irregular, and it is unclear whether non-interacting areas will disappear.

Type 2 Basic Research can be considered as independent form of basic research by determining whether the research defined as Type 2 Basic Research has a unique body of knowledge created under its umbrella, and if so, whether that body of knowledge is essentially different from the aforementioned body of knowledge created by Type 1 Basic Research. It is important to seek out the relationship between the two bodies of knowledge in considering the relationship between science and society, but this will not be considered here. Simply stated, the body of knowledge of Type 1 Basic Research is, as mentioned above, a system that explains or provides understanding of all phenomena that we can experience by creating disciplines that are initially non-interacting and by slowly integrating these disciplines. The motivation of the research is intellectual curiosity. If this is defined according to the same terms used for aforementioned Type 2 Basic Research, it will be:

"Creation of new knowledge by using existing knowledge of a discipline that is consistent with the knowledge of that discipline".

Here, Type 1 Basic Research is mainly considered as "normal science" as described by Thomas Kuhn [2], but it should be pointed out that what Kuhn calls the "paradigm shift" is the integration of disciplines or the creation of new disciplines which are important but particular to his theory.

Both definitions concentrate on use of knowledge, but Type 1 uses the knowledge of a single closed discipline whereas Type 2 is not limited by discipline. In general, use of knowledge in a certain discipline is formulated by experiments or by a logical thinking process, but there is no formulated method for using knowledge in multiple disciplines. Moreover, the

output of Type 1 research is knowledge, while it is an artifact for Type 2 research. If the realized output is knowledge, its validity can be logically confirmed, but if it is an artifact, its validity can only be demonstrated by actual use in society. This brings forth the following distinctions:

(1) In Type 1 research, the researcher exercises originality in selecting subjects from the body of knowledge of a given discipline and in selecting the research method, experimental or analytic, appropriate for the discipline. In Type 2 research, the researcher must establish a knowledge subset without limitation by discipline, choose the method, experimental or analytic, that enables the use of knowledge from the diverse candidates, and integrate them into a meaningful whole.

(2) In Type 1 research, the realized output is knowledge, and good results are incorporated into the body of knowledge of each discipline. In Type 2, the realized output is an artifact and good results are put to use by society.

Looking at these distinctions, it should be noted that the difference is two-dimensional. First, the way of using knowledge is different, and this leads to different activities. Second, the significance of the realized results is different, and this is the difference of the recipient. The following table summaries this concept.

As it can be seen from the table, there should be four categories due to the two-dimensionality of the system, where items (A) and (B) are blank. This is a result of historical development where Type 1 Basic Research aims for the production of knowledge, while Type 2 aims to make a contribution to society. This is also the cause of segregation between society and academia and should be dissolved. In Type 1 Basic Research, currently there are great expectations for contributions to society, but merely providing knowledge is insufficient. Recently, this expectation has been met in the form of advisory contributions by diverse researchers such as climate change warnings in meteorology or bioethical advice in biology, and this is a supplement to (A). On the other hand, Type 2 cannot be called “basic research” if it does not affect the body of knowledge, so the hole specified by (B) is unacceptable.

Here, what exactly goes in (B) must be clarified. Traditionally, in research that produces artifacts, the artifacts leave the researchers’ hands to be evaluated by society. As a result, the structure and function of the artifact become public property, but the process of realization is unrecorded and lost. Recall the first distinction. In Type 1 research, the process is formulated and shared by almost all researchers, and although there is originality in the novelty of the selected knowledge, there is no particular originality in the selection method itself. In Type 2 research, however, the selection method is far more varied with no standard, hence originality is required. Originality of the selection method is an important factor of research, because without it there will be no uniqueness of knowledge necessary to realize the original artifact. Nevertheless, there is no way to record the efforts spent in individual research. As a result, Type 2 researchers are not justly evaluated and remain unrewarded. This means the researchers’ efforts fail to become public property in society, and this constitutes a major loss to society when so much intellectual work is conducted in order to produce artifacts in enormous quantities. The elimination of this situation or the recording and systematization of knowledge selection is one way of supplementing (B).

Activity / Reception	Knowledge of a single discipline	Knowledge of an unlimited discipline
Effect on academia (body of knowledge)	Type 1 Basic Research	(B)
Effect on society (real value)	(A)	Type 2 Basic Research

There is another issue for (B). When knowledge is selected from multiple disciplines as mentioned above, steps to integrate knowledge are taken. There is no standard integration method, so originality is required in individual research. Integrated knowledge can be called “a temporary discipline”, and only when this is established, can the researcher become capable of rational thought for artifact realization. In general, the forming of this temporary discipline is a creative activity, however, it is often unrecorded and disappears. It may be named and recorded only when the artifact wins social acknowledgement from the market, but this is an exception. Heat engine engineering, automobile engineering, and aircraft engineering are relatively mature disciplines, but most disciplines have a lower level of maturity where knowledge is simply arranged linearly. Furthermore, there is nothing recorded for new artifacts in new fields. The problem is that temporary disciplines of engineering lack universality, and they not only cannot be applied to other disciplines, but their creation process is not indicated. The task necessary now is to record the original creation of the temporary disciplines of individual research while learning from past experiences of such creations, and then to seek a universal method. This is the issue of (B).

Only when these issues are resolved can Type 2 Basic Research be called true basic research. This new journal, a collection of original papers of Type 2 Basic Research, attempts to resolve the issue.

4 Original paper of Type 2 Basic Research — Characteristic of the journal

Although it has not been pointed out clearly so far, decision of the knowledge selection method, the selection of

knowledge, decision of the method of using the knowledge, the integration of knowledge from different disciplines, and the creation of temporary disciplines are all synthetic actions, and if divided into broader classifications of logic such as deduction or induction, it is hypothesis formation or a process of logical abduction[Term 1)]. In other words, there is no guarantee for the uniqueness of the results. This is an essential quality of synthesis or "making something". There is neither a guarantee for the validity of the synthesized artifacts, nor optimality. In general, a guarantee is granted by a process different from synthesis. For example, the derivation of a principle in theoretical research is synthesis, but its validity is verified by deductive analysis of its consistency with existing theory and by induction through experiments. For artifacts, this is verified by actual use in society. From this perspective, Type 1 Basic Research is totally different from Type 2 Basic Research. Considering the logical structures of Types 1 and 2 research, they both include abduction, but the importance of abduction is greater for Type 2 research through all stages of the research process. Furthermore, in Type 1 Basic Research, the verification process is done by researchers themselves or by other researchers in the same discipline, but in Type 2 Basic Research, it is demonstrated in society, which is unrelated to the world in which research is conducted.

There is uncertainty in whether processes including abduction will succeed or not, and since this is where originality is called into question, differences in verification demonstrate differences in the evaluation of originality. In Type 1 Basic Research, the originality of knowledge newly acquired as a research result is measured by the scale of contribution it makes to the existing body of knowledge, and the processes in reaching the transient hypothetical stage fades into the background and is not evaluated. In Type 2 Basic Research, the research result is evaluated after it is realized as a product by industry and is used by society, but this takes time, and there is no evaluation at the time the research result is obtained. Therefore, a different evaluation method or the "validity of abduction[3]" must be used. Points to be evaluated include the concept of societal contribution, the decision of knowledge selection method, the selection process and result, and the creation of a temporary discipline; these are all part of the abduction process. The original papers of Type 2 Basic Research submitted to this journal record these in detail, and the knowledge contained within will become public property and be evaluated at the same time. This evaluation is that of the validity of abduction, and the mission of the journal is to formulate it.

Even in Type 1 Basic Research, the same problem arises as the importance of advice to society is recognized. Selection of background knowledge, when it was decided that advice was necessary, and application of knowledge from the discipline are abductions that determine the originality of the advice. Since a final evaluation depends on use of advice by society, the evaluation of the validity of the abduction process is sought at the moment advice is given.

The papers submitted to the first issue are original papers diligently written by researchers based on a certain agreement on what is Type 2 Basic Research reached after numerous discussions on the topics mentioned herein, while taking into consideration the history of the institute and its undertaking of Full Research since 2001. The authors communicated interactively with the first-appointed referees of the journal, and the concept of an original paper of Type 2 Basic Research evolved. Now, the journal is finally being published. Although there is no standard definition of what exactly constitutes Type 2 Basic Research as mentioned in the previous section, please note that a common method is used. The validity of a set societal contribution is stated, scenarios for its realization are portrayed, the knowledge selection method for executing the scenario is proposed, and though not explicit, the temporary discipline in which the selected knowledge will be used is created. Some Type 1 Basic Research is also conducted in the created temporary discipline. Here, there are four synthetic procedures as mentioned previously, so there is quadruple abduction. Their statements, portrayals, proposal, and creation methods and contents vary by paper, but these are distinctly different from traditional expressions such as formation, skills, customs, and formalities, clearly expressing the logical structure of the research procedures.

Terminology

Term 1: abduction: (Logic) A syllogism or form of argument in which a hypothesis is accepted that, if true, would best explain the relevant evidence.

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Mass preparation and technological development of an antifreeze protein

— Toward the practical use of biomolecules —

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[Translation from *Synthesiology*, Vol.1, No.1, p.7-14 (2008)]

Antifreeze protein isolated from the blood serum of Arctic and Antarctic fish is an extraordinary biomolecule that binds to ice and preserves cell structure. We recently discovered that Japanese edible fish species also contain an antifreeze protein, and established a method of isolating the protein from fish muscles. We determined that the isolated antifreeze protein consists of a mixture of many isoforms that together are more active than any single isoform. Mass preparation of antifreeze protein is currently under investigation to provide material for a variety of studies and industries.

Keywords : Antifreeze protein, 3D structure, ice-binding, mass preparation, cell preservation, ice nucleus plate

1 Objective

Antifreeze protein (AFP) can inhibit ice-growth by accumulating on the surface of ice nuclei formed in near-freezing water, and can preserve cell function under hypothermic conditions (-0 °C). The objective of this study was to develop new technologies so these properties of AFP can be applied in industry and medicine. Figure 1 compares the principles of current cryotechnology without AFP and the expected cryotechnology utilizing AFP. Common perception is that water freezes at 0 °C; however, spontaneous freezing at 0 °C hardly occurs when liquid water is placed in cold environment such as in the refrigerator (-18 °C). Unfrozen water below 0 °C is generally called supercooled water [1]. Freezing is triggered by natural formation of numerous ice nuclei in supercooled water (Figure 1A, top). The generated ice nuclei successively undergo crystal growth by adsorption of surrounding water molecules, and finally occupy the whole space (Figure 1A, bottom). Thus, a common block of ice is inevitably polycrystalline and not a single crystal of water molecule.

The temperature range between -7 °C~0 °C is generally called the “zone of maximum ice crystal formation”. This means that within this temperature range, water-containing materials such as foods, cells, and tissues rapidly develop internal ice crystals [2]. Since rapid growth effectively destroys the inner structure of the materials, this temperature zone is not preferable for freezing storage. Conventionally, this problem was overcome using deep freezers that operate at - 60 °C ~ -80 °C or liquid nitrogen (LN_2, -196 °C), as they reduce the exposure time of the materials to temperatures that promote ice crystal formation thereby minimizing crystal formation (Figure 1B). The minute ice crystals that form at these lower temperatures do not effectively destroy the internal structure and allow preservation of quality and/or activity of these materials in the deep freezer or LN_2. Special refrigerators that mechanically inhibit ice crystal growth have also been developed.

Although these techniques are useful in sample preservation, they generate carbon dioxide (CO_2). Global reduction of CO_2 is a priority in addressing global warming. In seeking an alternative cryopreservation strategy, we began considering

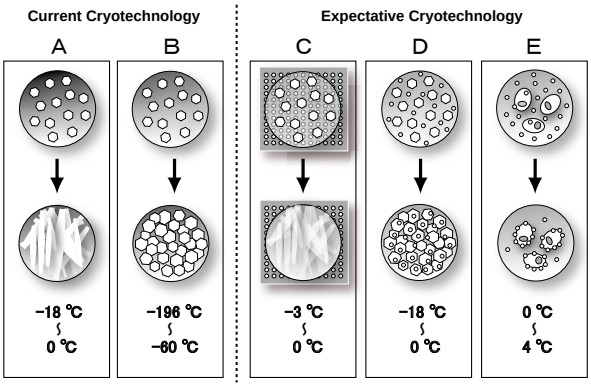

Fig. 1 Comparison between current and expected cryotechnologies.

Large circles in panels A~D represent supercooled water, and small hexagons indicate ice nuclei. The small circles shown in panels C~E represent AFP. Two large squares illustrated in C represent ice-nucleation plate by assembly of AFP. Large circle in E represents cell-preservation fluid containing AFP. A: Infinite numbers of ice nucleus are naturally created in supercooled water between -18 ºC and 0 ºC in a general freezing device. Each ice nucleus undergoes crystal growth, and the resultant polycrystalline occupies the whole space of water. B: Use of extremely low temperature (-196 ºC to -60 ºC) can effectively inhibit ice crystal growth, although it needs high-energy cost. C: AFP-assembled plate effectively freezes the attached water near 0 ºC. D: AFP can inhibit the ice crystal growth strongly even in general freezing device. E: AFP increases the viability of various cells near 0 ºC.

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AFP. For example, an AFP-assembled plate (Figure 1C) may be capable of ice-nucleation, enabling efficient freezing of attached water near 0 °C (Figure 1A). Strong inhibition of ice growth by AFP in home freezer (Figure 1D) and cell preservation with AFP near 0 °C (Figure 1E) [3, 4] also suggests the potential for AFP as an environment-friendly cryotechnology.

Since large amounts of AFP are required to achieve this goal, we conducted studies to develop a mass preparation method for AFP. In addition, we explored the potential of AFP in sample cryopreservation for industry and medicine.

2 Background

Organisms produce a variety of proteins with various functions including metabolism, transportation, storage, structural formation, and immunoreaction. Many enzymes are utilized commercially and medically. Proteins recovered from extreme environments including volcanoes, hydrothermal vents, deep sea, deserts, polar regions, and certain hazardous materials have industrial potential. AFP is an example of such protein. AFP was discovered in 1969 in the serum of Antarctic cold-adaptive fish [5]. Similar ice crystallization inhibition is demonstrated with biosurfactants [6] and poly vinyl alcohol [7], but their property (determined as thermal hysteresis activity [3]) is markedly weaker than that of AFP.

Modern technological developments have dramatically improved instrument sensitivity, reducing the amount of sample needed for experimental determinations. For example, 1 μg of protein is sufficient to analyze amino acid sequence and few milligrams enable determination of three-dimensional (3D) structure by employing nuclear magnetic resonance and X-ray diffraction techniques. Biochemically, 10~20 mg of protein represents a large amount [8], and techniques that yield quantities in grams or kilograms were not considered a priority. However, such quantities are necessary to enable AFP research to advance its utility in different fields such as engineering, medicine, and food technology.

Biotechnology has long been concerned with large-scale purification of target proteins [9]. Genetic engineering combined with large-scale culturing of the transformed cells has achieved production of commercial quantities of several proteins such as cold temperature active enzymes used in laundry detergent, starch processing, pharmaceutical proteins, diagnostic antibodies, and bio-ethanol. However, large-scale preparation of genetically engineered proteins is difficult [9]. Recognizing these continuing challenges, we decided at present it would be most prudent to consider other methods such as chemical synthesis and purification to mass-produce AFP from natural sources.

3 Scenario

Researchers from many different fields including biology, biochemistry, molecular biology, ice physics, biophysics, structural biology, and computer chemistry have studied AFP, and many papers have been published in reputable journals. Potential applicability of AFP in industrial and medical fields has been suggested [10]. However, this potential has not yet been realized. Production of AFP still involves using needle and syringe to collect the protein from serum of live fish. This arduous method and low product yield are reflected in the high purchase price of AFP (approximately USD 10/mg).

Typically, AFP is collected on-site (during Arctic fishing) and transported south. However, we have observed that fish near Japan (~43 ºN) also produce AFP [11]. To investigate this

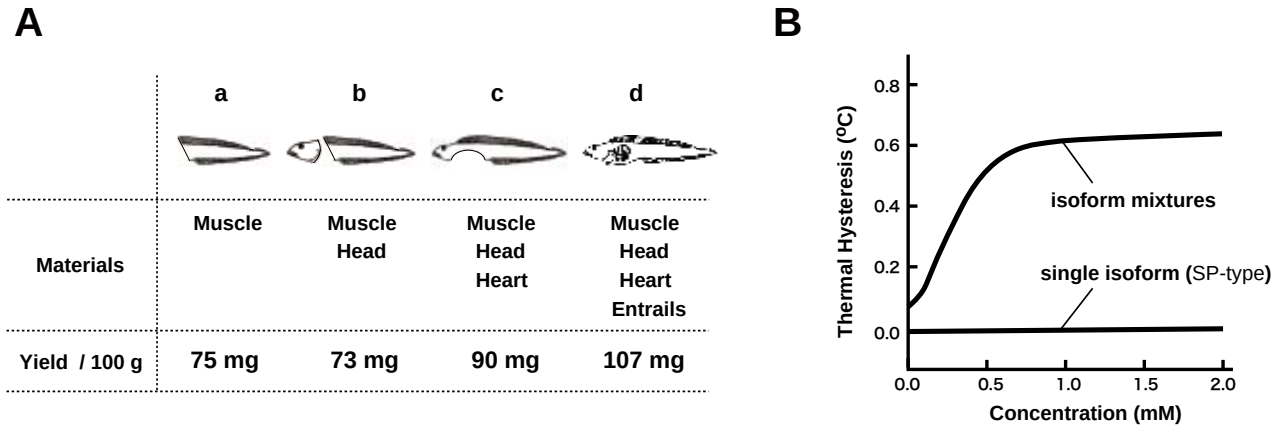

Fig. 2 Yield and antifreeze activity of AFP.
A: Results of total purified AFP (yield) per 100 g of different portions of an AFP-containing fish (material). B: Dependence of thermal hysteresis activity (i.e. antifreeze activity) on AFP concentration. A less active AFP isoform (SP-type) exhibits a substantial level of activity by addition of small amount of active AFP isoform [12].

further, we conducted an extensive survey of cold-adapted organisms in Japanese coastal waters with assistance of the Marine Bio-Institute of Sapporo Medical University and the Federation of Fisheries Cooperative Association of Notsuke. Various samples were also purchased from food stores and insect shops in Sapporo City. AFP activity was assayed using a photomicroscope system that enables detection of the ice-shaping ability using only 1 μL of sample [11]. Over 160 species of Japanese fish were examined, of which at least 50 species contained AFP. In addition, AFP was found in tissues of Japanese plants (wheat), insects (stag beetles), and fungi (basidiomycete).

Interestingly, AFP activity was detected in fish fillets, minced fish, and dried fish purchased from food markets. On detailed examination, it was found that AFP could be purified from fish muscle as well as from serum (Figure 2A). The figure shows that larger amount of AFP was purified from samples obtained from heart tissue. Since presence of high amounts of contaminants such as lipids, enzymes, and sticky substances necessitated additional purification steps, which lowered the preparation efficiency of AFP, fish muscles may represent the best choice for mass preparation of AFP.

AFP isolated from the Japanese fish was compared with the established version recovered from cold-adapted polar species for DNA and amino acid sequences, 3D structure, and ice binding ability. Although these analyses are ongoing, so far it was found that the amino acid sequences were similar, allowing their grouping as Types I~III. Similar result was also obtained for AFP from Japanese insects. Every Japanese organism expressed AFP as isoform mixture, as was the case for AFP from polar organisms. Especially, sample of eelpout (a species that lives off the east coast of Japan) was found to produce at least 13 isoforms of type III AFP. Initially, the presence of such large number of isoforms was perplexing. However, isoform mixtures of AFP possess higher antifreeze activity (thermal hysteresis) than single isoform [12]. Even an isoform with poor individual activity displayed enhanced activity in the presence of small amount of higher activity isoform (Figure 2B). Such cooperative enhancement was also identified for cell preservation activity of AFP in hypothermic conditions [13]. One should note that it is difficult to produce isoform mixture of AFP by genetic engineering and chemical synthesis.

The above findings prompted the scenario summarized in Figure 3 for practical use of AFP. The characterization and functional analysis of Japanese AFPs define the direction of the development of AFP technology (Figure 3A). Next, preparation of relatively large amounts of AFP isoform mixture can be achieved using fish muscles as raw material (Figure 3B). The isoform mixture can be used to perform various tests (Figure 3C), and holds potential for scale-up to industrial quantities.

4 Factors that determine technology

Highly purified sample is indispensable for research. In contrast, even poorly purified sample is generally sufficient for industrial and commercial use. In fact, enzyme used in detergents and food processing is partially purified product of cultivation [9], offering an attractive saving in preparation costs. Partially purified AFP can also be utilized in food industry and in ice slurries, since AFP functions in a solution containing large amount of impurities. In the rules and regulations of the Japanese food industry, partially purified AFP is categorized as natural extract while highly purified AFP is considered food additive. The former can be applied directly to various foods after careful safety check

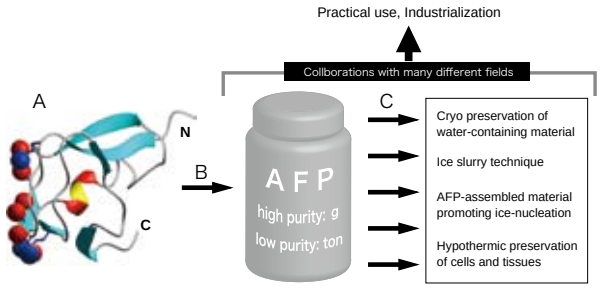

Fig. 3 Example of "Full Research" for AFP.
A: Biochemistry and molecular biology of AFP (Type 1 Basic Research). The ribbon representation shows a structure of type III AFP (PDB code = 1MSI) where polar atoms colored in red and blue constitute an ice-binding surface. B: Development of mass preparation technique of AFP (Type 2 Basic Research). C: High yields of AFP allow research collaborations with researchers from different backgrounds, leading to practical use and industrialization of AFP.

	A	B	C	D	···
Activity	++	+	−	++	
Resource availability	−−	++	−	+	
Molecular size	−	+	++	−	
Structural rigidity	++	−−	++	++	
Infrastructure	−−	++	−−	+	
Acid/alkaline tolerance	++	−	−	++	
Heat Stability	++	++	++	−−	
⋮					

Fig. 4 Evaluations of factors such as activity and resource availability for AFP species (isoform mixture) from fish A, B, C, and so on, needed for technological developments.
We divided the evaluation results into four grades: ++ (excellent), + (good), − (poor), and −− (very poor) (see text). The evaluation for element indicated by thick-framed box is an ordinary biochemical study. Activity and resource availability are found to be especially important for advancing the technological developments of AFP.

based on experience and knowledge of the manufacturing company, while the latter requires stringent tests before approval. This implies that highly purified AFP cannot be used for all technologies utilizing AFP. On the other hand, highly purified AFP is indispensable for preparation of cell preservation fluid or AFP-assembled ice nucleation plate (see below). Any initial examination of AFP, even in food technology, requires highly purified AFP to obtain detailed information of its effects. Therefore, in this study, we focused on the technological developments of both crude and highly purified AFP. Commercial use of the crude form would require production capacities in tons.

Technological developments are in progress according to the information shown in Figure 4. The columns show the species of fish (source materials) that contain AFP as mixture of isoforms, and the rows (such as activity and resource availability) are the factors needed for technological developments. The initial step of development is to deduce the activity of AFP sample from "A" (indicated by thick-framed box). In this step, sequential determinations and activity assay are done by preparing minute amount of sample, which provides evaluations for rows in column A (excellent [++], good [+], poor [–], and very poor [––]) with regard to technological developments. Further examinations for molecular size, 3D structure, acid/alkaline tolerance, heat stability, as three examples, are undertaken. Smaller molecular size, rigid structure, high acid/alkaline tolerance, and high heat stability are preferred in AFP technologies. This approach is similar to the one used in biochemical evaluations of sample. A noticeable point is that Figure 4 contains information that are irrelevant to academic research such as evaluations regarding the availability of natural resources and infrastructure (e.g. fishermen's union, fish sausage factory, storage warehouse, and marketing channel). However, all such information are important determinants for technological developments. In case of Figure 4, AFP from A will not become a target of development since its resource availability is very poor even though it has excellent activity. In contrast, AFP from B becomes the target although its activity is inferior to AFP-A, since sufficient resource availability compensates for the inferiority. For AFP-B, mass preparation method as well as AFP technology can be developed by utilizing its high thermal stability. AFP-C and AFP-D can also be developed since their resource availabilities are adequate. For AFP-C, poor infrastructure availability may raise the product cost. Although the significance for development of various factors differs, it may be concluded that availability of source material as well as activity are the principle determinants of technological development.

We tried to update Figure 4 based on the increasing knowledge of AFP, which is reflected in the increasing number of columns with time. The factors in the row will also be appended with time concerning safety (toxicity), shelf life, and recyclability of AFP as three examples.

5 Results

Figure 5 summarizes the elements relevant to mass preparation of AFP, such as AFP species (source materials),

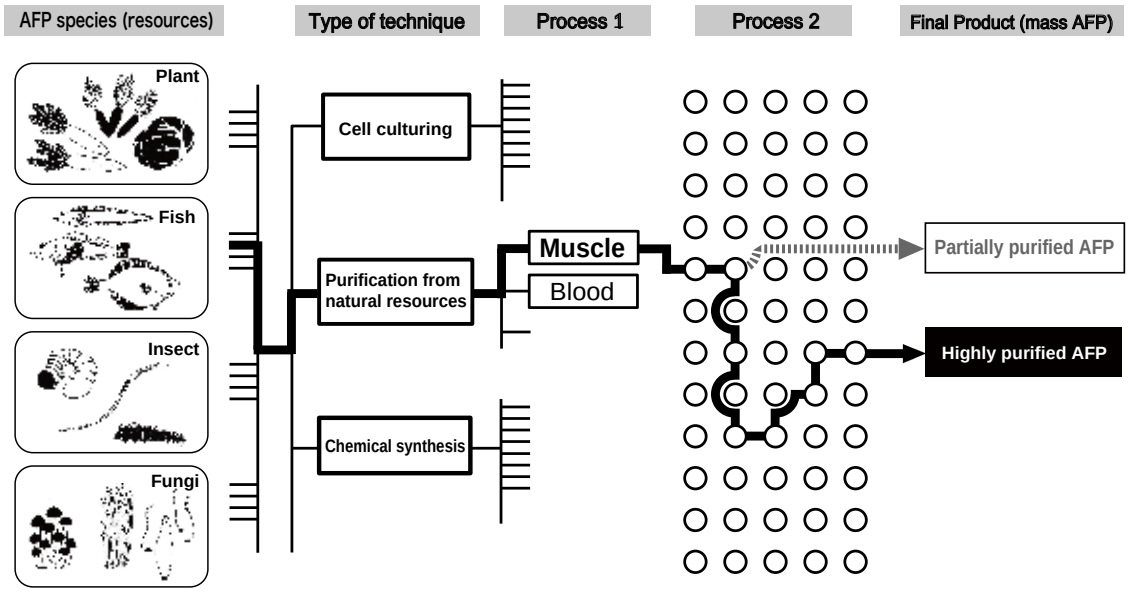

Fig. 5 Procedure for obtaining mass amount of AFP (thick arrows), which can also be used for collaborative studies and industrialization.

Open circles (○) shown in Process 2 indicate detailed methods to purity AFP such as heat denaturation, centrifugation, filtering, and chromatography. Initial methods in Process 2 are common for both partially and highly purified samples of AFP.

technique, and purification processes. The arrows connect our present choices of elements, thereby indicating procedures to obtain highly purified AFP (thick arrow) and partially purified AFP (broken arrow). The open circles (◯) indicate detailed methods to purity AFP such as heat denaturation, centrifugation, filtering, and chromatography, which were carried out using suspension fluid of minced muscle of AFP-containing species of fish. These methods were initially chosen based on Figure 4 and were further optimized by considering cost and time required to improve the preparation efficiency. Removal of certain procedures and rearranging others also contributed to improvement. For example, high-performance liquid chromatography (HPLC) was not selected because of its inefficiency and high operational costs.

As described, we chose AFP-containing fish as source material. After considering the quantity of fish resources and their price, we selected three species of edible fish which were captured at a fishery located on the east coast of Hokkaido and for which involvement of AFP types I~III were identified in our laboratory. These fish were not captured as merchandise but were "by-catches" of scallops and shrimps (i.e. they were food for by-catch fish). The by-catch fish are typically discarded as they have no market value. We were able to secure at least three tons of by-catch fish during the winter. Minced muscle was transferred to a cold storage warehouse for storage, and samples were transported to the laboratory as needed. For type III AFP, our efficiency of purification was approximately 3 g (99 % purity)/5 days/1 person. The collaborating company prepared crude AFP samples at 200-times higher efficiency than our laboratory, but this was still not the achievable upper limit. Figure 6A shows the appearance of approximately 10 g of high purity sample of type III AFP. Currently, we have amassed 240 g with market value of approximately USD 3 million. Raw material and preparation costs were extremely low.

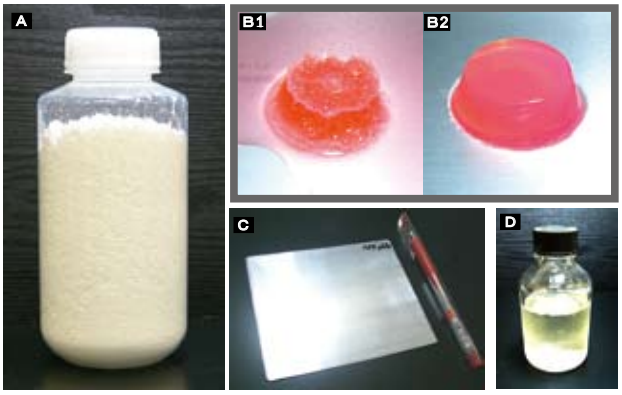

Fig. 6 Outcomes of the present study.
A: Approximately 11 g of highly purified type III AFP. The preparation efficiency of this sample is 3 g/5 days/person. B: Photographs of agarose gel in absence (B1) and presence of AFP (B2) after cold storage (-18 ºC). Addition of AFP can provide freeze tolerance to many water-containing materials. C: AFP-assembled aluminum plate that exerts ice-nucleation function. D: Cell preservation fluid containing AFP, which dramatically improves cell viability under hypothermic condition (0 ºC).

Acquisition of gram quantities of AFP enabled us to examine the cryopreservation effect of AFP on various water-containing substances such as processed food, soups, ice-sweets, noodles, bread, soft drinks, alcohol beverages, drugs, cosmetics, inks, polymer gels, polymer membranes, vegetables, fruits, seeds, meats, and seafood. Although the examinations are not complete, in principle, they are expected to become freeze tolerant by addition of AFP. For substance such as meat whose inner structure is complex, it is difficult to transfer AFP internally. Once the meat is minced, however, distribution of AFP is facilitated, and freeze tolerance can be expected.

Figure 6 shows some examples. Figure 6B1 is a photograph of agarose gel after overnight storage at -18 ºC in a home freezer. As frozen gel began to thaw, water flowed out from the inside of the gel. This occurred because the agarose network of gel was destroyed by growth of ice crystals (Figure 1A). Similar phenomenon was observed in the thawing of frozen meats, fruits, and vegetables, and this water flow is called drip in meats. We found that addition of slight amount of AFP effectively preserved the inner structure of frozen gel and stopped the water flow, as shown in B2. This was attributed to the inhibition of ice crystal growth by strong binding of AFP to crystal surface (Figure 1D). It should be noted that strong preservation effect of AFP was observed in the temperature zone of maximum ice crystal formation, between -7 ºC and 0 ºC, implying that AFP can replace LN_2 for high quality preservation of water-containing materials, and this may further save energy and reduce CO_2 emissions.

In this study, type III AFP was chemically or physically immobilized on a surface plane of metal by spraying a solution of highly purified protein (Figure 3). This type of AFP can form an ice-binding surface (represented by red and blue CPKs in Figure 3A), which binds specifically to a set of oxygen atoms of ice crystals [14]. This ice-binding site is located on the opposite side of the N-terminal end of this molecule. Given this knowledge, we assumed that if we connected the N-terminal end of type III AFP to the metal surface, the ice-binding surface would be directed outside of the metal surface. When performing this experiment, numerous AFP molecules should, in practice, be connected to the metal surface in that manner, creating a fairly large ice-binding surface on metal due to assembly of type III AFP molecules. Our assumption is that such large ice-binding surface will cause the assembly of ice-like structure in water placed on the surface. In other words, the AFP-assembled surface will have ice-nucleation function. Figure 6C is a photograph of an aluminum plate on which approximately

6.0×10^{11} type III AFPs were assembled per square cm. Detailed descriptions of this experiment will be presented in a separate paper. Here, we show some of the results. First, a droplet of water placed on the AFP-assembled plate froze at approximately 5 ºC higher temperature than the unassembled plate, consistent with ice-nucleation ability of the surface. Second, unidirectional freezing occurred from the surface of AFP-assembled plate, which led to formation of extremely clear ice. AFP could be assembled not only on flat metal surface but also on curved substances and particles in various sizes.

Figure 6D is a photograph of cell preservation fluid containing AFP. Human and animal cells could not maintain their functions in vitro for a prolonged time. In the fields of organ transplant and regenerative medicine, tremendous efforts are spent to achieve long-term preservation of cells and organs in both frozen and unfrozen states. Earlier in this report, we explained the effectiveness of quick-freezing using very low temperature (e.g. LN_2) for preservation of frozen substance (Figure 1). Here, we briefly report our results of cell preservation in unfrozen state, which will be useful in 1~21 day period before transplantation of cultured cells. We attempted to preserve approximately 10,000 unfrozen (0 ºC) human hepatoma cells (HepG2) without AFP. Ninety percent of the HepG2 cells died within 12 h using commercially available preservation fluid. In contrast, AFP-containing preservation fluid (Figure 6D) preserved 90 % of the HepG2 cells even after 72 h [13]. This preservative effect of AFP was also identified in cell lines of small intestine, kidney, umbilical cord, blood, cervix, and pleural effusion. Gram quantities of highly purified AFP were sufficient to examine the preservation effect on cells, but were insufficient for tissue and organ examinations. Further study is necessary to overcome this problem.

6 Future development

Amount of protein that may produce superior performance at molecular level can be insufficient for practical use. In other words, quantity has been a hindrance for expansion of basic research into practical technology. In the case of AFP, the ability to generate grams of product enables collaborative advances in different fields such as food, medicine, and engineering. More collaborations are expected, and product utilization of AFP is becoming a reality. We note with interest that the currently reported technique that brings the benefits of lowered energy consumption and CO_2 emission is derived from the classical extraction of target protein from natural resources. At the same time, our technique utilizes advanced studies from molecular biology to 3D structural analysis.

Applications of AFP in medical fields will require approval from the appropriate government agencies concerning aspects that include toxicity, mutagenicity, and carcinogenicity. These approvals may require time. It will also be necessary to construct AFP preparation facility that satisfies the regulation of Good Manufacturing Practice (GMP). Although much remains to be done, this study is an encouraging start.

In addition to applications in food industry, partially purified AFP may be used in the cold storage systems in office buildings. Most air conditioners work by lowering the temperature of a building through circulation of refrigerant. Replacement of refrigerant with ice slurry would save energy while maintaining the same level of air conditioning. Partially purified AFPs would prevent aggregation of ice slurry that often occurs during circulation.

Many biological compounds including antifreeze proteins have potential industrial applications. However, sufficient quantities of these compounds are required for research to further investigate their applications. AFP is one example. Bio-ethanol is another. This study was primarily based on the functional analysis of protein from organisms of Hokkaido. In July 2008, the G8 Summit was held at Lake Toya in Hokkaido. We would like to contribute to reducing global warming through our technologies.

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Discussion with reviewers

1 Quantitative Aspects

Question (Koichi Mizuno)

With regard to the ice-nucleation ability of AFP-assembled aluminum plate, is it possible to numerically quantify the superiority of this plate compared to other materials for freezing water near 0 °C?

Answer (Sakae Tsuda)

It is very difficult for us to give concrete answer to your question. Suppose that our plate can freeze a 1 mL water droplet at -1 °C, for which -18 °C of Tf was evaluated when the plate was not used, we need to evaluate the amount of energetic barrier which causes ice-nucleation in a water droplet. This energetic barrier, however, depends on many parameters, such as cooling rate, environmental perturbations, and contaminants, which can hardly be evaluated. As for difference in potential energy, approximately 40 J is estimated for 1 mL of ice crystal between -18 and -1 °C. Please note that we avoided complete descriptions of the performance of our developments due to future patentability.

2 Cell preservation ability

Question (Koichi Mizuno)

Did the authors attempt preservation of hepatocells (HepG2) near 0 °C without freezing them? The fact that 90 % of HepG2 cells die in 12 hours using commercial fluid seemed to me that 0 °C is not suitable for cell preservation. I imagine that AFP may be having some biological influence on the cells. Has detailed mechanism of such influence been clarified?

Answer (Sakae Tsuda)

The method to preserve cells and tissues from heart, liver, and kidney for 1~24 hours near 0 °C without freezing has actually been utilized in the medical fields, such as transplantation

and regeneration. This is called “hypothermic preservation”. It is important to have a certain period (1~10 days) before transplanting the cells to the patient, because the cells must reach culturing limit. The cell preservation activity of AFP is not common knowledge so far, since many papers report that AFP sometimes exerts no expectative activity, or performs worse than other substances. We think such uncertainties are due to insufficient amount of AFP needed to verify the reproducibility of data, and also due to imperfections in conducting this type of delicate experiments. Although some models have been proposed, it is necessary to clarify the cell preservation mechanism of AFP, and our AFP preparations in certain quantities are expected to contribute to future studies.

Development and standardization of accessible design technologies that address the needs of senior citizens

— Product design methodology based on measurements of domestic sounds and hearing characteristics —

Kenji Kurakata* **and Ken Sagawa**

[Translation from *Synthesiology*, Vol.1, No.1, p.15-23 (2008)]

With the recent trend of decreased birthrate and increased aging population, design that can be used by as many people as possible including the elderly, or accessible design, has been incorporated in consumer product designs. The authors have developed and propagated accessible design technology through the establishment of Japanese Industrial Standard (JIS) based on auditory and visual functions of elderly people. This paper uses JIS S 0014, a standard for adjustment method of sound volume of auditory signals, to describe the research process that leads to the standardization of accessible design from the perspective of Full Research.

Keywords : Elderly (older person/people), hearing, vision, auditory signal, standardization, Japanese Industrial Standard

1 Introduction

With the recent trend of decreased birthrate and increased aging population, that is, less young people and more elderly, the main users of consumer products including home electric appliances, information technology devices, and office appliances are shifting from young to elderly. Conventionally, the users were assumed to be young people when designing such products. However, in the society of decreased birthrate and increased aging population, there is more demand for “accessible design” or design that can be used by as many people as possible including the elderly.

This is not merely a superficial issue of difference in design preference between the generations. As the number of elderly users increase, there is a rising concern for cases of product misuse due to failure to see or hear information necessary to use the product correctly. Therefore, appropriate display of product use instruction to maintain high safety level is demanded ever more than before. Also, there is a tendency for the elderly to avoid using new products because they feel uneasy about using them safely. This may hamper replacement by purchase, and the entire market of the product may gradually shrink. However, looking at the situation from a different angle, this great shift in demographic structure is a good chance to pioneer a new market. Now, there is increased activity in developing new products or changing design specifications for the elderly who are new users untargeted before. Ever since 1990, interest in design method that addresses the characteristics of the elderly has been increasing in various product categories such as consumer products and office appliances.

With this social background, the authors have been involved in drafting and establishing the standards for auditory and visual functions in the Guidelines for the Elderly and People with Disabilities of the Japanese Industrial Standard (JIS)[1, 2]. In this paper, first, the significance and the necessity of accessible design standardization are explained. Next, using as example JIS S 0014[3], a standard for auditory signal of consumer products on which the authors worked to establish, the research process that leads to the standardization of accessible design technology will be discussed from the perspective of Full Research.

2 Significance and necessity of standardization

The authors have aimed for standardization through establishment of JIS and other standards ever since the start of development of accessible technology. One of the reasons is because, as elderly-friendly products started to appear in the market, confusions developed due to differences in design specifications by manufacturers or by product types, as well as to a gradual increase of inadequately designed products that carried the elderly-friendly label. The establishment of Guidelines for the Elderly and People with Disabilities series occurred due to strong requests from government and the industry that wished to improve the situation.

Aside from such a situation, there are many advantages in conducting ergonomic technology development including accessible design technology, with standardization in mind from the very beginning. First, since human characteristics are multidimensional, there are many factors to consider even when developing one technology. In case of auditory signal, aging characteristic of hearing is the subject of study, but to design sound that is easy to hear and recognize, the effects of at least three factors including frequency, sound pressure level, and time pattern must be studied sequentially. Academically, experimental condition for each

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factor can be set, and hearing characteristic can be broken down finely and studied for each condition. However, such piecemeal knowledge is not useful in actual design. The process of "integrating" individual research results into one methodology is essential for completed design technology.

Also, if the goal is the development of a technology that can be used effectively in actual practice, the result should not be researcher's self-indulgence. Design precision can be improved limitlessly by using complex design method and by creating intricate model of human characteristics. However, the more precise the model, the range of application becomes narrower. This will not lead to the development of technology that can be applied to diverse domestic environments. Moreover, good precision and usability of method often conflict with each other. Even if it is a good design technology, it is meaningless unless it is used widely in actual practice.

At the drafting stage of the standard, studies are conducted from aspects of academic accuracy and technological efficacy. The comments of on-site technologists as well as researchers are incorporated to create a standard methodology. The method standardized in this manner is expected to be used as a tool in actual design in wide-ranging fields over the long run.

3 Auditory signal of consumer product and its problem

"Auditory signal" discussed in this paper is sound emitted by the product itself or by the remote controller to notify the user of the operational status of the product. This includes sound set off as feedback when pressing a button on the control panel, sound to notify the end of action of the product, or sound to notify operation error or abnormality of the device. The usability of the product is improved and the occurrence of improper use can be lowered by appropriately designing auditory signals.

However, conventional auditory signal did not necessarily function as intended, and many became sources of claims from the users. The content of the claims can be roughly divided into two (Figure 1). (1) Cannot hear the signal: "I thought the signal went off but couldn't hear it". (2) Do not understand the meaning of the signal: "I can hear the signal, but don't know what it's supposed to mean".

In designing auditory signals, three levels of adjustment can be made acoustically: (a) frequency (pitch of sound), (b) sound pressure level (volume of sound), and (c) time pattern (time change of sound). If the auditory signal was appropriately designed on each level, aforementioned claims could have been avoided.

Inability to hear the auditory signal is a problem caused by inadequate selection of frequency and sound pressure level[4]. Human hearing declines gradually with aging. Elderly people with reduced hearing may not be able to hear sound that can be heard by young people. On the other hand, inability to understand the meaning of the auditory signals is because the signals were set off with different time patterns by product types and manufacturers[5].

To solve this problem, the Association for Electric Home Appliances proposed to establish JIS S 0013[6] in 2002 to set frequency and time pattern of auditory signals. In this standard, it was recommended that high frequency sound that cannot be heard by the elderly should not be used, and specific time pattern should be used for auditory signals with certain contents. Hence, frequency and time pattern, two of the three factors that must be addressed when designing auditory signals, were standardized.

The remaining issue was sound pressure level. If volume of the auditory signal is raised, the elderly with reduced hearing will certainly be able to hear. However, it may become a "noisy" sound for young users. Also, there is the issue of domestic sound in the place where the products are used. Auditory signal that can be heard in a quiet place may not be heard in the presence of interfering noise. Moreover, individual differences exist in the level of hearing ability, and the difference is notable in the elderly. The problem of volume setting of auditory signals was raised during the draft review of JIS S 0013, and it was an issue for which solution was strongly sought by consumer organizations and representatives of challenged people's organizations. However, the matter was put on hold since it was not easy to find an appropriate volume setting that could be heard readily by both elderly and young people in various domestic situations.

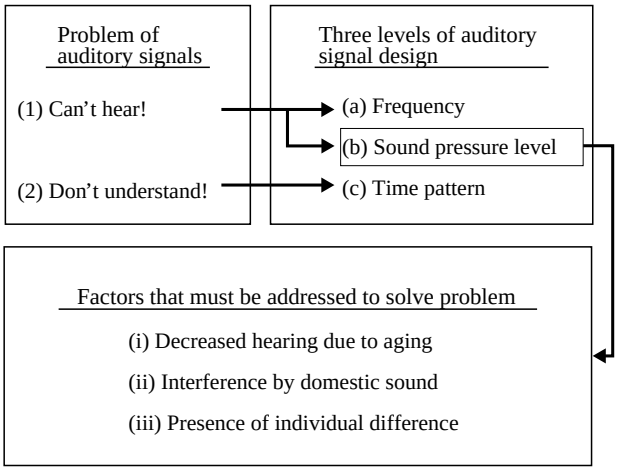

Fig. 1 Problems of auditory signals and issues to be resolved.

The authors, therefore, addressed the three factors: (i) decreased hearing by aging, (ii) interference by domestic sound, and (iii) presence of individual differences. Then, research was conducted to develop the volume setting method for auditory signals that can be heard readily by both the elderly and the young in actual domestic situations. As a result, JIS S 0014 was proposed and established.

4 Issues in development of volume setting method for auditory signals

There were several issues that had to be solved technologically for the three factors and addressed in developing the volume setting method for auditory signals. The solutions taken by the authors for each issue will be summarized using examples of some measurement results.

4.1 Accommodation of decreased hearing by aging

The volume setting method for auditory signal must appropriately accommodate the issue of decreased hearing due to aging. For young people, there is a long history of research on hearing sound in interfering noise, and the model for estimating the hearing level has been established. The sound becomes audible when the target sound level is higher than a certain level against interfering sound. Similarly, for the elderly with decreased hearing, it was assumed that whether the target sound could be heard or not can be estimated based on the difference of sound pressure level (SN ratio) of the two sounds. At that time, however, useful data that measured the least SN ratio needed for the elderly or the difference compared to young people did not exist at all.

Therefore, the authors started by measuring the hearing ability in presence of interfering sound for the elderly and young people. Figure 2 shows an example of the results. It can be seen that even under condition of the same interfering sound, the elderly cannot hear the target sound unless it was 5 dB higher compared to young people, and 10 dB for some frequencies in people with severely decreased hearing. From these measurement results, similar level of aging effect in hearing auditory signals in actual environment was anticipated.

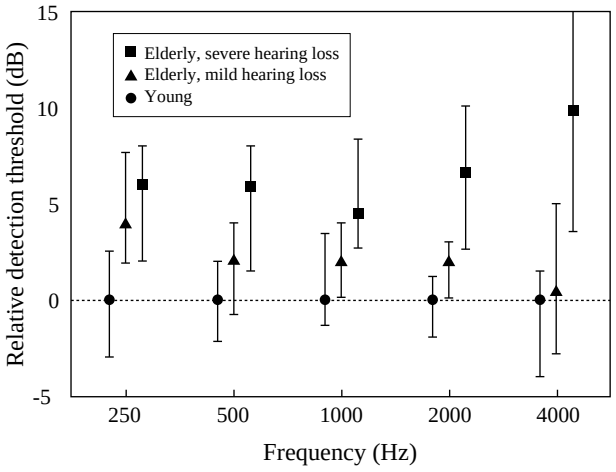

Fig. 2 Sound pressure level necessary for hearing sound in interfering sound (detection threshold).
Revised from Reference [7]. Setting young people as standard (vertical axis, 0 dB), relative increase in detection threshold of elderly people is shown.

Next, based on the above basic findings, sound pressure level of auditory signals needed in presence of real domestic sounds must be estimated. The problem was that the interfering sound used in the experiment described in Figure 2 was a relatively simple noise, but domestic sounds fluctuated in both time and frequency. The audibility of signals changed depending on type and scale of change. However, it is not realistic to experimentally investigate the auditory effect of all fluctuations. It was necessary to construct a simplified auditory model based on certain assumptions for a sound detection process.

Looking back at the researches in which the authors were involved pertaining to detection of sound from noise[8, 9] and basic research on hearing characteristics[10], it was projected that average energy content, rather than fine time fluctuation in sound, had greater effect on many auditory phenomena. Therefore, it was hypothesized that auditory signals could be heard when the ratio of average volume of auditory signal and interfering noise (SN ratio) surpassed a certain value (this was defined as “minimum value”).

Also, the level that could be heard clearly by the elderly with decreased hearing should be attained when the volume of auditory signal was raised above this value. Experimental investigation confirmed that the elderly perceived the sound just as loud as young people when the sound reached a certain level[11]. This sound level was defined as “maximum value”. By setting the sound pressure level of the auditory signal so it would fit between the minimum and maximum values, the model was simplified for designing auditory signals that could be heard at appropriate level even in the presence of fluctuating interfering sound.

The validity of the hypotheses as well as maximum and minimum values were investigated and measured by hearing

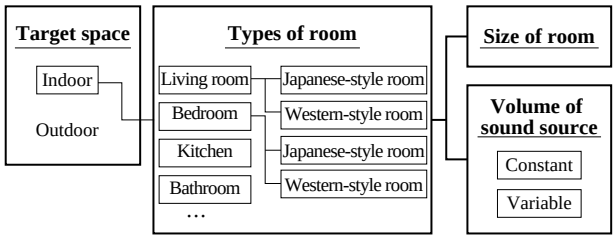

Fig. 3 Range of domestic sounds targeted in domestic sound database JIS TR S 0001[12] and factors considered.

experiment described in Section 4.3.

4.2 Accommodation of interference by domestic sound

The places where users use products are varied, and environmental conditions differ greatly. Even if the sound can be heard in a quiet laboratory, if it cannot be heard in an actual use situation, an auditory signal is not appropriately designed. The desired optimal volume needed for auditory signals differs according to the acoustic characteristics such as loudness of interfering noise, structure of frequency component, and time fluctuation. However, it is practically impossible to cover all product use situations and to establish volume setting method for every noise generated. Therefore, it is necessary to simplify the acoustic characteristics of domestic sounds that may be generated in the environment in which the product is used, and create a model that can be verified.

Therefore, prior to the proposal of JIS S 0014, various domestic scenes were assumed and domestic sound database JIS TR S 0001[12] that described the acoustic characteristics of typical noise generated in those scenes were compiled. The range of domestic sounds subject to measurement and the factors addressed are summarized in Figure 3.

First, space that will be the subject of study was limited to indoors. Products such as cameras are used both indoors and outdoors, but measurements would increase infinitely if outdoor environment was included. Considering the fact that many consumer products are used indoors, the subjects were limited to sound generated indoors. However, even by limiting the subject indoors, there are several rooms with different noise levels in a house like living room or kitchen. Moreover, sound difference in Japanese and western style rooms could not be neglected.

Volumes of the rooms differed. In a large room, the level of domestic sound differed depending on the location within the room. Therefore, in creating the database, measurements were taken in different locations of the room, and the effects were also described. Also, there were sound sources where volume greatly changed according to the manner of use such as sounds of water in the kitchen or television in the living room. For water sound, measurements were taken at several water volume levels, and for television sound, volume preferred by the elderly was measured in a separate experiment[13].

As a result of the measurements, the database contained over 350 measurements data for 16 types of domestic situations. An example of analysis of domestic sound entered in JIS TR S 0001 is shown in Figure 4. In case of domestic sound, the variation in acoustic characteristic due to differences in houses could not be neglected. Therefore, the database also shows the distribution of measurement values as shown in Figure 4[14]. By using this database, it is possible to study the degree of difference of noise characteristic in each domestic situation, or the degree of variation of characteristic due to differences in houses.

In general, one would imagine that the domestic sound characteristic would differ greatly if the houses were different. However, as shown in Figure 4, if limited to a single measurement situation, variation due to houses was only about 10 dB (see the interval between 5 percentile curve and 95 percentile curve in Figure 4). Rather, the characteristic difference between sound of particular measurement situation and another (for example, between water sound of sink and volume of TV in living room) was greater. Therefore, the sound of individual domestic situation was represented by frequency characteristic at 50 percentile value (see Figure 4), and it was assumed that domestic sound produced at home could be covered by selecting several typical domestic situations. Using various selected domestic sounds, auditory signal level that could be heard readily was investigated in an auditory experiment described below.

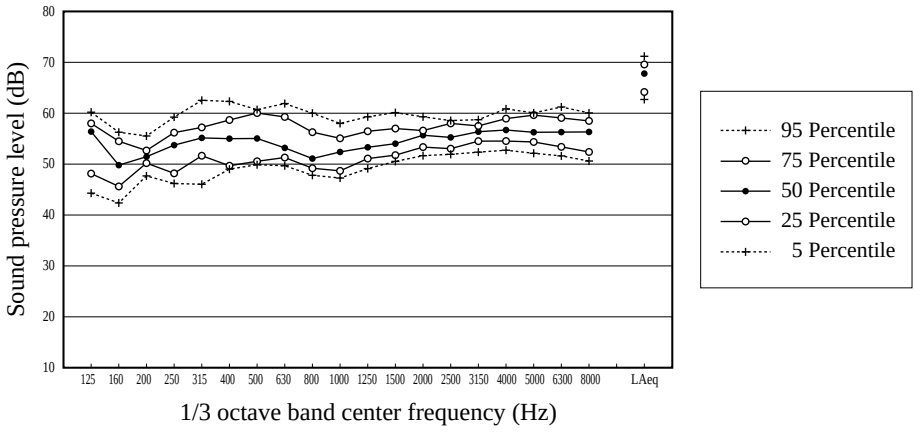

Fig. 4 Example of analysis diagram of domestic sound database TR S 0001[12] (sound of washing dishes in sink).
Shows the distribution of measurement values in several houses.

4.3 Accommodating individual difference

Based on the investigation in Sections 4.1 and 4.2, appropriate volume setting method for auditory signals could be established by calculating minimum and maximum values of sound pressure level of auditory signals that could be heard in interfering sounds. The last issue remaining was "individual differences". There were individual differences in human perception. Moreover, individual differences increased with age. Therefore, standard value applicable to the elderly could not be found by simply staring at the average measurement data. The proposed volume setting method could not be accepted as standard method unless it could be proven that it satisfied the characteristics of adequate percentage of the elderly. Therefore, it was necessary to experimentally confirm the possibility of universal application of the proposed method by accurately obtaining various measurement values to estimate the statistical distribution of individual differences.

In this study, what percentage of people could hear the auditory signals at which level of volume setting was measured in auditory experiment using several typical home domestic sounds (see Section 4.2). Young people, as well as the elderly, participated in the measurements to compare the differences in hearing characteristics of the two groups. Based on the statistical distribution of the measurement values obtained for the two subject groups, the level of auditory signals that could be heard by adequate percentage (for example 95 %) (minimum value), and the level which was judged "can be heard well" (maximum value) were estimated for each group. As an example, part of measurement results using the maximum value estimate (in case of 1,000 Hz auditory signal) is shown in Figure 5.

In this measurement, elderly and young groups rated the audibility of the auditory signal in 5-step evaluation. The marks in the figure show the rating value at about 95 percentile from the top for each group. For example, in the condition marked with "arrow," 95 % of the subjects in each group responded "4: Can hear well" or "5: Can hear very well" in measurement condition using certain domestic sounds. In another word, response of "3: Neither" or lower was less than 5 %.

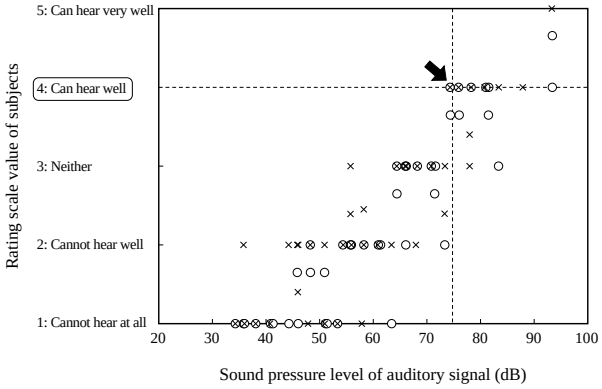

Fig. 5 Example of rating result to obtain maximum value for auditory signal (for 1,000 Hz auditory signal).
○: Elderly group ×: Young group

In this figure, "4: Can hear well" rating values (points above horizontal dash line in the figure) are distributed in the range above 75 dB (vertical dash line in the figure) sound pressure level for auditory signals. That is, in both subject groups, the percentage of subjects who responded "can hear the auditory signal well" at all measurement conditions dropped below 95 % when the auditory signal level was below 75 dB. Conversely, if the auditory signal was above this level, the percentage of subjects who missed the auditory signal would decrease further, but more people would perceive it as being "annoying", so it was not appropriate as volume of auditory signal of products used daily. Therefore, maximum value of the auditory signal was set at 75 dB. For minimum value, similar estimate was conducted for auditory signals of various frequencies based on the results of the auditory experiment.

Overlooking the above analysis results, maximum and minimum values could be set at a certain value in any auditory signal frequency or in any measurement condition using any domestic sound. This confirmed the validity of the auditory model created in Section 4.1. Since the interfering sounds used in the measurements covered almost all characteristics of domestic sounds (Section 4.2), the results of this measurement study should apply accurately to actual domestic situations.

The experiment inevitably increases in scale as measurement data are analyzed statistically to address individual differences. In fact, Figure 5 is based on total 5,600 items of data for 80 elderly and young subjects listening at 70 different condition types. Such large-scale measurement result is the basis for setting the minimum and maximum values for auditory signal volume[15, 16].

5 Volume setting method for auditory signal by JIS S 0014

Based on the above study result, the volume setting method for auditory signala as described in JIS S 0014 was prepared. The procedure is shown in Figure 6.

First, the sound pressure levels of auditory signal prototype and domestic sound generated in the situation where the product in which the signal will be used (for example, sound of water running in sink if the product is used in kitchen) are measured [Figure 6 ①]. Second, the sound pressure levels of

the two sounds are compared [Figure 6 ②], and whether the auditory signal is audible is determined [Figure 6 ③]. If the level difference (SN ratio) of domestic sound and auditory signal sits between minimum and maximum values, the volume of the signal is considered to be readily audible. If not, volume of the signal is adjusted [Figure 6 ④]. Since it is estimated that the auditory signal will be inaudible due to interference of domestic sound if it falls below the minimum value, volume setting of the signal is raised. Conversely, if it is above the maximum level, it is unnecessarily loud, so volume setting is lowered. By going through the above procedures, it is possible to create an auditory signal set at a target volume [Figure 6 ⑤].

6 Characteristic of accessible design technology development compared to conventional human science research

The process of accessible design technology development was described using as example JIS S 0014 volume setting method for auditory signals. Here, there are two points that differ greatly from conventional human science research from the perspective of Full Research (Figure 7).

First, characteristic data of great number of subjects are collected. In conventional research to clarify the mechanism of human perception or to verify the model (Type 1 Basic Research), discussions are based on measurement data on few subjects (Figure 7, Arrow ①). There, basic perception mechanism is considered common to all persons, and an "average" person is assumed. Individual differences are normally neglected as a kind of "error".

On the other hand, the subject of research in standardization of accessible design technology is individual differences in perception property including changes due to aging (Arrow ②). Therefore, data from several dozens to over 100 subjects depending on the study are collected. Individual measurement method and item are no different from the ones used in Type 1 Basic Research. However, human property research that was conventionally limited to the laboratory is extended to a design method that can be used in actual practice by analyzing statistical property of individual differences and universally applying the developed technology (Type 2 Basic Research).

For this purpose, the experimental condition for collecting perception property data must be set not just for conditions limited to the lab but conditions close to the actual home. Therefore, it is necessary to study which conditions should be set and whether the setting represents the actual domestic environment. In case of auditory signals, it was necessary to collect noises that were generated in the actual domestic situation where the products were used, and extract their acoustic characteristics (Type 2 Basic Research). The analysis of domestic sound is not the objective of research, but it is an essential process in testing the validity of the volume setting method for auditory signals.

The second characteristic is that emphasis was placed on simplification of the method. Accessible design technology must be an applicable method in actual product design. Design accuracy may increase by employing an intricate design method and by building a complex model of human perception function (Arrow ③). However, a complex design

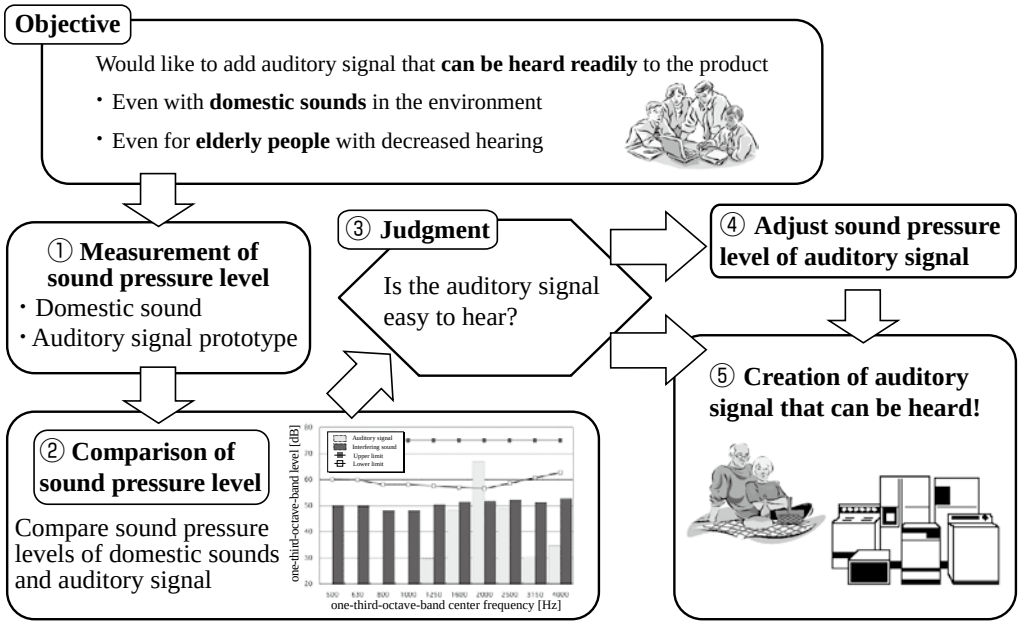

Fig. 6 Schematic diagram of volume setting method of auditory signal established in JIS S 0014 (modified from Reference [17]).

method cannot be used in actual design practice where cost reduction and speed are crucial (also, the designer may not necessarily be a specialist on hearing or vision). Complex model and method, in general, narrow the range of application. To propagate accessible design, it must be used in various products transcending the barriers of product category. How much the method can be simplified without limiting the application range yet maintaining design accuracy is the most challenging issue in the standardization of accessible design technology (Arrow ④).

Simplification of the model can be done by trial and error, but it is necessary to employ the basic findings of human property (product of Type 1 Basic Research). In case of auditory signals, it was necessary to simplify the auditory model on hearing auditory signals in noise (Section 4.1). However, it is impossible to study the auditory effect of all fluctuating sound. The model was simplified and experimentally verified, so the ease of hearing could be determined by the volume ratio between noise and auditory signals (SN ratio) by reviewing the general findings of various basic researches on hearing characteristics (Type 2 Basic Research).

7 Future issues in the standardization of accessible design technology

7.1 Accommodating new auditory signals and voice guide

With the establishment of JIS S 0013 and 0014, the standardization of basic specifications for auditory signals for consumer products is almost complete. However, requests for new standardizations are being placed by the industry, as auditory signals become prevalent.

First concerns auditory signals with complex acoustic structure. Current JIS addresses relatively simple sound with constant frequency and volume as subject of standardization.

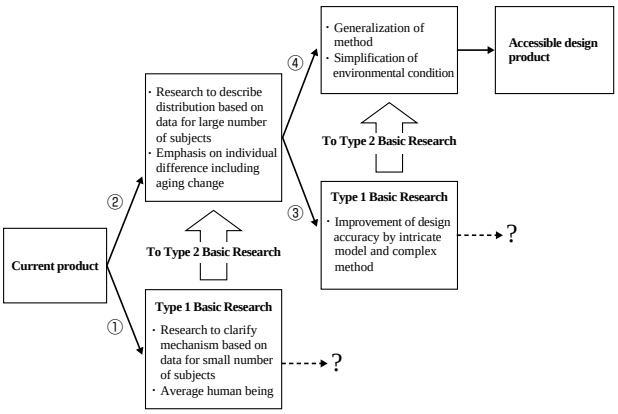

Fig. 7 Steps of accessible design technology development presented in comparison with conventional human science study.

However, with the advance and diffusion of new technology represented by the ringing melody of cell phones, there is interest in using complex musical sound as auditory signals. Second pertains to the use of voice. Products using voice guide instead of simple auditory signals are expected to increase, to communicate more information such as operating instructions to the users.

JIS S 0014 simplified the design method as much as possible, so designers who are not hearing or acoustic specialists can use it. However, authors have received comments that it is still "difficult". Major issue for the future is to develop current JIS into a method that can address more acoustically complex auditory signals and voice guide without increasing the complexity of the procedure.

7.2 Development of international standard

Fortunately, JIS Guidelines for the Elderly and People with Disabilities have been employed in designs of many products intended for accessible design. ISO standardization is currently in progress as a step in domestic standardization for guidelines including JIS S 0014 [17]. Like the volume setting method discussed in this paper, the design methodology based on basic human perception property is applicable, in principle, to products of any country. Accessible design technology is expected to be used effectively in countries other than Japan where birthrate is decreasing and the aging population is increasing.

In conjunction with international standardization, the authors are encouraging the standard setters to cite these standards in other product standards to widely propagate accessible design technology. Accessible design technology should become common regardless of the product type or country of production. That is because even if the product is well designed and elderly-friendly, it is inconvenient for the users if non-compatible designs coexist.

Careful manufacturing to match user characteristic and demand is the stronghold of Japanese corporations. If Japanese industry can lead the world market in the field of accessible design, Full Research can be called successful.

Acknowledgements

Much of JIS Guidelines for the Elderly and People with Disabilities, for which the authors created the draft, are based on the results of foundational research conducted jointly with the National Institute of Technology and Evaluation (NITE). Particularly, the cooperation of NITE was essential in conducting large-scale measurement for perception property of the elderly. We express our gratitude to all people who cooperated.

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Discussion with reviewers

1 Research process and structure of paper

Question (Motoyuki Akamatsu)

It will be better if an overall structure is presented that reveals the researcher's thinking "why standardization is best choice" for accessible design, specifying the demands, for example, the efficacy of standardization in accessible design, conditions for such standardization, and data collection based on these, and then providing the solutions. If the processes are clearly explained, as whether standardization is best, and if so, what kind of standard is good, it would be a great help to the readers.

Question (Hisao Ichijo)

Flow of the research is explained, but I think the elemental technology and the selection and integration process are somewhat unclear.

Answer (Kenji Kurakata)

By making the following revisions, overall structure was changed as indicated, and I think the significance and advantage of the standardization research were clarified.

- Addition of Section 2 on significance and importance of standardization
- Adjustment of explanation of Section 3 that summarizes design issue of auditory signal
- Revision of explanation of Section 5 on the actual application of the standard

2 On research subject

Question (Motoyuki Akamatsu)

It would be better if you mention detailed issues as well as the main framework of the subject. For example, in actual domestic environment, distances between the device and the user are varied, or there may be furniture between them. There are rooms with strong reverberation and dead rooms, and there may be differences because of them. It would be better to clarify to what degree issues were considered and reasons they were selected as research subjects.

Answer (Kenji Kurakata)

For detailed issues on domestic sound, we added explanations in "4.2 Accommodating interference by domestic sounds". For hearing characteristic of the elderly, we explained the technological issues in "4.1 Accommodating decreased hearing due to aging". I believe these additions will clarify the thought process that the authors went through.

3 On evaluation of research result

Question (Motoyuki Akamatsu)

I think you should show the level you achieved as research goal that you initially set and do a self-evaluation. I expect you to mention whether the resulting JIS is satisfactory or still unsatisfactory from the eyes of the authors.

Answer (Kenji Kurakata)

I think we achieved almost all research goals set initially for the technology established as JIS. However, due to technological advances that followed, new issues arose such as the use of auditory signals that cannot be accommodated by current JIS. This point is explained as future development in "7.1 Accommodating new auditory signal and voice guide", and this shall serve as our self-evaluation of the current status. Also, measures to propagate JIS are discussed in detail in the same section and "7.2 Development of international standardization".

4 On thinking about model simplification

Question (Hisao Ichijo)

I think it will be better to explain the process that lead to your thinking: average energy level greatly affects auditory phenomenon and simplification is the essence of the model.

Answer (Kenji Kurakata)

This thought process was achieved as an extension of the research that I have been previously involved in, so I cited References [9, 10]. Also, I clarified the authors' thought process by providing more explanation in "4.1 Accommodating decreased hearing due to aging".

5 Correlation between this research and Type 1 Basic Research

Question (Akira Ono)

Conventional research and this research are compared in Figure 7, and ② and ④ are positioned as Type 2 Basic Research, while ① and ③ are positioned as Type 1. I highly evaluate the fact that the authors succeeded in achieving the goal of standardization of accessible design by intentionally taking Type 2 Basic Research method. However, I feel that the results of ① and ③ that are positioned as Type 1 Basic Research may have some kind of significance in this research.

For example, can't research ③ be used to review, although perhaps partly, the validity of result of ④ that was reduced and simplified, since research ③ can present a complex and accurate model?

Also, I think research ① presents an average person, but doesn't it support the base of research ni ② that explains the variation and diversity of people? I would like to hear the authors' comment.

Since the reviewer holds image that Type 2 Basic Research is built upon the base of related Type 1 Basic Research result, I ask this question from my interest of seeing what kind of correlation there is in this study.

Answer (Kenji Kurakata)

I think you have made a clear point. As questioned, I think the standardization research for accessible design technology that the authors conducted fits the framework of "Type 2 Basic Research is built upon the base of related Type 1 Basic Research result". That is, the characteristic of this research is "sublimation" of Type 1 Basic Research result on human property to design method applicable to actual practice through Type 2 Basic Research including consideration of environmental conditions.

Also in Figure 7, presenting the comparison of this research and conventional research in either-or format was inappropriate. The figure should present the fact that combination with Type 2 at point of maturity, and then converting to Full Research, although understanding the necessity and importance of Type 1, were useful in realizing accessible design product.

Considering this point, in the final version, we inserted a figure that clarified the relationship between Type 1 and Type 2 Basic Researches.

A challenge to the low-cost production of highly functional optical elements

— Fabrication of sub-wavelength periodic structures via glass-imprinting process —

Junji Nishii

[Translation from *Synthesiology*, Vol.1, No.1, p.24-30 (2008)]

Factors, such as production cost, which impede practical applications of "sub-wavelength optical elements" with periodic structures smaller than light wavelengths, were targeted for alleviation through a combination of advanced Japanese glass molding methods and a novel imprinting process. Collaboration between material manufacturers, consumer-electronics companies, universities, and AIST under a clear sharing of roles enabled the fabrication of functions such as polarization rotation effects and antireflection effects on glass surfaces.

Keywords : Optical element, periodic structure, imprinting, glass, microfabrication

1 Introduction

Semiconductor technology and optical technology contributed to the formation of advanced information society. Optical technology has hundreds of years of history, and still receives high expectations because of the following two reasons. The first reason is the extremely large information capacity and communication speed. The second reason is that humans receive over 80 % of information through sight. The expectation for optical technology grows every day, because of the technological innovations of various kinds of hardware such as display, storage, and imaging devices, as well as the dramatic progress of mutual information exchanging environments through optical communication network. To respond to such expectation, the methodology in question now is how to establish secure "technology" from the results of optics accumulated as "science".

This paper focuses attention on optical elements which are expected to significantly affect the next generation technologies for information input and output (I/O). I shall describe the works to realize the industrial fabrication technologies of next generation optical components placed behind the current refraction and diffraction optics, by combining factors which are scientifically clarified and predicting future optical device technologies. Such technologies will be required in the fields of home electronics and information technologies in the next 10 to 20 years.

If the fabrication technology of next-generation optical elements is established for the future information I/O, users will be able to enjoy high-speed and effective imaging, storage, and replay a large-volume data including high quality images. On the other hand, manufactures will receive substantial advantages such as greatly simplified manufacturing process of optical elements without so much process energy, and also the reduction of number of optical parts, which will enable the production of advanced home electronic devices earlier than the neighboring countries.

2 Future direction and research objectives for industrialization

Optical elements and their production method have appeared since 1600 are shown schematically in Figure 1. Manufacturing in this field can be classified into "optical material" and "microfabrication". The development of materials with properties required through the design such as refraction index and dispersion, the precise processing following the characterization are continued repeatedly until they satisfy each other. During the period from 1600 to 1800, various theories were formulated in geometric optics and wave optics based on three optical elements: lens, prism, and diffraction grating. Such theory and optical design led the manufacturing. The manufacturing responded to the demands accurately, and in turn promoted further

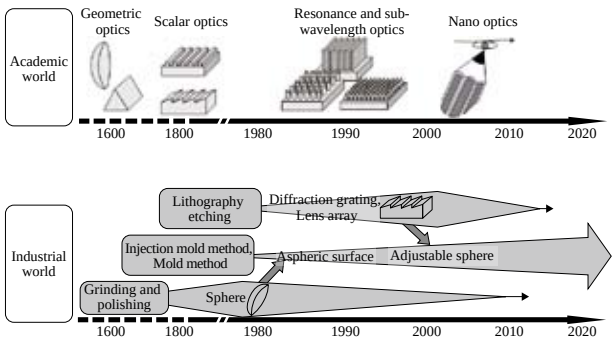

Fig. 1 Optical elements that appeared after 1600 and fabrication methods that contributed to the industry

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advancement of theory and design. This process has been continued to this day.

2.1 Barrier of cost

Let me direct attention to the field called “resonance and sub-wavelength”, for which the research was started around 1990. Computer simulations demonstrated that the highly functional elements could be actualized if the periodic structures comparable to wavelength of visible light or less could be fabricated precisely. Later, some basic studies on the fabrication of prototypes were carried out actively, alongside the progress of semiconductor microfabrication technology such as silicon[1].

The wavelength discussed in this paper is from visible to near-infrared region (wavelength about 400 nm to 2000 nm). If the period of structure is 2*n* times (*n* = 0, 1, 2, 3…) of the wavelength of incident light, the optical diffraction will occur. Such structures will also cause strong reflection and light trapping due to resonance of light within the periodic structure. When the period of structure decreases, diffraction and resonance do not occur, and the refractive index of such periodic structure can be considered as the average of air and material. This is the principle of optical devices classified in the “resonance and sub-wavelength” domain.

Although several optical elements have been realized in resonance and sub-wavelength domain, their applications were limited. Namely they were not installed widely in commercial devices such as home electronics products, because the industrial arena required an extremely low production cost and a large production scale of several million elements or more per month.

2.2 Barrier of function

The molding process and injection process invented in 1980 enabled the productions of aspheric lenses and diffraction gratings, which used to be difficult to fabricate at low cost with conventional grinding and polishing methods. The fabrication technology of precise molds accelerated the mass-production of several optical elements with various forms including aspheric lenses. For example, the glass lenses fabricated by the molding are used in almost 100 % of zoom optics for digital still cameras. Hundreds of millions of lenses are produced each year in Japan and neighboring countries. However, new demands arose for comprehensive suppression of ghost, spherical aberration, and color aberration, in addition to high-resolution, downsizing, and weight reduction. On the other hand, since the blue-ray with 405 nm wavelength is used in next-generation optical disc drive, which is called Blu-ray, the new optical element compatible with 3 wavelengths including conventional CD (wavelength 785 nm) and DVD (wavelength 655 nm) is required. To fulfill the needs of such functional elements, new technology is necessary to incorporate the several functions such as refraction and diffraction, structural birefringence without wavelength dependence, and antireflection with little dependence both on wavelength and incident angle, into conventional optical elements such as lens.

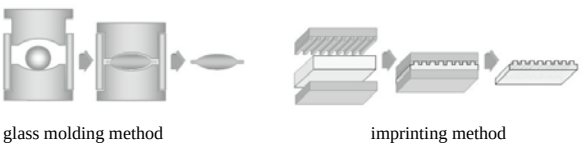


Fig. 2 Schematic diagram of glass molding method and imprinting method
Heat resistant, ultra-hard material is used for glass molding, while glass or silicon is used for imprinting mold.

2.3 Objective of this research

Conventional imprinting technology can be used only in resin because there is an upper limit in molding temperature. There was no report on the application of the imprinting process to glass that requires high temperature of several hundred degrees. Also, glass-molding process is used for the production of optical elements with flat surface such as lenses. Eventually, there was almost no approach to forming structures smaller than wavelength of visible light. Thus the objective of this study is to develop new fabrication technology of resonance and sub-wavelength optical elements, which have been fabricated using microfabrication technologies so far, through the development of glass imprinting process by combining the imprinting process for resin material used in the academia, and the glass molding process used in industry.

3 Scenario to achieve objective

The size required for the resonance and sub-wavelength optical elements is in the range of tens of nm to several μm. It is also necessary to fabricate microstructures on a large surface in a shorter time possible. It should be out of the range covered by the methods such as lithography and etching, laser process, or mechanical process, which are currently used in industry. Such microstructures should be formed mostly on the surface of lenses, prisms, or window materials. Therefore, it is advantageous to transfer such structures to the surface of the optical elements using the principle of imprinting process, if the thermally durable molds can be fabricated. The concepts of molding process and imprinting process are shown in Figure 2. Imprinting process was first reported by Chou et al. of Princeton University in the United States[2, 3]. It is a method where the mold with nano-structure is pressed against the resin, and the structure is transferred using ultraviolet light or heat[4]. So far, the products realized using the imprinting process are mainly based on the resin materials such as light

guide panels for liquid crystal displays. The technological level of Japanese molding process, on the other hand, is outstanding in the world. There are plenty of accumulated human resources, facilities, and knowledge. Unfortunately, the products based on the reliable glasses are only micro lens arrays and diffraction gratings with the period over 10 μm. Therefore, the glass devices in the resonance and sub-wavelength range have been an unexplored territory.

In this study, several research objectives were set based on the scenario shown in Figure 3, which were fundamental or intermediate technologies to accelerate the development of sub-wavelength optical element using glass-imprinting process. AIST studied the fundamental technologies using the vast amount of research results from the past, such as the development of glass compositions. On the other hand, the three processes including mold fabrication, coating for demolding, and the precision molding process relied heavily on the knowledge of the home appliance companies. Therefore, such works were conducted carefully and strategically while AIST supported the home appliance companies.

4 Development of new optical components through integration of elemental technologies

A central laboratory was established in Kansai Center of AIST to integrate the research potentials of home appliance companies, material companies and universities. The former companies install the optical elements fabricated by the molding process in the final products. The latter companies develop several glass materials appropriate for molding process. The universities conduct the advanced simulation research in optics and rheology. Here, it was important that the knowledge of microfabrication and characterization technologies for glasses and ceramics were accumulated within the AIST research group. An example of successful development of optical elements is described in the following sections.

4.1 Development of wave plate based on structural birefringence

Wave plate is used in the optical disc drive to separate the light traveling from the light source to the disc and the light reflected on the surface of a disc in order to detect the optical signal by the photo diode. The materials for the current wave plate are resin or crystal, which have different specifications depending on the operating wavelength. The next-generation optical disc drive, therefore, requires 3 wave plates depending on the wavelengths between blue and red, which is considered to be an obstruction factor for the downsizing of optical system and the reduction of production cost. Also, as wavelength of the light source shortens, sufficient light resistance is required for the optical elements. The glass wave plate based on the structural birefringence is a promising candidate for overcoming these issues.

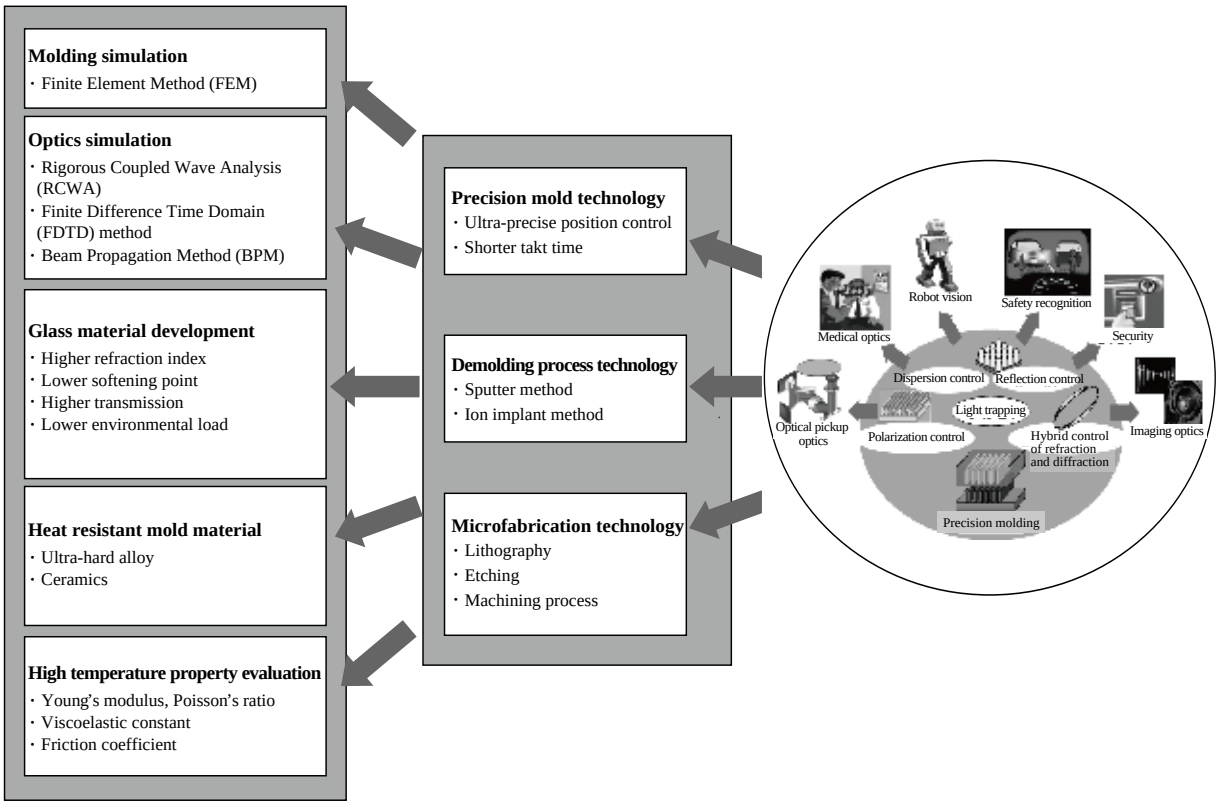


Fig. 3 Scenario to realize the fabrication of sub-wavelength optical elements using molding method

When one-dimensional microstructure with a period smaller than the wavelength is formed on the surface of transparent material, so-called “structural birefringence” appears, where the refractive index is different depending on the direction of electric field of passing light[5]. Even in optically isotropic glass, structural birefringence can be realized if anisotropic sub-wavelength structure is formed on the surface. Theoretical optimization of the structure is possible using the calculation methods such as the effective medium theory or the rigorous coupled wave analysis. Important parameters are period, groove width, and height of the periodic structure, and refractive index of the material. Especially, the optimization of groove width is an essential point in order to minimize the wavelength dependency of phase retardation. Moreover, height of structure can be lessened by increasing refractive index of the material. Glass material is advantageous to attain higher refractive index than resin, resulting in the lower height of structure. However, there was no report on whether such structure can be formed on the surface of glass or not, using the molding process.

In this study, as the first step, the period was fixed at 500 nm, and various heat resistant molds with various groove widths were fabricated to study the molding characteristics of glasses quantitatively. The results are shown in Figure 4. In the case of mold with groove width 330 nm, the structural height of the molded periodic structure reached 730 nm, which means an extremely high precision molding was possible. It is the first quantitative investigation on the correlation between the shapes of mold and the molded periodic structure obtained by imprinting. The most important point here was the demolding condition. When the mold was released from the glass at high temperature, microstructure formed on the glass surface was deformed by heat. When the demolding was carried out at low temperature, a mechanical damage was caused either in mold or glass or in both by the difference in thermal expansion coefficients between the mold and the glass. Optical glass that could be molded at relatively lower temperature than 500 °C was advantageous because the deterioration of the mold can be prevented.

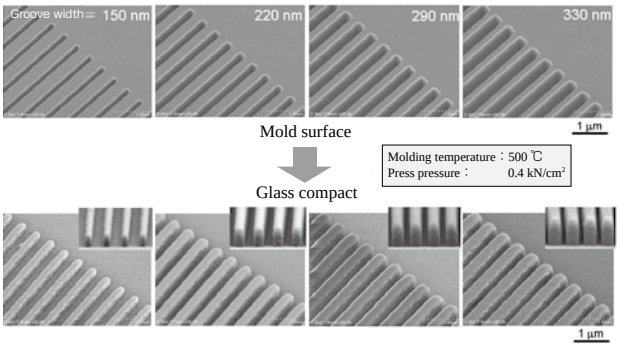


Fig. 4 SEM photographs of one-dimensional periodic structure mold and molded glass

However, the determination of demolding temperature became extremely difficult, because, in general, the viscosity of glass changed rapidly near molding temperature. To solve this issue, the researchers of companies, who have plenty of experience in the molding process, and the researchers of AIST, who are knowledgeable in material property and microfabrication, collaborated successfully. The demolding the periodic structure with the highest aspect ratio in the world was successfully accomplished in a short period. In this study, large surface area of 6 mm x 6 mm, as shown in Figure 5, was confirmed. The phase retardation attained by this structure was 0.1 λ[6], which was the first result to realize the phase retardation caused by the periodic structure via glass molding process. Molding of the structure with 300 nm period was also successfully achieved. The future goal is to attain the phase retardation of 0.25 λ in the wavelength region between 400 and 800 nm by optimizing the dimension of periodic structure, which is the requirement for practical use in the next generation optical disc drive.

4.2 Development of sub-wavelength antireflective structure

The improvement of the transmission efficiency of light by minimizing the unnecessary reflection is desired for glass optical components used in wide-ranging products such as home electronics, lighting, etc. Currently, antireflection film is coated on the optical elements for imaging and display panels. However, in principle, such films can not respond to demand for the antireflection independent against wavelength or incident angle. On the other hand, it was known that advanced antireflection could be achieved if periodic conical shape structure with the sub-wavelength period could be formed on the surface of elements.

Important point was to arrange the conical shape units two-dimensionally with a period smaller than the wavelength. The antireflection effect could not be achieved when the conical structure with the period comparable to wavelength

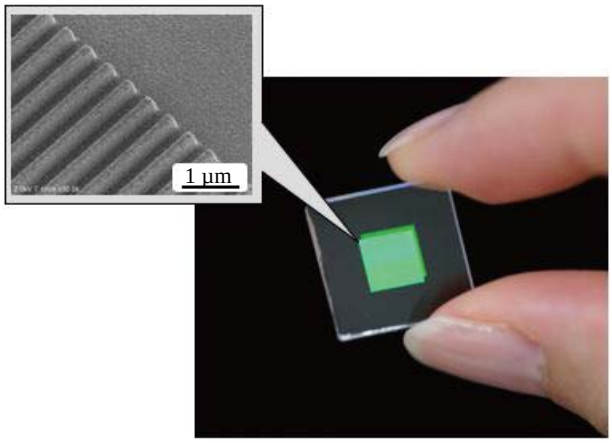
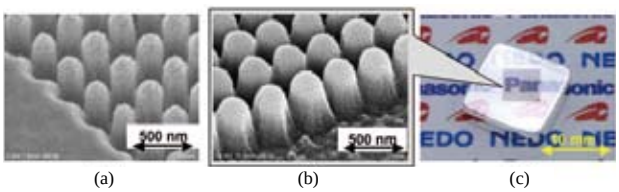


Fig. 5 One-dimensional periodic structure with large area showing retardation.

level cause the diffraction of incident light. In the case of the structures with the period sufficiently smaller than the wavelength, volume fraction of air was greater than the glass at the top area of the structure, and their volume fractions gradually reversed as the incident light traveled further into the structure. Thus the interface of glass and air seemed nonexistent for the incident light coming into the structure from various angles. Also, two-dimensionally isotropic arrangement canceled out the polarization dependence.

Although several theoretical analyses and the fabrication researches have been published for sub-wavelength antireflection structures, most of them dealt with resins such as acrylic[7], and never got beyond prototypes. There were some researches using electron beam lithography and dry etching for the fabrication of antireflection structure on the surface of glass [8, 9]. However, the mass production was difficult because of the prolonged fabrication time. Therefore, we decided to fabricate such antireflection structures using the glass molding process.

In this paper, I will describe the study in which silica glass was used as heat resistant mold. The metal thin-film coated on the silica substrate was patterned by electron beam lithography, and then the desired periodic structure was formed on the substrate by a dry etching process. The shape of mold was designed so as to minimize the reflection on the surface of glass. Figure 6(a) shows a two-dimensional periodic structure with period of 300 nm and the height about 550 nm. Using a vacuum coating process, a thin film was coated on the mold surface to prevent the thermal adhesion between the mold and the glass. A phosphate optical glass with refractive index of 1.6 was pressed at about 500 °C. Finally, an inverted periodic structure with height about 500 nm was successfully obtained as shown in Figure 6(b)[10]. Here, the important point was the temperature of demolding. The reflectivity on the surface of optical glass with periodic structure was measured precisely using an integrating sphere, which was 0.56 % at the perpendicular incidence and at the wavelength 462 nm. This value was lower than that of a single antireflection thin film coated on the glass surface. Therefore, the performance of this antireflection structure was in the practical level. Figure 6(c) is a photograph of the prototype. The surface reflectivity decreased with optimization of molding condition, and the characters under the glass plate could be read clearly from a tilted angle. A current target of this research is the pickup lens for optical disc drive and digital still camera lens. The development of curved surface mold using ultrahard materials in place of silica is in progress. This research will open a possibility of overcoming the problems such as low cost and mass production that delayed the practical uses of antireflection structures.



(a) (b) (c)

Fig. 6 SEM photographs of (a)mold and (b) molded antireflection structure. (c) External shot of molded glass.

5 Discussion

Vertical collaboration between companies, AIST and universities gathered from the three fields, i.e., materials, microfabrication, and devices, was effective beyond expectation. The optical glass technology in Japan is at the top level of the world. Actually, some glass materials suitable for imprinting are commercially available. However, many more hurdles must be cleared from the aspect of mass production. Glass companies are working efficiently on the three research issues of composition improvement, molding, and device characterization, with collaboration of AIST, mold material companies, and home appliance companies. However, since mold materials are not developed for the purpose to fabricate subwavelength structures with microfabrication process, the mold material and its production method must be optimized through close cooperation with manufacturers. If the results are adequately patented, these material technologies might be protected from the catch-up of neighboring countries. On the other hand, it is known that the glass materials at around the molding temperature range show viscoelastic behavior, but currently there are few data on such high temperature properties required for the molding simulation. In some cases, it is necessary to develop the measurement equipment of such properties, which will also be patented just like the materials.

On the other hand, three processes including the mold fabrication, the demolding thin film coating and the precision molding are faced with hard problems in terms of research strategy. Even if the technologies related to these processes could be patented, it would be extremely difficult to protect them from the catch-up of neighboring countries. Some believe that it may be of best interest to leave them as “black boxes”. Recently, there are moves to commercialize the technical know-how on fabrication methods as a recipe packaged with the production instruments for processing, coating, molding, or others.

Actually, some recipes are packaged with the equipments used in our research project. Therefore, anyone can fabricate the conventional devices using such recipes, which are based on the knowledge accumulated in the collaborative work between the equipment companies and the optical device companies. In the future, it will be extremely important

to achieve high performances in processing, coating, and molding equipments, in order to improve the mold fabrication and imprinting processes to a practical level. The optical device companies will be required to decide whether to continue the research and development entirely in a black box or to commercialize such knowledge as recipe by the collaboration with equipment companies.

6 Summary

The objective of the research described here is to develop the relatively small optical devices used in home electronic products such as imaging devices and optical disc drives. The technologies in this area are facing a fierce catch-up of neighboring countries, and are required to overcome the two issues of cost reduction and performance improvement. “Glass imprinting process” has potential to realize the reduction of component number, the manufacturing energy consumption and the cost. Therefore it is expected that this process becomes the core of next-generation fabrication process of optical components. For example, if the wavelength independent wave plate can be fabricated by this process, the number of wave plates necessary in next-generation CD/DVD drive is reduced to one-third. Also, the antireflection coating of the lens will become unnecessary.

Research and development for the sub-wavelength optical elements described in this paper will be applicable to large displays, lighting equipments, solar cells and so on. It is ultimately expected to reduce the energy consumed of information I/O devices with highly efficient control of optical signals. In order to realize such optical devices, the microfabrication technology and material technology must be fused efficiently. Until now, collaboration took place mainly between companies, and the universities and government institutes rarely participated. It was recognized that the technology was already completed not only in “Type 1 Basic Research” but in the field of “Type 2 Basic Research” as stated by AIST. However, after the efficient improvement of technology, we faced new technological barriers, that could not be solved by conventional disciplines. Therefore, researchers were required to return to both “Type 1” and “Type 2 Basic Researches” to extract issues and research subjects to be tackled, and to solve several problems efficiently and timely. Here the important point is the role of AIST assuming the missions of Type 2 Basic Research. AIST must maintain the potential to exhibit not only the research subjects directly linked to demand but also the research results obtained by the collaboration with companies and universities. Also AIST must centrally manage various materials and state-of-art infrastructures.

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Discussion with reviewers

1 Development of technology integration

Comment and Question (Naoto Kobayashi)

This research paper integrates "mold technology" and "nano-imprinting technology" for a breakthrough that allows practical application of high-performance optical element unavailable before, and in that sense it is extremely valuable. The realization of such integration represents true nature of Type 2 Basic Research.

Please comment on how we should think in terms of developing research and technology in combining technology where integration was considered impossible, as in this study, to use the experience of creating technology that never existed before, and to realize new values.

Answer (Junji Nishii)

It is clear that the reasons why "resonance and sub-wavelength element", which was actively pursued as academic disciplines, failed to become major industry because of "scale of manufacture" and "cost". I started working on this research thinking that the scenario for how to solve this matter was important. Here, I think it was important to consider the role of AIST that declares "Full Research" as its mission. I believe the research result should be directly reflected in people's lives or indirectly reflected in products of private companies. However, what is important here is the selection of subject for Full Research and the scenario beyond, and I think it's whether the research is in synch with policy set by government or whether the research can set the direction government should take. Subject selection for Full Research should not be by inspiration, on whim, or delusion, but it should be determined by whether it matches policy and demand.

As with other technologies, I think research and development for energy conservation is necessary in future optics technology. The case study discussed here should serve as foundation for "efficient use of light" in many optical devices.

2 Beginning of resonance and sub-wavelength optics research

Question (Naoto Kobayashi)

You mentioned that the research in the field called "resonance and sub-wavelength", which is the central issue of new technology described herein, started around 1990, but why was it started then (or in other words, why didn't it come to attention until then)?

Answer (Junji Nishii)

Researchers of interference, polarization, and diffraction of light were certainly aware of the importance of optical elements in the region of "resonance and sub-wavelength". However, no method for designing or manufacturing such elements existed, so it could not be tackled as research subject until the latter half of 1900s. Advances in computer simulation and microfabrication technology triggered the research. In the same way, there is potential for new technology to emerge depending on what comes out of the semiconductor technology.

3 Technological points in integration

Question (Akira Ono)

In this research, you succeeded in the manufacture of structural birefringence wave plate and sub-wavelength antireflection structure using glass imprinting method. I understand that the factor of success was to realize the integration of three intermediate technologies including "precision mold", "demolding", and "microfabrication" by integrating the elemental technologies as shown in Figure 3. Please explain, as much as you are allowed, the methods of integration that were critical in obtaining the result.

Answer (Junji Nishii)

As mentioned in the latter part of Section 3 and the first part of Section 4, it was important to accurately extract research subjects for multiple elemental technologies necessary to achieve the goal, and to clarify the scenario for their integration. Although this was an ordinary process, I discussed again and again with researchers of universities, AIST, and companies that wished to use the research result in future products. As a result, I obtained agreement that the central lab method was preferable to maximize a limited research budget. However, "precision mold" and "demolding" technologies were corporate knowledge, and AIST and the universities decided not to step into those fields deeply, and decided to carefully and strategically support the companies. However, since this was a joint research conducted in the same place, we did share findings that we didn't know before. Please note that any more disclosure of information is not allowed at this point, but I am aware that public funds were invested, so things that could not be patented will be shared in the form of know-how recipe under the strict management.

A strategic approach for comparing different types of health risks

— A risk assessment of toluene exposure using quality-adjusted life years —

Atsuo Kishimoto

[Translation from *Synthesiology*, Vol.1, No.1, p.31-37 (2008)]

The issue of social demands must be taken into consideration when developing a methodology for risk assessment of chemical substances. We classified the objectives of risk assessment into the following three categories: (A) to derive reference values, (B) to establish screening assessment to remove chemical substances of low importance, and (C) to set priorities based on comparisons of health risks and cost-effectiveness of risk reduction measures for different chemical substances. In this categorization, we demonstrated that while the existing risk assessment methods fulfill objectives A and B, they do not satisfy objective C. Therefore, the steps of risk assessment methodology were revised to fulfill objective C, and the effectiveness of the new methodology was demonstrated using toluene as an example. By adopting the loss of quality-adjusted life years (QALYs) as an indicator of human health risks, we could compare the health risks for different chemical substances as well as compare chemical substances and other risks such as accidents and infectious diseases.

Keywords : Chemical substances, risk assessment, social demands, quantification, comparisons, cost-effectiveness

1 Introduction

Concept of risk and methodology for risk assessment are essential in rationally addressing environmental, safety, and health issues. Human health risks from chemical substances are determined by two factors, toxicity (hazard) and exposure (intake). Low exposure to a highly hazardous substance may result in low risk, although high exposure to a substance of very low hazard may become high risk. In an established chemical risk assessment methodology, comparisons are conducted between NOAEL (no observed adverse effect level) derived from animal tests or epidemiological studies and actual or potential exposure levels. Then, judgment is made whether the exposure level of target substance is acceptable or not. This thinking is actually applied to establish various environmental and safety standards, as well as in screening assessments for removing chemical substances of low importance.

However, this is not the only expected role of risk assessment. To achieve the ultimate goal of minimizing the total risk in our society, it is necessary to quantify and compare the health risks of each chemical substance, estimate the cost-effectiveness of each countermeasure to reduce risk, and rank them accordingly. Methodology of risk assessment suited to these purposes has not yet been developed.

In this paper, we propose an alternative framework of risk assessment to address emerging social demands, by returning to the scheme of how conventional risk assessment was established. We then present an application of this framework to chemical substance, toluene [1]. It was a process of trial and error involving returning to social demands, reconsidering each element in a consistent manner, and reintegrating each step into one consistent risk assessment process.

Toluene is a clear, colorless, and highly volatile liquid at room temperature. Most of the toluene emitted into the environment disperses into the atmosphere. Its volume released into the atmosphere is largest among the 354 chemical substances reported in the PRTR (Pollutant Release and Transfer Registers) system in Japan. Toluene is also known as one of the major indoor air pollutants, and a non-binding guidance value was set by the Ministry of Health and Welfare in 2001. In the second section, we review the relationship between social demands and risk assessment methods. In the third section, we present improvements in the steps of risk assessment and their application to toluene. In the final section, the implications are discussed.

2 Social demand and risk assessment methodology

The current procedures for chemical risk assessment are conducted according to the gray arrows in Figure 1 (from bottom to top). They are divided into two types depending on their objectives (social demands). First is to derive reference values, such as environmental standards or acceptable daily intakes (ADIs), which are compared with measured or estimated exposure levels. Examples are environmental standards and guidance values set by the Ministry of the Environment, and also the indoor guidance values, the tolerance values for pesticide residue, and the standard control concentrations for occupational settings set by the Ministry of Health, Labour and Welfare. The social demands they meet include protecting vulnerable people (such as

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children) and most highly exposed groups in our society. The reference values are derived from NOAEL in animal tests divided by sufficiently large uncertainty factors. Therefore, even if the exposure level slightly exceeds the reference values, no adverse effects will appear in most people.

Second is to conduct screening-level risk assessments. Examples are: the Environmental Risk Assessment prepared by the Ministry of the Environment; the Initial Risk Assessment prepared by the Ministry of Economy, Trade and Industry; and the various risk assessments prepared by the Food Safety Commission. Worst-case scenarios are applied not only to toxicity assessment but also to exposure assessment, in which the 95 percentile of measured or estimated values[Term 1] are often adopted as the exposure levels. The social demands that they cover include delisting substances that pose no or very small risk to society even if their toxicity or exposure is overestimated. These are screening-level risk assessments. The substances that are not delisted should be subject to detailed risk assessment, and precautionary measures are sometimes taken at this point.

These methodologies of exposure assessment, toxicity assessment, and risk characterization were developed to cover the social demands for setting reference values or for screening purposes. In contrast to the risk assessment procedures (gray arrows in Figure 1, from bottom to top), each step was developed in the reverse direction (white arrows in Figure 1, from top to bottom). The bottom line is that the current elemental techniques have been optimized to address particular social demand, and are not necessarily optimal responses to other social demands.

Today, there are emerging social demands in the field of chemical risk management. We must compare the health risk of a chemical substance being used now with the risk of a proposed substitute. We must deal with the trade-offs between chronic disease risks and accident risks. We must also assess the cost-effectiveness of risk reduction measures to maximize risk reduction within budget constraints. Current toxicity assessment with conservative assumptions (that are used to overestimate risks in case of uncertainty and variability) and exposure assessment with worst-case scenarios cannot be used to address these new social demands. When a risk assessor does not recognize the close relationship between methodology and social demand, he or she may naively apply the current procedures (Figure 1) to the assessment for some other purposes. As a result, the risk is overestimated, the effectiveness of risk reduction measures is also overestimated, and the cost-effectiveness ratio turns out much better than the expected (average) one. Since the extent of conservativeness (overestimation) is different in each case, we cannot compare the risks for different chemical substances. To address the third social demand in addition to the first and the second, it is necessary to travel downstream of risk assessment procedures, i.e. the social demands, and reconsider proper methods for each step upstream from scratch, just as when the current risk assessment methodology was first developed.

3 Quantification strategy to compare different kinds of risks

3.1 Casting back from social demands

We considered the conditions necessary for each step of risk assessment to address the social demands, in reverse direction of risk assessment operations. The white arrows in Figure 2 show this review process.

It is necessary to present the magnitude of various risks with common metric to compare them with other types of risks and set priorities for various risk reduction measures. The necessary condition of the common metric for health risks is to combine mortality risks (loss of life years) and morbidity risks (loss of quality of life). We decided to adopt quality-adjusted life years (QALYs) proposed and applied in the area

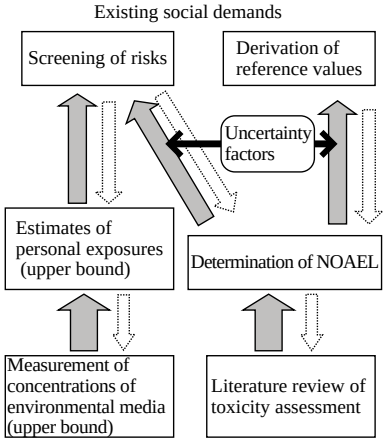

Fig. 1 Conventional process of risk assessment and social demands

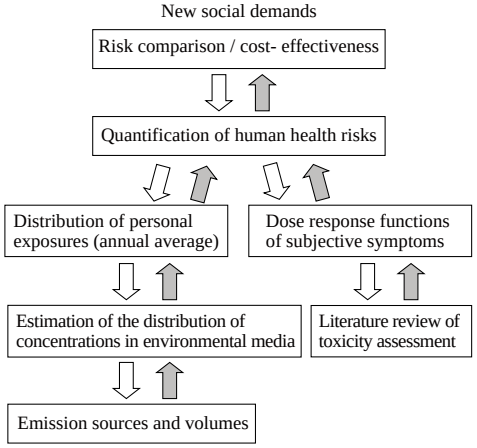

Fig. 2 Reexamination of elemental techniques for new social demands

of medical science. The volume of QALYs is represented by the gray area in Figure 3, where the vertical axis is quality of life (QOL) from 0 (death) to 1 (normal health) and the horizontal axis is age from birth to death. When the QOL is reduced to the dashed line for some reason, the loss of QALYs corresponds to the reduced area. Using QALYs as health risk metrics in risk assessment makes it possible to consistently capture not only loss of life expectancy, but also loss of QOL.

It was necessary to multiply the number of cases of various symptoms, including death, by the QOL weight from 0 (death) to 1 (normal health) to quantify human health risks resulting from exposures to chemical substances as loss of QALYs. The number of cases showing various symptoms was obtained by substituting the annual average exposure levels into the dose response functions[Term 2] that describe the relationship between the intake of substance and the probability of symptom presentation. The dose response functions should be preferably derived from human epidemiology studies with chronic endpoints of established diseases or subjective symptoms. The individual exposure level used in the calculations was expressed as annual average, which is described as the weighted average of indoor and outdoor concentrations. In order to estimate the national distribution of atmospheric concentrations by running the atmospheric dispersion model, the distribution data for emission volumes was necessary. These values should be preferably estimated as a central tendency or average estimates (and distribution profile if possible), instead of mere upper bound estimates.

On that basis, we reexamined the current methodology for each step of risk assessment. As a result, we found that almost all of the existing methodologies were not directly applicable. Therefore, following the gray arrows in Figure 2, we performed risk assessment for toluene step by step by revising slightly, making rough assumptions, or developing new methods.

3.2 Estimation of emission volumes

Initial risk assessments placed less significance on estimation of emission volumes or search for emission sources since they were based on measured concentrations in the environment or human bodies. However, to conduct simulation of the effect of proposed emission control measures, it is necessary to know the emission sources and volumes. For example, suppose that the share of some emission category was assumed to dominate but the actual share was less than half. This means that the effect of the emission control measure was less than half of the assumed effect. Even if the emission sources are discovered, items with large uncertainties, such as unintended emissions and natural sources, are often ignored or underestimated, and this may lead to underestimation of the total emission volume. In case of toluene, there are no estimates of evaporation from automobile fuel tanks and extra emissions (cold-start emissions) that occur before engines are warmed up at the beginning of PRTR.

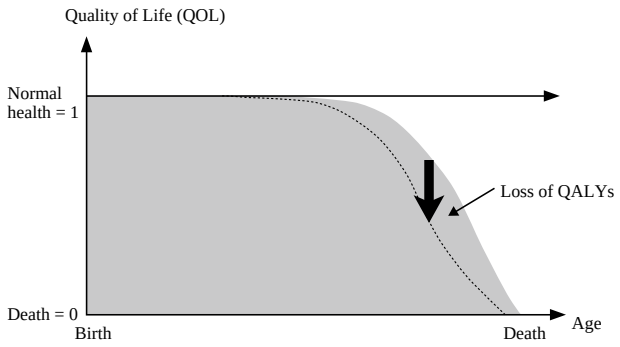

Fig. 3 Concept of quality adjusted life-years (QALYs)

3.3 Estimation of personal exposure distribution

Concentrations of chemical substances tend to be measured at locations and times that the concentrations may become high. The outdoor measurement data are biased toward values measured near the emission sources, and the indoor measurement data are biased toward values measured in newly-built houses. Therefore, we did not have information on the total exposure for Japanese residents. In addition, risks from outdoor and indoor concentrations are usually evaluated separately. Since most of the indoor data are daily averages for houses, information on annual average and inter-house and within-house variabilities are not available.

For outdoor concentrations, AIST-ADMER (Atmospheric Dispersion Model for Exposure and Risk Assessment) has been used to predict the regional distribution of concentrations with a horizontal resolution of 5 km for all Japan [2]. To run this model, estimated emission rates were allocated to 5 x 5 km square grids and meteorological data were collected from National Meteorological Observatories and from the Automated Meteorological Data Acquisition System (AMeDAS). The annual average concentrations within these 5 x 5 km square grids were between 0 and 67 $\mu g/m^3$ and the arithmetic mean was 1.5 $\mu g/m^3$.

For indoor concentration, it was necessary to obtain the within-house variability in the annual average "indoor concentrations of indoor origin". The daily average data for 207 houses were obtained through the Freedom of Information Law from the Ministry of Health and Welfare [3]. The concentrations of toluene tended to be higher in indoor environments than in outdoor environments due to multiplicity of indoor emission sources. Since indoor toluene consists of ambient toluene that infiltrates indoors, as well as toluene emitted from indoor sources, "indoor concentrations of indoor origin" were defined as indoor toluene concentrations minus outdoor toluene concentrations. We assumed that these data followed

lognormal distribution, which was called the (A) 24-hour average inter-house variability. To estimate (C) annual average inter-house variability, we designed the following procedures.

First, we estimated the variability of the daily average "indoor concentrations of indoor origin" in a house, i.e. (B) 24-hour average within-house variability. Next, we assumed that (A) equaled (B) plus (C), i.e. (C) would be obtained by subtracting (B) from (A). It was assumed that "indoor toluene concentrations of indoor origin" were proportional to the emission rate from indoor sources and inversely proportional to the residential air exchange rate (AER). However, we could not find the annual data for either emission rates or AER. After expert interviews, we judged that the daily variability throughout the year for toluene emission rates from indoor sources was virtually zero under all possible temperature ranges, and that the daily variability throughout the year for 24-hour average AER ranged from 0.5 times per hour to 10 times per hour (range in which 95 % of the values fell). Assuming these variabilities were all independent of each other, the annual average "indoor toluene concentrations of indoor origin" could be described as lognormal distribution whose geometric mean was 15.72 μg/m^3 and geometric standard deviation was 4.28. The distribution of personal exposure was calculated as a weighted average of indoor and outdoor concentrations, applying the result of a time-budget survey that showed that Japanese residents spent approximately 90 % of their day indoors and 10 % outside [4]. Figure 4 shows that the distribution moves from left to right with addition of each emission source category.

3.4 Derivation of dose response functions from epidemiological study

The goal of toxicity assessment in conventional risk assessment is to derive NOAEL from animal tests or epidemiological studies and set reference values. However, since the type and severity of toxicity endpoint and the extent of conservativeness (extent of overestimation) are different for different chemical substances, it is difficult to compare the risks from the NOAEL or reference values. We attempted to derive the relationship between health effects and exposure levels, i.e. dose response functions, from the results of an epidemiological study [5]. Among various subjective symptoms investigated in the epidemiological study in which subjects were workers at gravure printing factories, eight symptoms that were found to have significant associations between exposure levels and incidence rates were selected, and their dose response functions were derived as shown in Figure 5. The vertical axis indicates the incidence rates, and the horizontal axis shows the exposure levels. As the exposure increased, probabilities of incidence for each symptom as well as the expected number of symptoms increased.

3.5 Quantification of human health risks

The distribution of personal exposure concentrations (Section 3.3) was substituted into the dose response functions (Section 3.4), and the incidence numbers obtained were then multiplied by their severity. The health risks for residents in Japan from exposure to toluene were finally quantified as total loss of QALYs. The severity of each symptom and some combinations of symptoms were expressed in terms of QOL index, where 0 meant death and 1 meant normal health. QOL indices were calculated based on the Health Utilities Index

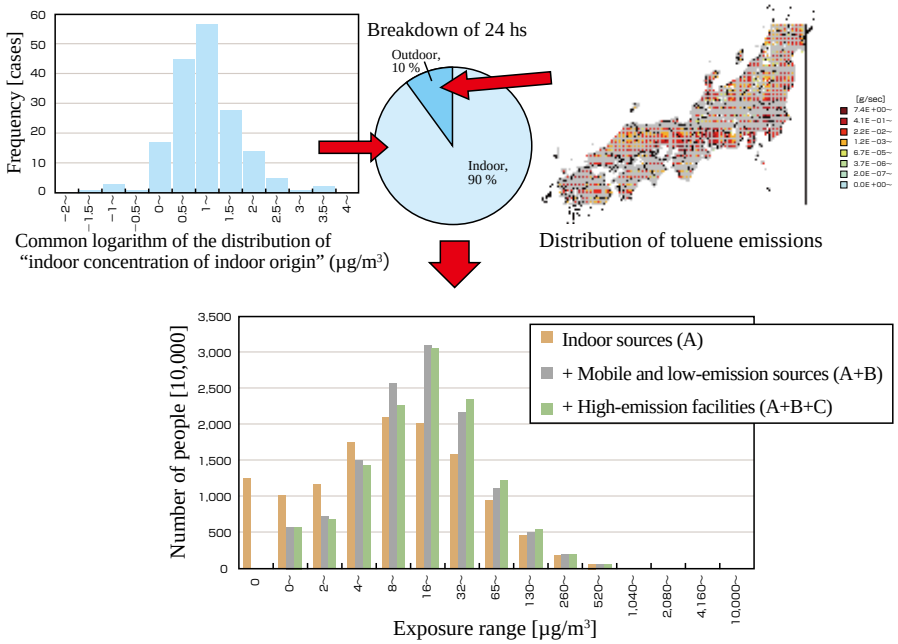

Fig. 4 Distribution of personal exposures (annual average) of Japanese residents

* "High-emission facilities" indicates those emitting more than 300,000 tons per year.

3 (HUI 3), a multiple attribute utility scale which is often used in the medical field [6]. HUI3 has eight attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain. Each attribute has five or six levels. This means that, theoretically, total 972,000 health conditions can be assessed using HU13. The health risks for all residents in Japan from exposure to toluene were finally quantified as the loss of 197 years per annum, as shown in Table 1. If similar procedures were applied to other chemical substances or other kinds of risks, we could quantitatively compare their amounts of risk and would be able to allocate resources more rationally.

3.6 Cost effectiveness of risk reduction measures

Since atmospheric modeling and dose response functions clarified the linkage from emission sources to human health risks, we could simulate the health benefits of introducing emission control measures at the sources and express them as "QALYs gained". By estimating the annual costs of emission control measures, "cost per QALY gained" could be calculated by dividing costs by the QALYs gained. In this study, we calculated the cost-effectiveness in the case where 10 % of the total emission volume of toluene reported to the PRTR was reduced by installing Regenerative Thermal Oxidizers (RTOs). The cost per QALY gained was calculated to be approximately 1.6 years. Since it costs about JPY 33,000 to 100,000 to reduce 1 ton of toluene using RTOs (100,000 to 7,500 Nm^3/hr), it costs JPY 430 million to 1.3 billion annually to reduce 13,000 tons (10 % of emission volumes reported to the PRTR). Therefore, the "cost per QALY gained" was estimated to be approximately JPY 270 to 810 million. This indicator of cost-effectiveness can be used to prioritize risk reduction measures for various types of hazards other than chemical substances, such as infectious diseases, accidents, and natural disasters.

4 Discussion

Table 1. Annual loss of QALYs resulting from exposure to toluene in Japan

	Loss of QALYs (years)
Indoor sources	159
Mobile and low-emission sources	28
High-emission facilities	10
Total	197

The conventional method of risk assessment was originally created by combining elemental techniques that were developed by casting back from social demands to set environmental standards or to conduct screening-level risk assessment. These elemental techniques were established as standard techniques of risk assessment practices, and were respected as academic fields with their own experts. Therefore, when new social demands for risk assessment arise, experts of each elemental technique are expected to apply the existing methods without modification. Since the users of risk assessments are usually not experts, they cannot examine the methodologies of each elemental technique. Once the technology is established as a discipline, it evolves independently. However, leading-edge research does not necessarily satisfy new social demands. There is no guarantee that a necessary elemental technique that may fulfill new social demands will emerge endogenously from academic fields.

In this research, we sought the most suitable methods and revised each elemental technique to fulfill new social demands, i.e. different types of risks were compared and priorities were set based on cost effectiveness. We are aware that some of the assumptions lack firm foundations from an expert standpoint. Although these issues must be resolved, it is also important to accurately explain future research requirements to experts of the disciplines. We must also demonstrate that the methodology presented in this paper can be applied to other chemical substances and other types of risks.

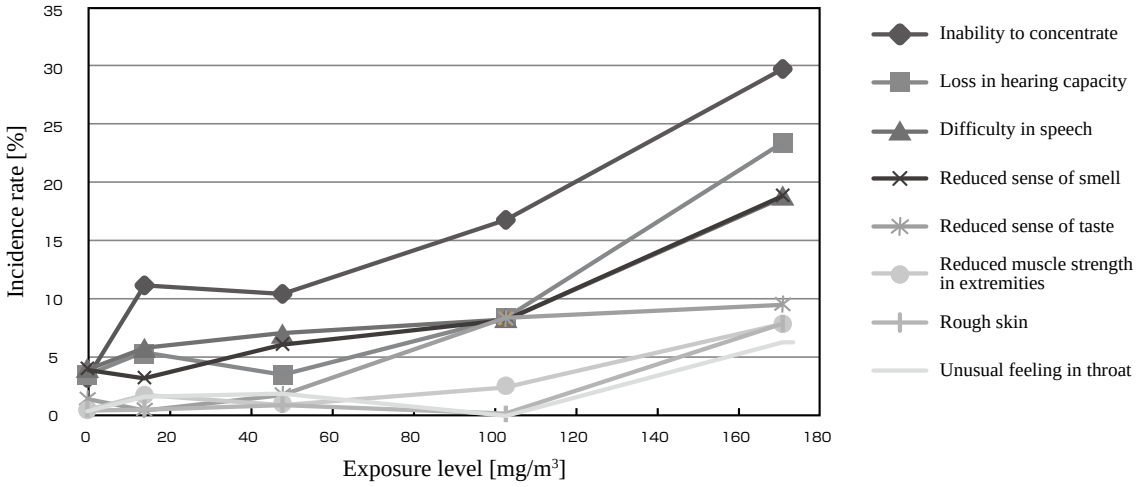

Fig. 5 Dose response relationships of subjective symptoms

Users of risk assessment, or risk managers, must convey the social demands or prescribe the methods of risk assessment to the risk assessment community to ensure that the risk assessment methodology can fulfill newest social demands. Although risk assessment is an interdisciplinary field, this does not mean that it is sufficient to combine works from different fields. We must make sure that each step of risk assessment is consistent, with the goal of fulfilling the given social demands.

Terminology

Term 1. The value is larger than 95 % of the measured values.
Term 2. Percent change in incidence rate of health effects due to intake of chemical substances.

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Discussion with reviewers

1 The relationship between QALYs and healthy life expectancy

Comment and question (Akira Ono)

It is significant that different kinds of risks were assessed using common metric of loss of life years to enable comparison of the risks. Until now, discussions about the risk tended to be unrealistic such as, "it is absolutely safe" or "accidents never happen," but the application of QALYs to the risk assessment will enable reasonable judgments about risks and more flexible response to risks.

What is the relationship between the QALY as described in this paper and the so-called "healthy life expectancy?"

Answer (Atsuo Kishimoto)

"Healthy life expectancy" indicates the expected years of life in good or fairly good health, which correspond to the period when the QOL is not far from 1 in Figure 3. In other words, the QOL during period with illness or disability is considered to be virtually 0. In contrast, in the usual concept of "life expectancy," the QOL for the entire period of life is implicitly considered to be 1. The concept of QALYs is positioned between "life expectancy" and "healthy life expectancy," and reflects the health status most accurately.

2 Comparability with other types of risks

Question (Akira Ono)

Is it possible to apply the proposed methodology to accident risks, such as nuclear plant accidents caused by earthquakes, and compare these risks quantitatively with chemical substances? Is it possible to apply it to international risks such as for avian flu, or global risks such as climate change?

Answer (Atsuo Kishimoto)

Since QALYs are indicators that combine mortality effects (loss of life years) and morbidity effects (loss of QOL), it is applicable to almost all human health risks, including ones caused by nuclear plant accidents. In conventional risk assessment procedures, health risks are estimated according to worst-case scenarios. Since the extent of conservativeness in these different risks varies, it is difficult to compare them. The features of the proposed methodology are: 1) risks are expressed using the common metric of QALYs, and 2) risks are estimated as central tendency estimates, i.e. expected values. When these two conditions are satisfied, any risks are comparable to each other. Although it can also be applied to international risks, it seems to me that the issue of who will be the most affected will become the more important point than the aggregate risk values. The application of QALYs to intergenerational issues such as climate change remains to be discussed.

3 Uncertainty in the number of QALYs

Comment (Akira Ono)

I think that the work of making the scenarios for fulfilling new social demands, from top to bottom in Figure 2 was the key to this research. In doing so, it became gradually clear, that the existing elemental techniques must be revised or replaced by new

ones. This is a great achievement.

However, I imagine that the work has not yet been completed although elemental techniques are being revised or developed. Assumptions were made without foundation. The quantification of human health risks and calculation of cost-effectiveness were implemented even though there was a huge uncertainty about the results. Is it possible to assess and quantify uncertainty in case sufficient data and information are lacking?

Answer (Atsuo Kishimoto)

In this paper, we set priority on deriving concrete numbers, since it was important to exemplify the whole process of proposed methodology, starting from social demands as indicated by the reviewer. As a result, we admit that the discussion on uncertainty i.e. the range of distributions remains to be addressed. At the same time, it is necessary to develop a simplified methodology that can be applied to cases with less data.

4 Compatibility of this article to the journal

Comment (Masayuki Kamimoto)

The content of this article is consistent with the spirit of *Synthesiology*, since it proposes a new methodology of risk assessment by adopting back-casting process and QALYs, and then applies the methodology to the case of toluene. It also describes the process of revising each step of risk assessment and obtains good results.

5 Comparability with other types of risks

Question (Masayuki Kamimoto)

You state, “We must also demonstrate that the methodology presented in this paper can be applied to other chemical substances and other types of risks”. Is this applicable to other substances with enough data?

Answer (Atsuo Kishimoto)

Yes, it is applicable to other substances with sufficient data. It is also applicable to other types of risks such as traffic accidents, since there is a wealth of statistical data. We are now investigating a methodology that is applicable to cases with scarce information.

Technologies for the design and retail service of well-fitting eyeglass frames

— Toward the mass customization business —

Masaaki Mochimaru* and Makiko Kouchi

[Translation from *Synthesiology*, Vol.1, No.1, p.38-46 (2008)]

The ultimate goal of this research is to realize a mass customization business that enables any consumer to easily obtain a well-fitting product. As the first step towards this goal, an IT-based product recommendation system for eyeglass frames was developed. Using this system, a customer's 3-D face shape is measured, frames of the proper size are recommended, and the impression of the customer wearing an eyeglass frame is simulated for style recommendation. Technologies such as face measurement, size recommendation and impression simulation are integrated based on a 3-D face shape database. When the system is used in a retail shop, the contents of the 3-D face shape database can be expanded, and statistical information on face shape and/or impressions of the face and eyeglass frame can be utilized for product design and retailing services.

Keywords : Human sensing, Kansei engineering, Service engineering

1 Introduction

The design concept of "One Fits All" is one solution for universal design. With this idea, one size of product is supposed to comfortably fit all users. This concept is appropriate for designing public facilities and buildings. The "One Fits All" concept is also attractive to manufacturers, as they can reduce manufacturing costs by mass producing just one size. However, it is clear that "One Fits All" is not universally applicable. For instance, one size of shoe cannot fit everyone. For personal products, users are interested in whether they fit their own bodies, not others. While consumers usually use public products designed based on the "One Fits All" concept, they tend to prefer customized products designed for themselves.

Customization based on the skill, know-how and experience of craftsmen has a long history. This type of customization strongly relies on the skill and experience of craftsmen, and it is difficult to apply this approach to mass customization. The aim of this study is to identify human factors that are related to product fitting, to quantify the variations in such factors, and to propose a method to realize mass customization based on engineering. The ultimate goal of this study is to realize a new solution for universal design that can provide customized products "Only For Your Body" for "Anybody", at reasonable prices.

2 Research scenario

Four different solutions have been proposed for providing products of appropriate size. The first solution is "Population Grouping", in which the product provider classifies consumers into several groups, and provides different products for each group to improve the fit. The second solution is "Adjustable Products", in which the product size is adjustable. The third solution is "Finding Well-fitting Products", in which the retailing system can select well-fitting products for specific customers from several candidates (produced based on the first or second solutions) according to customer parameters. The fourth solution is "Mass Customization", in which the whole product or important parts of a product are designed and manufactured based on customer parameters. Although this may seem similar to traditional tailor-made production, "Mass Customization" is based on engineering rather than on the know-how or experience of a specific craftsman. Figure 1 shows the features of the four solutions. Conventional mass production and traditional tailor-made production are located at both ends. The squares indicate cost, the triangles indicate delivery time, and the filled circles indicate customer satisfaction. As Fig. 1 shows the conceptual characteristics of the four solutions, the vertical scale is not meaningful.

"Population Grouping" is the most popular solution. It requires somewhat higher costs than one-size products, but delivery time is shorter because all size variations of product can be stocked. "Adjustable Products" is a typical solution for products such as car driver's seats and office chairs. Additional costs are required for manufacturing adjustable products. In these two solutions, consumers have to select or to adjust the product by themselves. If they do not have sufficient knowledge or experience for selection, the performance of the product can be poor because of a loose or tight fit. The result of our study on shoe fitting [1] is a good example. In this experiment, volunteer subjects selected

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the best fitting shoes from candidate shoes of a wide range of lengths and widths. Subjects with narrower feet selected wider shoes and, subjects with wider feet selected narrower shoes. In the actual market, only shoes of normal width are available. These results suggest that subjects understand the fitting of shoes of normal width as ideal, irrespective of their own foot width. According to various tests, tight fitting shoes block blood flow, while loosely fitted shoes allow larger in-shoe foot movements and larger impact against foot.

The third solution, "Finding Well-fitting Products" includes a service system to recommend suitable products for specific users based on his/her own parameters. Additional costs are required for this recommendation system. If the number of alternatives is too large, the complete range cannot be stocked in the shop, thus resulting in longer delivery times. "Mass Customization", the fifth solution, has been realized as an insole customization service for running shoes. Using a foot scanner, the customer's foot shape is measured at a retail shop, and insoles are immediately manufactured for the customer at the shop. Such processes require additional costs because customization takes time, and special equipment is necessary for manufacturing.

The "Mass Customization" solution is thought to have the greatest potential to satisfy users. However, there are two obstacles. The first is investment by the provider. It is necessary to re-design products for customization, and equipment is required for measuring the user and manufacturing custom parts. Because the investment for mass customization is quite large, it is a difficult decision for the provider. The other obstacle is investment by the customer. There are customers who are willing to pay the additional cost for customized products based on traditional tailor-made customization. However, the market for mass customization is not apparent. Mass customized products are more expensive than mass produced products, and are cheaper than traditional tailor-made products. Customers who prefer traditional tailor-made products may not purchase cheaper mass customized products, while the majority of customers may not pay the additional costs for mass customized products. It may be an effective strategy for creating an apparent market of mass customization to allow the user to experience well-fitting products with a smaller investment. Therefore, we took the "Finding Well-fitting Products" solution as a tentative step towards "Mass Customization" in order to allow the user to experience a good fit at a reasonable price. An IT-based "Finding Well-fitting Products" system can store user body data and purchasing behavior as the system operation log, and the stored information can be utilized in product sizing for "Mass Customization". Good experiences may induce additional investment by users. Subsequently, providers are encouraged to invest in equipment.

The aim of this study is to integrate technologies for the "Finding Well-fitting Products" solution based on the concrete application of research into eyeglass frame retailing. The domestic market size for optical goods is 100 billion yen per year (2002). There are around 15,000 eyeglass shops in Japan. Figure 2 shows the final goal image of the system that would be operated in these retail shops. Customer's facial photos are taken at a retail shop, and a 3-D shape of the customer's face is generated from multiple photos. Based on the measured data, the system recommends a suitable size of eyeglass frame from prepared candidates. Elemental technologies for size recommendation include measurement technology that is simple and inexpensive enough to be used in retail shops, designing technology considering human face shape variations, and size recommendation technology. The system also recommends styles of eyeglass frame that makes the customer look intelligent, gentle, etc. This system shows the simulated impression ratings by a third party for the combination between the face of the customer and the selected eyeglass frames. These style recommendation services could be provided by shop clerks through traditional tailor-made customization based on their know-how and implicit knowledge obtained through experience. In this

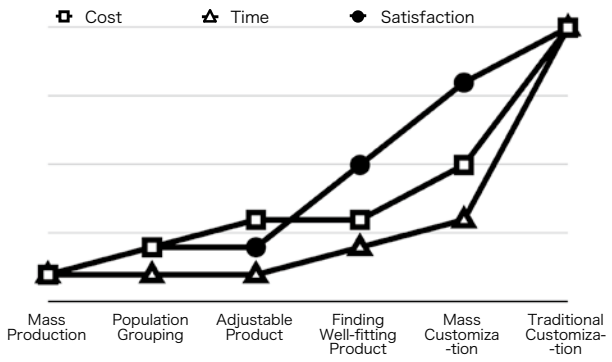

Fig. 1 Cost, delivery time, and satisfaction of customers with various manufacturing methods.

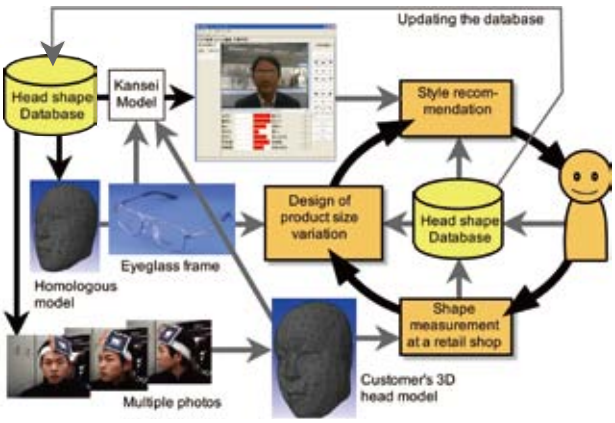

Fig. 2 A system to produce eyeglass frames according to the "Finding Well-fitting products" approach.

study, we developed a computerized recommendation system based on explicit knowledge. Three elemental technologies (easy measurements, size recommendation and style recommendation) were developed based on a database of 3-D face and head shapes. These technologies may be applied to the business through a scenario, as shown in the right side of Figure 2. With this scenario, the database can be expanded continuously through the business cycle. In the present paper, we describe the database of 3-D face and head shapes and the three elemental technologies. Subsequently, integration of these technologies and validity for actual retail services are discussed.

3 Elemental technologies

3.1 Homologous human body shape modeling and database of 3-D face and head shapes

The database of 3-D face and head shapes was the technological foundation of the three elemental technologies. In this section, general methods for human body measurement and homologous shape modeling are described. Subsequently, concrete technologies for applications such as head scanning technologies and head modeling methods are described.

Optical scanning technologies are used commonly for human body shape measurement. A patterned light source is projected onto the body surface, and the reflected light is captured by camera from a direction different from the light source. The 3-D coordinates of the surface are calculated by triangulation [2]. The human body shape obtained by scanning consists of 3-D coordinates of a large number of data points (many millions) and 3-D coordinates of dozens of anatomical landmarks. Anatomical landmarks are feature points based on anatomical correspondence. Many landmarks are defined based on specific positions on bones. An expert anthropometrist palpates and determines the landmark locations, and places markers on the skin surface before scanning. Most body scanners can automatically detect the markers on landmarks and calculate their 3-D coordinates. Landmark locations have the same anatomical meaning in all subjects, and all subjects have the same number of landmarks. However, the number of landmarks is too small to represent the 3-D body shape.

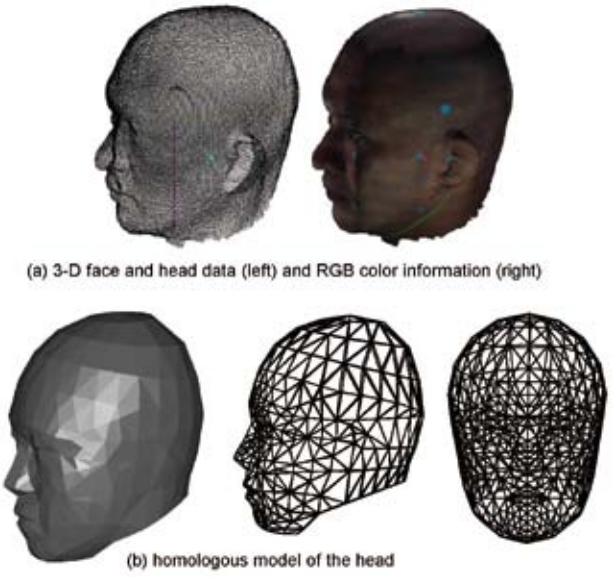

Fig. 3 Examples of 3-D face and head data (a) and homologous model of the head (b)

The number of data points on the body surface is large enough to represent the 3-D body shape, but the number differs between subjects. It is difficult to compare 3-D body shape in different subjects, as the number of landmarks is too small to describe body shape, and the number of data points on the body surface differs between subjects. Therefore, we proposed homologous body shape modeling. With homologous body shape modeling, the body surface shape of any subject is described with the same number of data points and the same topology. We proposed polygonal representation. Body shape is described with k piece of 3-D coordinate vector $\overline{T}$, which has $k \times 3$ components. The average body shape of m persons can be calculated easily from multiple shape vectors $T_1, T_2, ...$, and T_m. By analyzing the matrix $M=[T_1, T_2, ..., T_m]$ using the principal component analysis (PCA), eigenvector P is obtained.

Body shapes for m persons can be represented in the eigenspace by using principal components A_1 - A_m. When n principal components explain sufficient variance, human body variations can be described in the eigenspace of n dimensions (n<number of data points). Reducing the number of items to represent human body variations is effective for product sizing. Moreover, virtual homologous body models can be generated from eigenvector and principal component scores. A virtual homologous body model is calculated by the following equation:

$$T = \overline{T} + P(n) \times A(n) \quad ... (1)$$

where, $P(n)$ indicates first n eigenvectors, and $A(n)$ indicates scores for first n principal components.

Commercial systems are available for 3-D face and head shape scanning. For eyeglass frame design, the conventional scanning system had several technical issues; regions behind the ears were occluded, anatomical landmarks were not automatically obtained, and a homologous model was not automatically generated. We developed a new face and head scanning system to solve these issues. Twelve visible ray projectors were located around the head, and patterned light was projected onto the head. The human head with the light pattern was captured by 12 cameras. The projectors

and cameras were carefully located in order to reduce the occlusion of regions such as under the chin, under the nose and back of the ear. Using this system, the head shapes of 52 Japanese males (18-35 yr) were measured. The obtained data consists of millions surface data points, RGB color information of the data points, and around 80 anatomical landmarks (Figure 3(a)). A homologous head model without the external ears consisting of 485 vertices and 838 polygons was then generated (Figure 3(b)).

3.2 Size variation design[4]

Conventional eyeglass frames vary in size. The sizing method is very simple; lens width and temple length are changed in proportion. The sizing method does not represent variations in the human face. Thus, we designed a new sizing system that could effectively cover the variations in the human face using a mid-facial homologous shape model consisting of 211 vertices (Figure 4). As mentioned in Section 3.1, PCA can compress information on shape variation. However, PCA is not efficient enough for grouping subjects because it is based on linear transformation. Therefore, we used the multi-dimensional scaling method (MDS). The inter-individual shape distance was defined by the following formula:

$$D_{ij} = | T_i - T_j |$$

where, T_i indicates the vertices vector of i-th subject and T_j indicates that of j-th subject. The inter-individual distance D_{ij} is calculated from the summation of the Euclidean distances between the corresponding vertices. When the number of subject is m, the distance matrix ($m \times m$) of inter-individual shape distances is calculated. By analyzing the distance matrix using MDS, the location of each subject is assigned in a low-dimensional space. The fit of the model is evaluated using RSQ, the squared correlation coefficient between elements of original distance matrix and elements of the distance matrix calculated from the obtained low-dimensional solution.

Fig. 4 Homologous model for the middle face

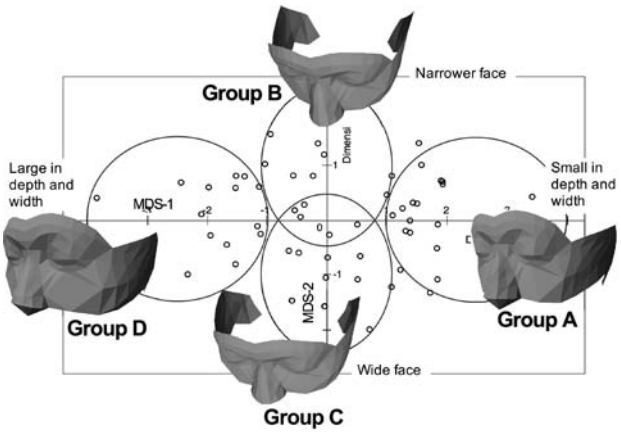

Fig. 5 Distribution of middle face shapes in 52 young adult male Japanese

Analyzing the variation in mid-facial shapes by MDS, the coefficient of determination (RSQ) was 0.95 for the 5-dimensional solution, whereas at least 15 principal components are needed to explain 95 % of the total variance. Figure 5 shows the distribution map of the subjects based on the scores for the 1st and the 2nd scales of the MDS. The obtained MDS scales were interpreted using correlation coefficients between the MDS scores and facial dimensions. The 1st scale was related to the face size, particularly the depth, and the 2nd scale to the face width and the inclination of the face. These two scales account for 83 % of the variation in the Japanese face. The 3rd scale was related to shape of the nose, and the 4th scale to the proportion between the face width and the interpupillary distance. The 3rd and the 4th scales are not strongly related to fitting of the eyeglass frames.

We decided to develop 4 eyeglass frame sizes considering profitability of manufacturing and distribution. Four size groups were defined as shown in Figure 5; namely subjects were divided into 3 groups based on the scores for the 1st scale representing the size, and the mid-size group was divided into two groups based on scores for the 2nd scale. The average face shape to represent the size group was calculated for each group. Well-fitting eyeglass frames were designed and manufactured based on the average face by the collaborating company (Figure 6).

In order to validate the fitting of new eyeglass frames, 38 male subjects were recruited (average age, 24.5 yr). For each subject, the location in the MDS distribution map (Figure 5) was estimated by multiple regression based on 15 facial dimensions, and the size group was determined. New frames for the 4 size groups and a conventional frame of the same style design were used for the validation study. The tightening force and the slip range after the subject shook the head were measured. Sensory evaluation of fitting was also conducted using a 5-point scale rating. New frames of the

Fig. 6 Preproduction sample of eyeglass frame using the new sizing system

proper size got significantly better scores for overall fit than the conventional frames ($p<0.01$). Moreover, the tightening force was significantly smaller in the new frames ($p<0.01$). On the other hand, no significant differences were observed in slip range. Thus, the new frames fit without slip and had a smaller tightening force.

3.3 3-D head shape reconstruction from multiple images[5]

Location in the subject distribution map could be estimated from 15 face dimensions, and a suitable size of eyeglass frame could be selected. An expert anthropometrist is necessary to obtain reliable face dimensions, thus it is difficult to use this method in actual retail shops. In addition, 15 face dimensions are not sufficient for reconstructing 3-D face shape, which is used for computer graphic representation (Figure 2), while the special 3-D face scanner mentioned in Section 3.1 is too large and expensive to use in retail shops. Therefore, a novel measurement method for human body shape was developed.

The variation in human bodies can be represented in the eigenspace with a smaller number of independent dimensions (Section 3.1). Namely, any human body shape can be described using only dozens of principal components rather than millions of data points. Therefore, we developed a new method for reconstructing, rather than measuring, the 3-D head shape of an individual. The average head shape is used as the initial shape, and unknown values (principal component scores describing the individual shape) were obtained by minimizing the differences between camera images and the projected image of the 3-D head shape reconstructed from principal component scores ($A(n)$ in equation (1)) Reconstructed 3-D head shape was projected into image planes based on calibration parameters of multiple cameras. The difference between the real 2-D image and the projected image was evaluated by the edge distance of two images. The principal component scores $A(n)$ were optimized to minimize image differences, and the optimal 3-D shape was obtained from the optimized principal component scores (Figure 7). The calculated 3-D head shape was compared with 3-D shape measured by the head scanner (Section 3.1), and the average error was found to be 2.0 mm.

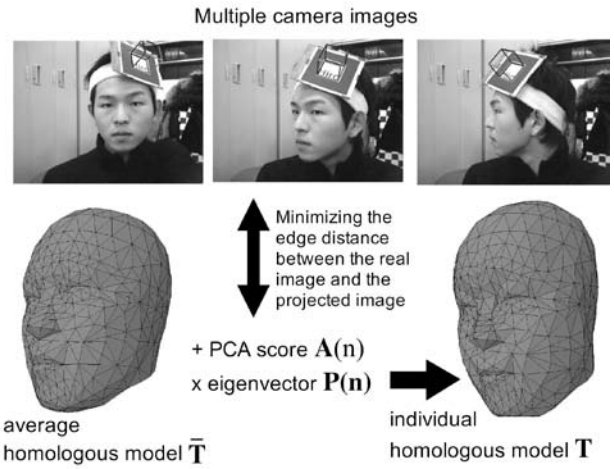

Fig. 7 Reconstruction of 3-D face and head shape from multiple images

This technology is not a measurement technology, but is a reconstruction technology using multiple cameras based on the database of homologous body shapes. However, this technology has a similar function as a measurement technology, because 3-D head shape can be obtained from multiple cameras to an accuracy of 2.0 mm. As this method is not based on triangulation between a camera and projector, patterned light projection and scanning processes are unnecessary. A homologous model of an individual can be obtained by simultaneously capturing images with multiple cameras. Face dimensions are extracted from the model, and used for recommendation of eyeglass frame size. Furthermore, even when part of the head is occluded, the reconstructed model is always complete.

3.4 Computational estimation of the impression for the face and frame[6,7]

Size recommendation can be realized by size variation design technology (Section 3.2) and individual head shape measurement technology (Section 3.3). In this section, style recommendation technology is described. This technology is for estimating the impression ratings of the combination of an individual face and a selected eyeglass frame.

Words were used to describe the impression of the face and the eyeglass frame. In a preliminary experiment, we selected 42 adjectives from about 100 words obtained from a dictionary. Photographs of 10 different faces with different eyeglasses were presented to young adult female subjects and impression of each photograph was rated against the 42 adjectives. The ratings were analyzed using a factor analysis, and 4 factors were extracted. The 4 factors were interpreted as “gentle - stern”, “cool - hot”, “cheerful - quiet” and “younger looking - older looking”. The following 3 pairs of adjectives were added based on the original marketing research of the collaborating eyeglass frame maker: “sophisticated - unstylish”, “natural - unnatural” and “optimistic - nervous”. Impression ratings for these 7 pairs of words were obtained for images of a face and frame by experiments using sensory evaluation. We hypothesized that impression rating could be estimated as a function of shape factors for the face and eyeglass frame. Therefore, we identified this function based on experimental data, and validated the performance of this function using actual data.

Generated virtual face images were used for the experiment. Virtual face images were generated to cover the variations in young adult male Japanese faces using the database of

3-D face and head shapes. Head data was analyzed by MDS, and virtual 3-D homologous face models with scores of +3 standard deviation (s.d.) or –3 s.d. for only one of the 4 scales, such as (+3 s.d., 0, 0, 0), (–3 s.d.,0, 0, 0), (0, +3 s. d., 0, 0), etc., were generated. Virtual shapes at the center of distribution (average shape) or located between 2 scales were also generated. In total, 18 representative face models were generated.

The homologous model described in Section 3.1 did not contain color information, such as eyebrows and lips that influence impression; therefore, a 2-D frontal face model including such information (Figure 8) was generated for each of the virtual shapes. The 3-D model of an individual was deformed into each of 18 generated models using the Free Form Deformation technique. Using each of the obtained transformation grids, the scan data of the individual with color information was deformed. The obtained representative 3-D face shape with color information was then projected onto the frontal plane. From the projected 2-D face with color information, a 2-D frontal face model including eyebrows and lips was created. The average texture of the young adult male Japanese was mapped onto the 2-D face model [8]. Through this process, 18 representative face images with color information were generated. Twelve eyeglass frames of different materials, types and shapes were selected. In order to reduce the time needed for each experiment to 30 minutes, 12 sets of 18 images were selected from 216 images (18 faces × 12 frames). Every set contained different faces and different frames.

Participants were 300 young adult females. They evaluated one set of images (18 images) randomly selected by the web questionnaire system. The impression rating was evaluated by the visual analog scale method (VAS). Participants evaluated the image by moving the pointer on the scale between each pair of words in the web system (Figure 9). A computational model to estimate the impression rating from shape factors of the face and the frame was obtained by multiple regression (stepwise procedure). The dependent variable was the impression rating for each pair of words, and explanatory variables were the face dimensions and proportions, eyeglass frame dimensions and proportions, principal components of lens shape descriptors. Multiple correlation coefficients ranged from 0.784 to 0.901 for all impression ratings. Dimensions and proportions of the faces and eyeglass frames, and principal components of lens shape were contained in the explanatory variables for all impression ratings (Table 1).

For the validation study, the following 12 face images were used: (1) virtual face images that were not used in the main experiment to develop the model, (2) a virtual face image that was close to the average face, (3) deformed actual face images, and (4) images that were used in the main experiment. Twelve images of faces with eyeglass frames were presented to another 59 young adult female participants, and impression ratings of 7 pairs of adjectives for 12 images were obtained. Comparing the impression ratings for validation images of (4) with those for the same images in the main experiment, it was found that the participants of

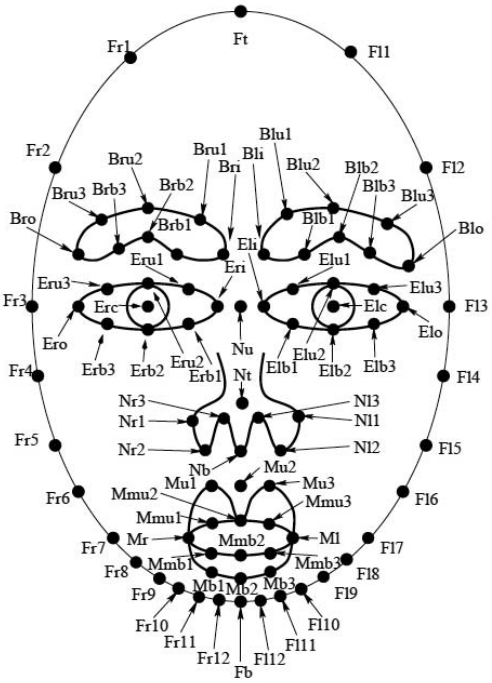

Fig. 8 2-D front face model used. From Mukaida et al., 2002

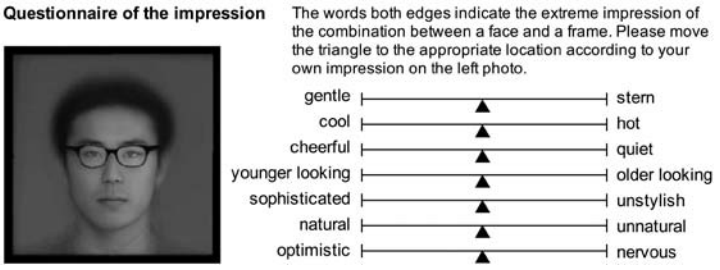

Fig. 9 Example of Web-based questionnaire for impression rating

Table 1. Number of variables adopted in estimation functions (stepwise multiple regression)

Word pair describing impression	R	Face measurement	Eyeglass frame measurement	PCs for lens shape
Gentle－Stern	0.892	11	3	1
Cool－Hot	0.901	8	5	2
Cheerful－Quiet	0.821	8	1	1
Younger looking－Older looking	0.784	8	3	2
Sophisticated－Unstylish	0.834	5	6	2
Natural－Unnatural	0.871	5	3	1
Optimistic－Nervous	0.863	9	1	1

the validation study were equivalent to those of the main experiment. The residual error between estimated ratings and actual ratings for validation images were calculated for images of (1) and (2). The error was within 10 % for all impression ratings. Moreover, a similar error range was observed in the deformed actual face images of (3). It was confirmed that the computational model could be utilized for real face images. The hypothesis of this study, that impression rating can be estimated by a function of shape factors of the face and eyeglass frame, was thus validated.

3.5 Style recommendation system

A style recommendation system based on the computational model to estimate impression ratings (Section 3.4) was developed. This is part of the recommendation system in Figure 2, but focuses on style recommendation using 2-D face images. Customer images are captured by a USB camera connected to a PC, and a 2-D homologous face model (Figure 8) is generated automatically. In the present system, the interpupillary distance is measured directly and the value is used for scaling. Scaling problems can also be solved by camera calibration in the future. Images of 12 eyeglass frames used in the experiment and their shape factors are registered in the system. Obtaining a 2-D model of the customer, the impression ratings of all pairs of adjectives for 12 eyeglass frames are calculated immediately. The ratings are presented on the system as a relative scale for the 12 frames with a composite image of the face and selected frame (Figure 10).

4 Integration of elemental technologies

The aim of this study is to realize a solution for “Finding Well-fitting Products” through an application study aiming to fit eyeglass frames to individual customers. Elemental technologies were developed for this purpose and they were integrated to realize the solution presented in Figure 2. Three elemental technologies described in Section 3, size variation design, head shape reconstruction, and estimation of impression ratings, were integrated into an off-line system. Part of this system was completed as a demonstration.

Fig. 10 Style recommendation system for eyeglass frames based on Kansei (sensibility) modeling.

The most important foundation in this study is the database of 3-D face and head shapes. Homologous modeling and the database are essential for integration. All elemental technologies developed in this study require the database. For instance, the head shape reconstruction method requires the database obtained using another measurement method. The reconstruction method itself is not complete without the database of homologous models of head shape. This promotes the advantage for system providers who have a database. The system provider can keep the advantage of the database by applying the system. When the provider applies the system at a retail shop, the database can continuously be expanded by adding customer data to the database. The compiled data can be used for both proper size grouping of products, as well as for robust shape reconstruction using a multi-camera system.

5 Discussion

In this section, the industrial and social validity of this study are discussed. Based on the size variation method described in Section 3.2, new eyeglass frames with proper sizing were developed by the collaborating company and were sold on the market. Subsequently, the company used the sizing method for other eyeglass frames. It was thus confirmed that the method is valid for industry.

The 3-D shape reconstruction method described in Section 3.3 has a similar function as 3-D shape scanning technologies, but with this method, complete 3-D shapes can be obtained very quickly and without laser scanning. The error of 2 mm is larger than the 0.5 mm of conventional scanning technologies [3], but is small enough for size and style recommendation. The system contains multiple digital cameras, and registration and time control for projectors and cameras are not required. The features of the system, such as its low cost, size, lack of laser projection, and quick and complete measurement, are superior to conventional systems for retail use. The style recommendation system described in Sections 3.4 and 3.5 is only used for demonstration purposes. This system has been received well by visitors, with comments such as “it is fun to select eyeglass frames with this system”.

Throughout this study, the obstacles to investment from providers were reduced by the development of efficient size variation designs using existing manufacturing resources,

and a low-cost head shape measurement system. When this recommendation system is operated in retail shops, providers can store the information on face shape and product selection from the log of the recommended system. Such information can form the foundation for "Mass Customization". From the customers' point of view, recommendation technologies for both size and style induce investment in more expensive products. Such interaction between providers and customers creates a new solution for universal design, "Only For Your body" for "Anybody".

Storing body data through retail businesses using the developed system may lead to the formation of intellectual infra-structure. Databases of human body shape have been collected and stored by institutes that have special equipment and skills based on government funding. The data has been obtained cross-sectionally in specific locations over short periods of time. The Research Institute of Human Engineering for Quality Life (HQL) measured 34,000 Japanese during 1992-1994, and they measured other 8,000 Japanese during 2004-2006. In North America, 4,000 people were measured in CAESAR project in the last decade. In contrast, longitudinal human body data can be stored at distributed retail shops by the developed system. History of body shapes for an individual can be stored in many locations around the world. Large amounts of human body data can be stored on a daily basis. This would allow social intellectual infra-structure. It is also expected that the funding resources to create this infra-structure would shift from governmental to nongovernmental sources. Stored human body data without personal information could then be used for size variation design (Section 3.2) and measurement technology (Section 3.3). Relationships between body shape and buying history could also be utilized for creating new Kansei models. In the future, a practical system for retail shops may be developed with the collaborating company, and the system could be applied to an actual retail shop.

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Discussion with reviewers

1. Methods for improving fit

Question (Motoyuki Akamatsu)

Authors listed 1) Population Grouping, 2) Adjustable Products, 3) Finding Well-fitting Product, 4) Mass customization, and 5) Traditional customization as methods for improving the fit. I believe that Method 3) is for improving the fit obtained by Method 1), rather than a method located between Methods 2) and 4). Therefore, I believe that Method 3) should be considered as a secondary method to make up for the shortcomings of Methods 1) and 2). Because both methods depend on the subjective judgment of the user, true conformity cannot be attained. In addition, Method 3) is the basis of Method 4).

Answer (Masaaki Mochimaru)

Thank you for your comments. As you stated, 3) Finding Well-fitting Product does support the shortcomings of 1) Population Grouping and 2) Adjustable Products. Therefore, we revised the text as follows: After describing 1) Population Grouping and 2) Adjustable Products, we state that good fit cannot be obtained if the selection depends on user preference, citing our previous study as an example. We then state that Method 3) Finding Well-fitting Products overcomes these issues.

Your last comment indicates that the relationship between the characteristics of users and characteristics of products will be accumulated by providing services for "Finding Well-fitting Products", and such information will be the basis for "Mass Customization". We agree with this opinion. As our original manuscript did not mention this point, we now discuss it in the Discussion.

2. Grouping subjects and the validity of evaluation

Question (Motoyuki Akamatsu)

Please explain the grouping of subjects into 4 groups. Did you evaluate the validity of each evaluation study with regard to which group the 38 subjects belonged and the differences between each subject and average shape in the 4 groups?

Answer (Masaaki Mochimaru)

(1) Grouping subjects

As the shape variation followed the normal distribution, there was no scientific way to divide subjects into a limited number of groups. Theoretically, the more groups, the better the fit. Therefore, in this study, the collaborating company examined the maximum possible number of groups from the viewpoint of profitability in manufacturing and distribution, and decided on 4 groups. We then had to determine how to cover the variation within the limit of 4 groups. In this study, we divided the scores for the 1st scale, which explained the largest variance, into 3, and the group with near average scores for the 1st scale was divided into 2. As shown in Figure 5, Groups A and D cover larger areas than Groups B and C. This is because by setting different ranges of scores for the 1st and the 2nd scales between the 4 groups, we attempted to minimize the difference in shipments between the 4 groups. In other words, numbers of people who would be assigned to the 4 groups are about the same in number. Such reasoning is described in reference [4], and we have added an overview to the manuscript.

(2) Evaluation study

We recruited subjects so that the numbers of subjects assigned for the 4 groups did not differ substantially. Because 3D shape was not measured for the 38 subjects, the shape difference between each subject and the average for each group is unknown. However, the difference was within 3 mm for head dimensions. This is described in the reference cited, but we now mention it in the text.

3. Head dimensions measured

Question (Motoyuki Akamatsu)

Section 3.3 describes "using 15 face dimensions". How did you decide the 15 face dimensions?

Answer (Masaaki Mochimaru)

Details are described in the reference cited. We measured about 50 items for all subjects. The 15 measurements were adopted for regression equations to estimate the scores for the 1st and the 2nd scales, using stepwise regression analysis. We intentionally selected measurement items that can be measured easily and reliably, and performed the stepwise regression analysis several times. We did not describe the details in the text.

Our initial plan was to use these 15 measurements rather than 3-D shape for selecting eyeglass frames (see references), but this was not accepted by the collaborating company, as retail staff do not possess the necessary skills in anthropometry. Therefore, we decided to develop a low-cost head measurement system.

4. Future works

Question (Motoyuki Akamatsu)

Please include a discussion of the future direction of the project, areas that need to be improved, and technical breakthroughs yet to be realized.

Answer (Masaaki Mochimaru)

Of course, there are some areas that require further work. For example, the effects of hairstyle on style recommendation have not been investigated. It is clear that there is an effect based on the results of preliminary experiments, but we currently lack the computer graphics technology to naturally change hairstyles. Future works include designing parts (nose pad and bow) and finite element analysis for estimating the pressure distribution between these parts and the face, as well as the sensation of touch. Another incomplete aspect is the technology for utilizing the information on product selection and satisfaction. Without this technology, simultaneous data accumulation, updating size variation designs and Kansei evaluation are impossible; this system is merely a tool for sales support. This will be studied further after systems such as that presented in this paper are practically used in shops.

5. Other applications of this technology

Question (Motoyuki Akamatsu)

Similar systems may be used for other products, such as clothes and shoes. Will the technologies for other products be the same as with this system, or is there something specific to eyeglass frames?

Answer (Masaaki Mochimaru)

We believe that this approach for measuring the human body and selecting the best fitting products from size variations has general applications. Such methods are already used for running shoes in shops. However, applications for selecting clothes are not very popular, as few consumers would be willing to undress for a 3-D scan. We believe that improved technology for 3-D measurement for clothes, or other businesses related to body scanning may solve this problem.

For recommendations based on Kansei modeling, style design and fit are more independent elements for eyeglass frames and running shoes, while they are closely related with shoes and clothes. Therefore, the present system that recommends size and style independently may not be applicable to shoes or clothes. However, recommendation systems for those products are possible and should be studied in the future.

Improving the reliability of temperature measurements taken with clinical infrared ear thermometers

— Design and establishment of a new calibration system traceable to the national standards —

Juntaro Ishii

[Translation from *Synthesiology*, Vol.1, No.1, p.47-58 (2008)]

Infrared ear thermometer was developed and rapidly spread in Japan in the late 1990's, but users began to question the reliability of the temperature readings. AIST developed a new national standard for the calibration and conformity assessment of new ear thermometers, and also designed and organized the traceability system, conducted technological verification, and improved reliability of measured temperature, to meet the demands of Japanese industry and consumers. An international comparison of national measurement standards among Germany, UK, and AIST was conducted and the equality of the standards was experimentally verified to maintain international reliability.

Keywords : Standard, traceability, infrared, clinical thermometer, reliability, blackbody, radiance temperature

1 Introduction

Along with blood pressure and heart rate, body temperature is one of the most basic vital signs of the human body that is used for medical diagnosis and health management. Since body temperature measurements are taken at home as well as in medical institutions by physicians and nurses, clinical thermometers require high reliability and utility as measuring instrument.

Mercury-in-glass thermometers have been used for a long time, but there were problems of glass breakage and use of mercury that is harmful to the human body. Later, when high-precision thermistor was developed as temperature sensor, clinical electronic thermometers with thermistor sensors became commercially available, and its use spread rapidly due to ease of handling and safety. It is widely used to this day. However, there were still problems with clinical electronic thermometers since the sensor must be held close to measured body-site such as the armpit for around five minutes to measure the body temperature accurately making it unpractical for emergency patients in serious condition, and temperature measurement in newborns and infants were difficult.

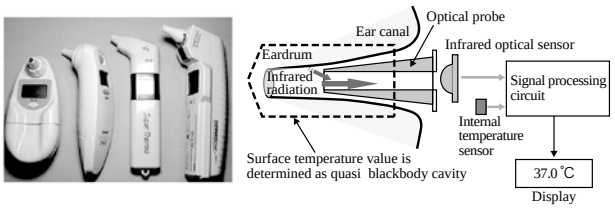

Fig. 1 External appearance and structure of ear thermometer

In the 1990s, a U.S. company developed a new infrared clinical thermometer in which measurement was taken by inserting the sensor probe into the ear canal (hereinafter will be called "ear thermometer"), and was marketed in the United States and Europe. Figure 1 shows the external appearance of ear thermometers and the schematic diagram of the measurement principle. Ear thermometer consists of optical probe, infrared sensor, compensating internal temperature sensor, signal processing circuit, and display unit. The tip of the optical probe is inserted into the ear canal, the intensity (radiance[Term 1]) of infrared radiation at around 10 μm wavelength emitted from eardrum and skin surface of inner ear canal is measured, and the temperature of measured part is determined from the relation of Planck's law of thermal radiation[Term 2]. The calibration of temperature reading is conducted by using the ear thermometer to measure the radiation from ideal blackbody cavity for which accurate temperature is known.

The human skin surface has emissivity[Term 3] close to unity in the thermal infrared wavelength region, so it is a suitable object for infrared radiation thermometry. The method of measuring skin surface temperature from thermal radiation measurement has been also applied successfully to breast cancer diagnosis technology using thermograph. In newly developed ear thermometers, eardrum and surrounding ear canal were selected as cavity to be measured, and therefore effective emissivity (ε) of the measured area approached the condition of almost ideal blackbody (ε=1), and the accuracy of body temperature measurement was greatly improved. Also, measurement could be accomplished in a short time of about 1 second by introducing advanced infrared sensor technology. This ear thermometers overcame the issues of conventional contact type (thermal equilibrium type) clinical thermometer, and drew attention as third-generation clinical

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thermometer that enabled “short measurement time” and “non-contact measurement”[1].

In Japan, ear thermometers were introduced as instrument for medical specialists in the beginning of the 1990s. In 1996, it was formally approved as a medical device for general use, and became commercially available. The number of production and sales of ear thermometers in the Japanese market increased rapidly, and in a few years, reached around one million a year. The reasons for this rapid expansion were the fact that new ear thermometer satisfied user demands, and that the manufacturers had high hopes for this new innovative product that appeared in clinical thermometer market that reached maturity since the development of clinical electronic thermometer about a quarter of a century ago[2].

On the other hand, with rapid diffusion of ear thermometers, questions and claims against the reliability of temperature readings of ear thermometers were made by users and consumer organizations, and drew attention of mass media such as newspapers and magazines. Therefore, as the national metrology institute of Japan, AIST started a research project to improve measurement accuracy of ear thermometers. After adjustments with manufacturers, users, and administrative bodies, the traceability system was established by 2002, and technological and social infrastructures were laid to maintain accuracy of temperature readings of ear thermometer.

Also, the standard facility for calibration of ear thermometer which resulted from this research was provided to national standard institutions of Asian countries when severe acute respiratory syndrome (SARS) epidemic occurred in Asia in 2003, and helped to prevent the spread of infection[3].

2 Public-private cooperation for problem solution

Currently, mercury-in-glass and clinical electronic thermometers are designated “specified measuring instruments” under the Measurement Law administered by the Ministry of Economy, Trade and Industry. Instrumental error test (verification test) is conducted for all thermometers along with pattern approval test under government control. In contrast, testing and inspection according to technical guidelines of respective companies are conducted under responsibility of the thermometer manufacturers, for maintaining the reliability of temperature readings for newly developed and marketed ear thermometers.

Ear thermometer attracted attention for its usability, and its use spread immediately after it became commercially available. On the other hand, complaints from users increased concerning its performance and reliability including differences in measurement principle and usage compared to conventional clinical thermometers. In 1998, the National Consumer Affairs Center of Japan, a public institution that conducts surveillance study from standpoint of consumer protection, reported “Attention! Ear Thermometers Tend to Measure High”,[4] and subsequently newspapers and magazines wrote that “the temperature readings show large variation” or “measurement is higher than actual temperature”.[5]

In such a situation, “Survey and Research Committee for New Clinical Thermometer” was established in 1998 with members from the government (former Ministry of International Trade and Industry; former Ministry of Health and Welfare), medical professions, consumer organizations, clinical thermometer manufacturers, AIST (formerly National Research Laboratory of Metrology, Agency of Industrial Science and Technology). The committee conducted questionnaire survey to manufacturers and retailers of clinical thermometers, medical institutions, and consumers, to study the situation in Japan. According to this survey, while manufacture and sales of ear thermometer reached nearly 1 million per year, it became clear that neither medical specialists nor consumers had sufficient understanding of performance, measurement principle, usage, or reliability of ear thermometers[2].

With cooperation of the committee members, AIST checked the temperature readings of ear thermometers in the market using an existing simple blackbody furnace, and found that some types of thermometers presented bias and large variations of 0.5 °C or more in temperature readings.

Through this survey, two points were highlighted as technical issues arising from rapid market expansion of new ear thermometers:

(1) Provision of sufficient information to users about measurement principle and proper usage
(2) Establishment of technical standard, and traceability system for calibration and conformity assessment of ear thermometer

Of the above two points, (1) was an issue mainly for manufacturers, retailers, and industry, while immediate effort by the government centering on AIST was strongly in demand for (2).

The committee also conducted survey for the status of stand ardization,measurement standard and traceability[Term 4] for ear thermometers. Work on ear thermometer was done primarily in the United States, which was first in the world to market the product, and Germany, where it diffused widely after acquiring the technology from the U.S. In the United States, industrial

standard was established by American Society for Testing and Materials (ASTM)[6], while national measurement standard system was slow to develop. In Europe, the preparation was in progress for the European Norm (EN)[Term 5] lead by Germany that was center for major manufacturers[7] of ear thermometers. In Germany, Physikalisch-Technische Bundesanstalt (PTB), a national metrology institute, actively engaged in the technical development of measurement standards for ear thermometers.

3 Setting research goals and scenario for achievement

As issues to be tackled by AIST described in the previous section, establishment of traceability system for ear thermometers to satisfy user demand was set as a goal, and it was also desirable to utilize the results of technical development obtained in the process of achieving the research goal for performance assessment of ear thermometers. Specifically, 0.2 °C (95 % confidence level) was set as the technical goal for uncertainty of temperature readings (measurement result) in ear thermometers at a commercial level. Since the maximum permissible error for measurement methods for mercury-in-glass and clinical electrical thermometers was set at 0.1 °C, some users requested 0.1 °C uncertainty for ear thermometer. However, estimating the currently existing technical level of ear thermometers on market, and considering the fact that 0.2 °C uncertainty was employed in drafts of the industrial standards[6, 7] in the US and Germany, the Survey and Research Committee for New Clinical Thermometer concluded that the goal for Japan should be 0.2 °C[2].

To achieve this goal, AIST considered the necessary essential technology and scenario as shown in Figure 2. Research goals of AIST were set as follows: (1) development of performance test technology for conformity assessment[Term 6], (2) development of calibration technology for radiance temperature scale of ear thermometers for accuracy management, and (3) establishment of national primary standard for radiance temperature scale that serves as basis of traceability system. To meet these goals, AIST started “the development of high-precision blackbody radiator (standard blackbody furnace)” as a common and key technology. In the development of blackbody radiator (BBR), elemental technologies were designated as follows: (A) technology for precise thermostatic fluid bath needed to realize stable and uniform temperature field, (B) technology for quantitative assessment of radiant property of blackbody cavity, and (C) design and manufacture technology to realize optimal blackbody cavity for calibration of ear thermometers.

4 Adoption of measurement management system for Japan

Figure 3 shows how temperature scale of ear thermometers leads to the national primary standard via chain of calibrations (the traceability system) from the viewpoint of technical practicability. There were major technologies to be developed in each phase of traceability, and an issue was to whom the responsibility for the technical work at each phase would be assigned in the social system of metrological management. For calibration and assessment of ear thermometer, which is based on the principle of infrared radiation thermometry, BBR emitting ideal blackbody radiation traceable to correct temperature scale was necessary. The main component of BBR is a reference thermometer that provides standard temperature scale and a blackbody cavity that is a source of thermal radiation and a thermostatic fluid bath. Therefore, we considered what should be the most appropriate system under which each component could be managed to control the quality of the BBR.

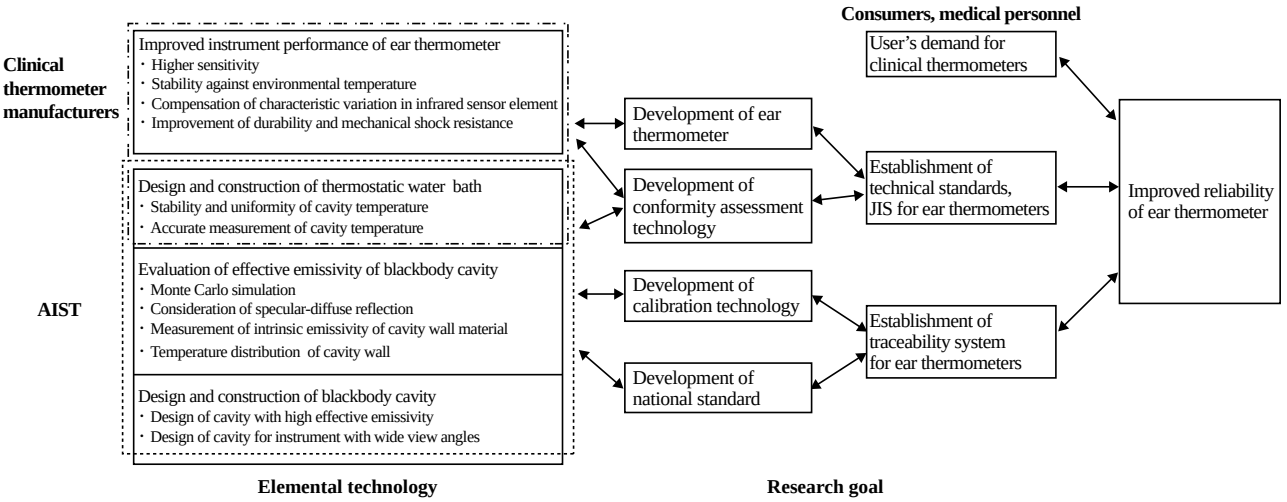

Fig. 2 Research goal and scenario for improving reliability of ear thermometers

In general, ear thermometer manufactured by companies is calibrated against the working standard BBR available in the company. The working standard BBR is also calibrated against the higher level standard BBR, and this standard BBR is traceable to national standard for temperature with high-precision contact thermometer. Practical BBR for body temperature range requires a reference thermometer to accurately determine the temperature of blackbody cavity, and a high-precision platinum resistance thermometer (PRT) can be used. For this PRT sensor, calibration system (traceability system) based on the national standard in AIST had already been established and is actually in operation. Using this traceability system, it is possible to calibrate the temperature scale at sufficiently small uncertainty level of less than 0.01 °C for the reference thermometer.

If the goal value of uncertainty of clinical thermometer reading is 0.2 °C, the uncertainty of working standard BBR, which will be used for calibration and assessment for clinical thermometer of a manufacturer should be approximately 1/3 or less (in this case 0.07 °C or less) of uncertainty for the clinical thermometer. Moreover, the higher-level standard BBR must have even smaller uncertainty (for example, 0.04 °C or less) than the working standard BBR of the manufacturer.

Next, various technical works are necessary at each phase of a chain of calibration as shown in Figure 3, and a choice must be made on which sector will be responsible for these works. As shown in the lower part of Figure 3, after careful comparative review of the three potential measurement management systems, the system that matched the current technological and social situations was selected.

(1) Testing and inspection are done based on verification scheme of the Measurement Law (measurement management system in which verification of all products is conducted under government authority through law enforcement).
(2) Traceability of manufacturers' working standard BBR to national standard for temperature (high-precision standard PRT sensor at AIST) is required by industrial standard, and specification of working standard BBR is also established by industrial standard (measurement management system totally dependent on autonomous activity of manufacturers in industry).
(3) The government (AIST) provides new calibration service for radiance temperature scale[Term 7], while traceability to AIST radiance temperature standard is established by industrial standard for manufacturer's working standard BBR (measurement management system in which responsibility is shared by government and manufacturers in industry).

The following discussion and selection were done for each of the above measurement management systems.

4.1 Measurement management system based on verification of Measurement Law

The Measurement Law in Japan designates measuring instruments that are particularly important to economic activities and services as "specified measuring instrument", and also requires a pattern approval test for structure and specification of the measuring instrument as well as a test of instrumental error for each measuring instrument. In case of clinical thermometer, conventional mercury-in-glass and electronic thermometers have been manufactured and sold after being designated as specified measuring instruments by the Measurement Law. Under the measurement

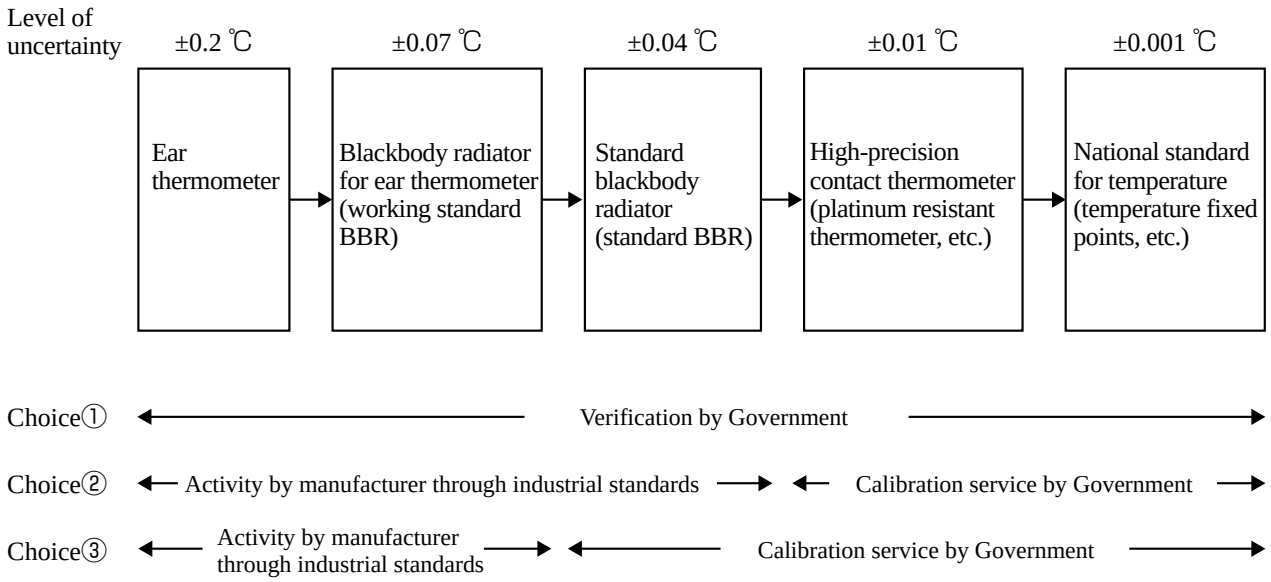

Fig. 3 Traceability and measurement management system of ear thermometer

management system of the Measurement Law, the main body of management is the government (Ministry of Economy, Trade and Industry) that administers the law, and testing and inspection are also conducted according to rules set by the Measurement Law. All clinical thermometers sold on the market are guaranteed by the government to have certain level of specification and accuracy designated by law, and consumers and users, who may not have technical knowledge of the product, can expect to be able to purchase and use a measuring instrument of a certain quality.

In case measurement management is based on Measurement Law, detailed rules and standard must be determined for procedures and equipments for calibration and assessment. Although this scheme is extremely important from the point of fairness and openness of calibration and assessment, the manufacturer's technological autonomy for measurement management may decrease accordingly. This may become an obstruction for improving production performance (accuracy) through new technical development as well as new product development. In other words, management by Measurement Law is effective in case the methods and equipment for calibration and assessment are commonly available and the product technology has already matured.

Reviews were done by the Survey and Research Committee for New Clinical Thermometer and subsequent JIS Committee established in 2000 for the adequacy of designating ear thermometers as specified measuring instruments. As a result, for ear thermometers, it was concluded that designation of a specified measuring instrument by Measurement Law should be left as a matter of future deliberation for the following reasons: (1) a common method and equipment of calibration and assessment are not widely available among manufacturers, and (2) the product technology is still in a development phase, so early regulation by law has the risk of withholding the advancement of product technology in future.

4.2 Measurement management system by industrial standardization

Measurement management system based on autonomous activity of manufacturers by technical standardization (industrial standard document) is thought to be on the opposite end of enforced measurement management by Measurement Law. High quality working standard BBR can be realized by manufacturers by establishing composition and specification of the practical BBR accordong to an industrial standard document such as JIS, and by sharing essential technology including quality management process. In addition, by using contact thermometer, for which traceability to the national standard is established, as reference thermometer, it can be expected that the manufacturers will conduct calibration and assessment at a certain target level or higher.

If such measurement management system can be introduced, merits include: (1) the government sector will not have to take on more work because it will not be required to launch a new calibration service, and (2) compared to regulation by the Measurement Law (Section 4.1), improvement of calibration and assessment technology and standard equipment can be done flexibly and easily to accommodate future product developments, and therefore will not obstruct development and efficiency of the manufacturers' own calibration and assessment technology. On the other hand, total dependence on autonomous system of industrial standard does not have the force of regulation by law, so introduction and operation of technology and equipment will be done under the responsibility of the manufacturers of clinical thermometers. Moreover, since sharing of technological information including standard facility will be limited almost entirely to documented information, there is a risk that it may not be applied appropriately in practice.

To review the adequacy of the above measurement management system from a technical aspect, AIST conducted questionnaire survey on standard facility and measurement management approach used by manufacturers and retailers of ear thermometers in Japan through opportunities such as Standardization Committee, and also actually visited the manufacturers. According to the result, many manufacturers already had large-scale manufacturing and inspection processes for ear thermometers, and many had already introduced and were operating standard equipment (working standard BBR) created on their own. Therefore, in the situation at the time, even if AIST led the standardization of working standard BBR, it was determined that, for economic reasons, it would be difficult for the companies to replace the standard equipment immediately. Moreover, manufacturers of ear thermometers overall had high technology for mercury-in-glass thermometers and thermistor electronic thermometers, but did not have advanced technological experience in managing BBR for ear thermometers, which differed greatly in principle. Therefore, it was concluded that maintaining long-term reliability of ear thermometer in the Japanese market under measurement management system by industrial standardization only was not practical at the time.

4.3 Measurement management system based on calibration service for radiance temperature scale by the government

Based on the conclusions of Sections 4.1 and 4.2, a measurement management system in which AIST provides new calibration service for radiance temperature scale of working standard BBR in industry was considered. This system is positioned between the aforementioned two cases.

In case of Section 4.2, traceability to national standard is maintained for the reference contact thermometer of working standard BBR, while the blackbody cavity is regulated by

industrial standard (technical standard document). Here, direct traceability to national standard is maintained for radiance temperature measured by the ear thermometer. For radiance temperature scale, existing calibration service is not yet organized as in contact thermometers, so the government must take some responsibility for design and establishment of new traceability system for ear thermometers. However, if it becomes possible for AIST to provide direct calibration service of radiance temperature scale of working standard BBR, the clinical thermometer manufactures will be able to make the uncertainty estimation of the calibration and conformity assessment, without necessarily having advanced technology or knowledge for the structure or operation of working standard BBR, because they can rely on the high technological expertise of AIST (the government). Also, the manufacturers may develop their own technology including working standard BBR, and may be able to utilize the equipment they currently own. Therefore, this method was adopted because in current technological and social situation, the cost to the government can be minimized while maintaining high reliability of ear thermometers .

5 Development of national standard for radiance temperature

Urgent issue for AIST after choosing the measurement management system described in Section 4.3, was the development of national standard for radiance temperature, which will serve as the primary standard for the ear thermometer. It would be preferable if results of these technical developments can also be used widely in performance tests including calibration of ear thermometers in industry.

Conventional mercury-in-glass and electronic clinical thermometers are contact thermometers in which the sensor probe is placed in contact with the human body site to reach thermal equilibrium state to measure the temperature.

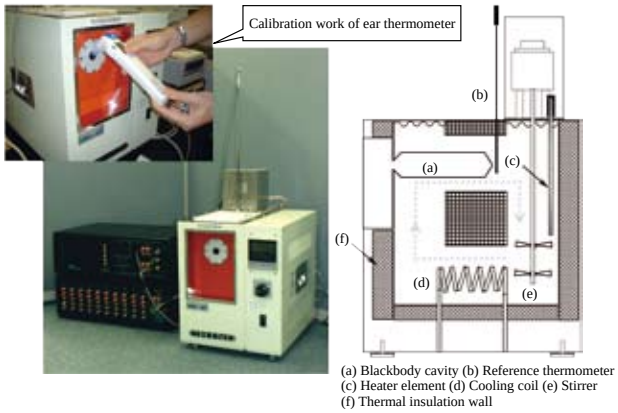

Fig. 4 Standard BBR for calibration of ear thermometer developed by AIST (external appearance and cross sectional view)

Therefore, they can be calibrated or assessed by placing them in a thermostatic fluid bath using high-precision liquid-in-glass thermometer or platinum resistant thermometer as a reference thermometer. Also, evaluation of uncertainty of calibration and management of calibration equipment can be done relatively easily.

In contrast, ear thermometer is an infrared radiation thermometer that measures radiance in the infrared wavelength region and estimates body temperature based on Planck's law. Therefore, it is technically impossible to directly compare temperature scale against contact thermometer such as liquid-in-glass or platinum resistant thermometers. Calibration and assessment of infrared radiation thermometer must be conducted against standard "blackbody radiator (blackbody furnace)" that generates ideal thermal radiation (blackbody radiation) according to Planck' s law. The authors have been working on the development and characterization for high-precision blackbody radiation source in room temperature region, and they started the development of standard BBR especially for calibration of ear thermometer based on these elemental technologies.

Figure 4 shows the standard BBR for calibration of ear thermometer developed by AIST. High-precision platinum resistant thermometer was employed as standard of temperature scale (reference thermometer), and metal blackbody cavity was installed horizontally in precise thermostatic water bath. When standard BBR realized the radiance temperature scale, the components of uncertainty could be classified as follows:

(1) Uncertainly of calibration of reference thermometer

(2) Uncertainty of cavity temperature measurement by reference thermometer

- (2)-1 Uncertainty of temperature measurement of water in bath
- (2)-2 Difference between measured temperature of water and temperature of inner surface of cavity (heat loss effect of cavity)

(3) Effective emissivity of blackbody cavity (difference from ideal value 1)

- (3)-1 Cavity emissivity of blackbody cavity under isothermal condition

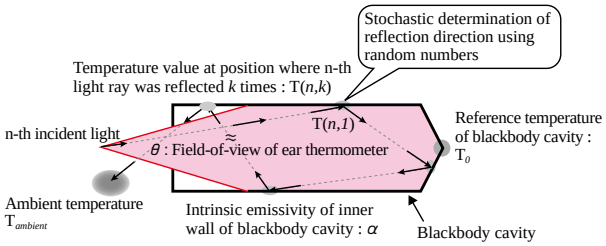

Fig. 5 Evaluation of effective emissivity of blackbody cavity by Monte Carlo simulation

(3)-2 Effect of temperature distribution of cavity wall
(4) Stability and reproducibility of the system

Compared to conventional type of industrial infrared radiation thermometer, ear thermometer has much wider field-of-view, so accurate calibration cannot be achieved when ordinary shape of cavity designed for thermometers with small view angle is used. Therefore, a shape of cavity with sufficiently high effective emissivity for ear thermometer having wide-angle was newly designed based on the Monte Carlo simulation[8]. Figure 5 is a schematic diagram of the Monte Carlo simulation. Light ray bundles were entered into the cavity from outside of aperture opening, the reflection on wall surface was simulated using random numbers, and the effective absorptivity (corresponds to effective emissivity) of the cavity was calculated from the probability of absorption of the incident ray bundle in the cavity. The reflective property of the cavity wall was expressed by a model composed from perfect diffuse reflection and specular reflection. Then, the effect of temperature distribution on the cavity wall was also quantitatively evaluated by inputting measured temperature distribution in the water bath to the simulation.

Intrinsic emissivity of coating material of cavity wall was measured with a Fourier transform infrared spectrometer system developed at AIST. The measurement uncertainty of spectral emissivity data was evaluated at 1 % or less[9], and was taken into account as an uncertainty of intrinsic emissivity of cavity wall. Measured emissivity data was used as parameter for Monte Carlo simulation to evaluate the effective emissivity of cavity. Also, effect of heat loss by convection of air and thermal radiation in the blackbody cavity was evaluated using high-resolution infrared radiation thermometer[10].

Table 1 shows the performance (uncertainty budget) of standard BBR, which is the national standard for radiance temperature scale developed by AIST. For reference thermometer, about 5 mK uncertainty was maintained by calibrating the standard platinum resistant thermometer against AIST's national standard temperature fixed point cells, and the reference temperature of the cavity was measured at around 5 mK level of uncertainty in the thermostatic water bath shown in Figure 4. Effective emissivity of 0.9995 or more was achieved for the cavity by designing the cavity shape suitable for ear thermometers with wide view angles, and uncertainty of radiance temperature resulting from this was set at 20 mK or less. With these technological developments, radiance temperature scale traceable to the international temperature scale (SI unit for temperature) at approximately 0.03 °C uncertainty (95 % confidence level) was achieved for human body temperature range (32 °C~42 °C)[11].

Table 1. Uncertainty budget of standard BBR developed by AIST

	Temperature of blackbody cavity			Unit
	32 ℃	37 ℃	42 ℃	
Component of uncertainty	Uncertainty			
Calibration of reference thermometer	5			mK
Temperature measurement by reference thermometer (including stability of water bath)	5			mK
Heat loss inside cavity	<1			mK
Effective emissivity of isothermal cavity	8	12	16	mK
Effect of temperature distribution of cavity wall	2			mK
Effect of change in ambient temperature ($T_{ambient}$=23±2 ℃)	2			mK
Combined standard uncertainty	11	14	18	mK
Extended uncertainty (95 % confidencelevel)	22	28	36	mK

The technology developed for standard BBR was also employed as recommended specification for standard equipment in JIS for ear thermometers which will be explained later[12]. Currently, it is commercially available as working standard BBR for body temperature range from a manufacturer which participated in this joint development[13].

6 Calibration of working standard BBR in industry against the national standard BBR at AIST

Next, specific calibration method was reviewed to link between the national standard BBR of AIST and working standard BBR of manufacturers in this new measurement management system. As mentioned in Section 5, AIST developed the standard BBR as national primary standard for radiance temperature scale, and the actual calibration will be done by either transporting the manufacturer's working standard BBR to AIST to be calibrated against national standard BBR or by transporting standard BBR of AIST to the manufacturer to calibrate the working standard BBR.

6.1 Uncertainty estimation for calibration of working standard BBR

Simulated calibration experiment was conducted to estimate the uncertainty when working standard BBR was calibrated against national standard BBR at AIST. Aside from standard BBR, which is the national standard, a BBR for simulated calibration was prepared at AIST. Four types (about three thermometers for each type) of high-resolution (displayed temperature resolution 0.01 °C) ear thermometers provided by several manufacturers were used for direct comparison measurement of radiance temperature of the blackbody cavities. In the experiment, AIST standard blackbody furnace and BBR for simulated calibration were run simultaneously, and were stabilized at nearly identical temperature for calibrating the radiance temperature (e.g. 37.0 °C). While monitoring the temperature of each reference thermometer, the difference in radiance temperature between

the two BBRs was measured using the high-resolution ear thermometers. Comparison measurements were repeated about 10 times for each thermometer, and after evaluating the average and variance of radiance temperatures, the temperature difference of reference thermometer was corrected and the calibration results were calculated.

Figure 6 shows the results of the verification experiment. The average values of radiance temperature differences of the two BBRs were almost zero within the range of variation. However, the variation (standard variation) of calibration values was around 0.03 °C. This variation in value was uncertainty factor that occurred additionally in radiance comparison calibration of the BBR. From these results, approximately 0.06 °C (95 % confidence level) was obtained as uncertainty of calibration result in combination of uncertainty of radiance temperature scale of the national standard BBR with the uncertainty of direct comparison measurement with ear thermometers with high resolution mode[11]. This uncertainty satisfied the uncertainty level required for calibration of working standard BBR (approximately 0.07 °C or less).

6.2 Verification of uncertainty of calibration by collaborative experiment with manufacturers

Joint measurement experiment was conducted by AIST and ear thermometer manufacturers to verify the uncertainty level estimated in the simulated calibration experiment as mentioned in the previous section, as well as the validity of the proposed calibration scheme. For this round robin experiment, AIST constructed a standard BBR that could be transported. The standard BBR was transported to seven Japanese thermometer manufacturers by commercial carrier, and the differences with radiance temperatures of working standard BBRs of the companies were measured by the direct comparison method mentioned above.

Figure 7 shows the measurement results[14]. The results of the comparison measurements at each manufacturer have variations of about 0.03 °C, but it was confirmed that the radiance temperature scale of working standard BBR of each company agreed with the standard BBR of AIST within 0.05 °C. This showed that the radiance temperature of working standard BBR of thermometer manufacturers could be calibrated at uncertainly of 0.07 °C or less, and it was concluded that requirement for calibration and assessment of ear thermometer was met sufficiently based on this traceability scheme.

7 Calibration service system and verification of international equality

In establishing traceability system, along with development of national standard and dissemination of temperature scale, an important issue is to verify whether the Japanese national standard and calibration service are equivalent to those of other countries. For this purpose, quality management system in accordance with ISO/IEC 17025 standard[Term 8] was organized for calibration service of working standard BBR for ear thermometer conducted at AIST. By operating the quality management system, the quality of calibration service can be maintained based on third party approval.

To verify equivalence of the national standard developed by AIST to the national standards of other countries, international comparison measurements were conducted among national metrology institutes of Germany and United Kingdom. Figure 8 shows the result of the international comparison measurement conducted between Physikalisch-Technische Bundesanstalt (PTB) of Germany and National Physical Laboratory (NPL) of the UK[15]. The standard BBRs of AIST and PTB were transported to NPL, and radiance temperature scales were compared directly. From the

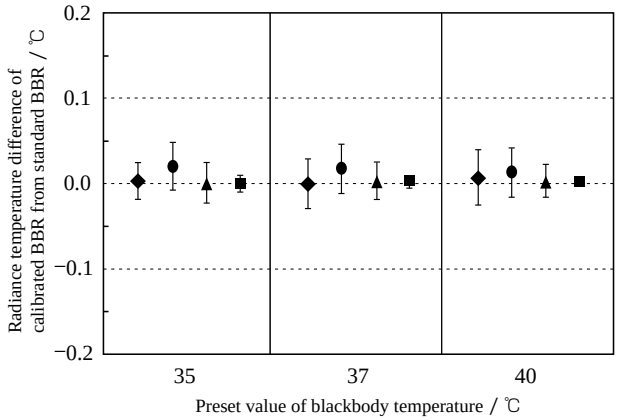

Fig. 6 Verification result for calibration of radiance temperature scale of working standard blackbody furnace against national standard BBR at AIST

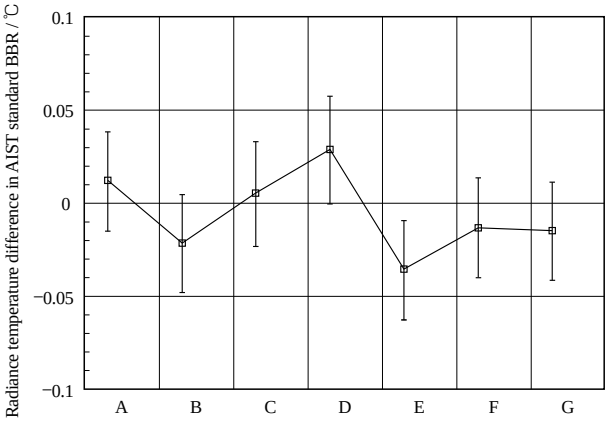

Fig. 7 Result of round-robin comparison measurement of working standard BBRs of clinical thermometer manufacturers with AIST standard BBR
Blackbody temperature is 37 °C. A~G are participating manufacturers.

results of this international comparison, it was confirmed that radiance temperature scale realized on each national standard agreed well within the uncertainty level claimed by each institute (about 0.03 °C). The result of this international comparison measurement was the first report in the world for standard BBRs for clinical infrared thermometers, and it became a model case for later international comparative measurements in this field. In the Asia-Pacific region, AIST has also conducted a similar international comparison with National Measurement Institute of Australia (NMIA) and obtained satisfactory measurement results.

8 Summary of research results

AIST conducted research and development as the national metrology institute to improve reliability of new clinical infrared ear thermometers, and obtained the following results.

– Developed national standard (standard blackbody radiator) with high precision (uncertainty level 0.03 °C)
– Designed and established new traceability system for radiance temperature for calibration of working standard BBR. Uncertainty level of calibration achieved was 0.06 °C.
– Verified international equivalence of national standard by conducting international comparison measurement with foreign national metrology institutions. Also, maintained quality of calibration service in accordance with ISO 17025 with third party approval.

These results are applied to measurement management system for maintaining reliability (uncertainty level 0.07 °C) required for calibration and assessment of clinical thermometers, while providing autonomous activity for standard equipment of thermometer manufacturers. They contribute to the improvement of reliability of temperature readings of ear thermometers in the Japanese market.

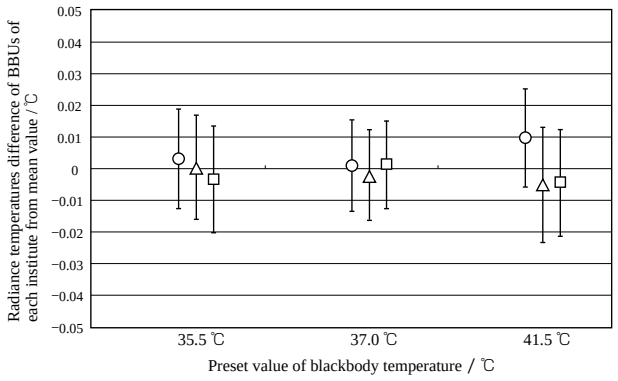

Fig. 8 Result of international comparison of national standard BBR in body temperature region
○ AIST △ NPL UK □ PTB Germany

9 International cooperation to prevent spread of SARS

Development of standard blackbody radiator and calibration technologies for ear thermometer by AIST was an advanced effort in the world at the time, and the technical achievements are highly evaluated by other countries. In 2003, severe acute respiratory syndrome (SARS) occurred in the Asian region and developed into international crisis. With request of national metrology institutions of Singapore and Taiwan, the standard BBRs and technology developed by AIST were provided swiftly, and enabled to make calibration and assessment of clinical infrared thermometers for screening patients with fevers at airports and seaports. This activity was highly appreciated as a case of international research cooperation of measurement standard technology in a serious social problem that threatens safety and security[3].

10 Conclusion

The efforts to establish traceability system and to disseminate standard technology for new ear thermometer were described. Development and dissemination of new measurement standard were conducted to make ear thermometers more reliable to users and to strengthen international competitiveness of Japanese manufacturers for clinical infrared thermometer that has totally a different measurement principle from conventional types of clinical thermometers. AIST developed the world's highest quality national standard based on advanced radiation temperature standard and infrared measurement technology that had been accumulated at AIST, and built new traceability system so high quality standard can be used widely by industry and users. These results contributed greatly to improve reliability of body temperature measurement through calibration service and standardization process by AIST.

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The author is grateful for the support and cooperation by Tomoko Fukuzaki of National Institute of Metrology, as well as many persons in and outside AIST concerned in developing this research.

Terminology

Term 1. Radiance : Amount of radiation energy emitted in specific direction by unit time, unit area, and unit solid angle, for light emission from light source. Unit [$W \cdot sr^{-1} \cdot m^{-2}$].

Term 2. Planck's law of radiation: Law of physics governing the thermal radiation characteristic (relationship of temperature and spectral radiation energy distribution) of ideal blackbody. It was formulated by Planck in 1900. Since emissivity is less than 1 in

actual body, radiation characteristic is Planck's law multiplied by emissivity value of the surface.

Term 3. Emissivity: Index expressing an optical property of thermal radiation source. Emissivity is 1 in case of ideal blackbody, and actual thermal radiation source have emissivity value between 0 and 1. In general, emissivity of material surface changes depending on material as well as wavelength, angle, and surface roughness.

Term 4. Traceability: General term for measurement management system from national standard or international standards to user-level measuring instrument through chain of comparisons (calibrations).

Term 5. European Norm (EN): Also known as European Standard. Uniform standard for Europe issued by the Comité Européen de Normalisation (CEN) and Comité Européen de Normalisation Electrotechnique (CENELEC), which are expert committees of the European Union.

Term 6. Conformity Assessment: Act of checking whether product, service, or process satisfy the required standards or directives. It may also be used as general term for testing, inspection, and assessment procedures.

Term 7. Radiance Temperature: Temperature calculated from radiance value at any wavelength region when light source is assumed to be ideal blackbody in accordance with Planck's law. In case light source is ideal blackbody, it corresponds to the thermodynamic temperature, but if it is not blackbody (emissivity is less than 1), the radiance temperature will be different from the thermodynamic temperature of light source.

Term 8. ISO/IEC 17025 Standard: International standard document for quality control of services conducted by testing and calibration institutions. Quality control based on this standard and third party approval are conducted for calibration services of physical standards provided by National Metrology Institute of Japan, AIST.

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Discussion with reviewers

1 Future technological issues for improving reliability of ear thermometers

Question (Akira Ono)

The point that excels in this paper is that it describes not only a technological development, but is a comprehensive discussion that also addresses balance of social systems such as verification, calibration service, and industrial standards.

I think the traceability system established according to the result of this study is satisfying to keep the tolerance of ear thermometers to ±0.2 °C. On the other hand, what is the level of long-term stability for the ear thermometers themselves?

Also, which points do you think need R&D in the future to keep the tolerance to ±0.2 °C or less for commercial ear thermometers? I would like to hear the author's view on both technological development of thermometer and technological development of measurement standard.

Answer (Juntaro Ishii)

At AIST, an examination of long-term stability and reproducibility of several commercially available ear thermometers in the market were conducted by periodical calibration over one and a half year against the standard BBR of AIST in 1999. The results showed that most ear thermometers have long-term stability of approximately 0.2 °C or less, and some ear thermometers go over 0.2 °C in the period of about half a year, and in some the temperature scale change was as great as 0.4 °C (Figure a shows the results). It is difficult to specify the cause of the long-term instability, but in general, they are due to the drift of infrared sensor responsivity, the change in characteristic of compensation temperature sensor, and the deterioration of the performance of the optical element.

If the goal is to keep the tolerance of the commercial ear thermometer to 0.2 °C or less, I think it is necessary to employ design and specification that can maintain the long-term stability of at least one year against the standard BBR, and this should be the technological development goal of the ear thermometer by manufacturers.

Moreover, for the metrological control of clinical thermometers used in medical institutions, regular performance check about once a year may be effective, in addition to the initial assessment when products are shipped out. For such a regular check, it is necessary to develop and spread a practical BBR calibrator that can be used at medical institutions and thermometer dealers.

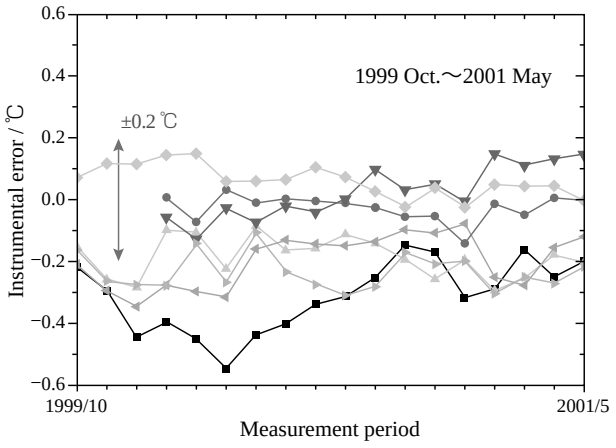

Fig. a Long-term stability of temperature scale of commercial ear thermometers

Also, as discussed in the paper, the uncertainties that occur during the calibration of working standard BBRs by the comparison measurement method are relatively large (variation is about 0.03 °C by standard deviation) in the present traceability scheme of radiance temperature, and we are aware that it is difficult for the thermometer manufacturer to conduct hierarchical organization of working standard BBRs within the company. For this, I think a technological development is necessary for conducting radiance comparison measurement at smaller uncertainty using standard BBRs. Until now, commercial high-resolution ear thermometers were applied as a radiance comparator, but currently, we are working on the development of high-performance infrared radiation thermometer with small measurement variation compared to the ear thermometers, and are obtaining good experiment results toward realization of the radiance comparison measurement at smaller uncertainly of around 0.01 °C.

2 Other methods for calibration of working standard BBR

Question (Akira Ono)

I think as a method for calibrating working standard BBRs of thermometer manufacturer against national standard BBR of AIST, there is a method of using infrared ear thermometer itself as the transfer (traveling) standard, other than a direct comparison of blackbody cavities described in the article. Also, I think there is a method of removing the blackbody cavity from the working standard BBR of thermometer manufacturer, transport it to AIST, and calibrate against the standard BBR. How do you evaluate such calibration methods compared to the direct comparison method?

Answer (Juntaro Ishii)

Figure b shows the transfer standards and calibration schemes for realizing traceability of radiance temperature scale.

· On method of using ear thermometer as a transfer standard

Using ear thermometer as a transfer standard will reduce the cost of transportation compared to a larger BBR system, and for manufacturers, there is a merit that it is relatively easy to calibrate several working standard BBRs using the transfer standard thermometer in the house. However, since the standard radiance temperature scale is realized and maintained on ear thermometer which will serve as a transfer standard, superior transport stability and long-term stability shall be required in addition to the basic performance such as the temperature resolution.

AIST conducted experimental verification for calibration scheme of using ear thermometer as a transfer standard along with direct comparison scheme by transporting BBR. According to the experiment, in the scheme using thermometer as transfer standard, the level of variation of calibration increased to 0.05 °C~0.1 °C. This large variation occurred due to the level of stability and reproducibility of ear thermometer during traveling,

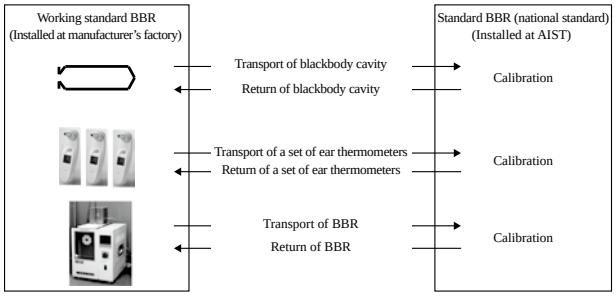

Fig. b Options of transfer standard

and was directly reflected in the uncertainty of calibration of working standard BBR. Therefore, since the realization of calibration uncertainty of 0.07 °C or less, which was set as a development goal, became difficult to achieve, we could not employ this calibration scheme. I think this method should be reconsidered if the transfer standard (radiation thermometer) with a higher stability and reproducibility can be successfully developed in the future.

· *On method of transporting blackbody cavity*

In case of BBR for ear thermometer a blackbody cavity which is thermal radiation source is placed in a thermostatic water bath with sufficiently good temperature uniformity and stability, and temperature of water near the bottom of the cavity is measured using calibrated a reference thermometer. With the thermostatic fluid bath, it is possible to realize temperature uniformity of about 0.01 °C using devices available commercially, and for long-term management of performance, parameters such as the temperature distribution in the water bath can be checked regularly using a contact thermometer with high temperature resolution such as the reference thermometer.

On the other hand, effective emissivity of the blackbody cavity is its performance index which is expected to change greatly not only due to the shape and the material of the cavity but also by the optical property and the deterioration of coating of the inner wall of the cavity, and it is not easy for thermometer manufacturers or testing institutions to quantitatively assess on their own. Therefore, it will actually be possible to calibrate the effective emissivity of blackbody cavity, if it is possible to remove the blackbody cavity from the working standard BBR of the manufacturer, transport it to AIST, install it in the thermostatic water bath of AIST in which the performance is examined, and conduct comparison measurements of radiance temperature with the BBR (blackbody cavity) of national standard. In this case, the client of the calibration service will have a merit of not having to transport large thermostatic water bath system, and will be also able to conduct the long-term measurement management within the company through a group management method by using a set of exchangeable (standard) blackbody cavities calibrated against national standard BBR.

If this calibration scheme could be realized, it would have been a unique and practical traceability system in the world for the effective emissivity of blackbody cavity, but survey showed that existing working standard BBR at thermometer manufacturers have wide variation in shape and specification of blackbody cavity, and there were reports of difficulty in removing and transporting the cavity part in manufacturer's BBR, so we could not put it to practice.

3 Trend of international standard

Question (Akira Ono)

The main subject of this article was measurement standard for ear thermometer, but standardization (document standard) is also an important point. What is the state of international industrial standards for ear thermometers?

Answer (Juntaro Ishii)

As mentioned in the paper, JIS for Japan, ASTM for the United States, and EN for Europe are established as product standards for ear thermometer.

From 2005, the work for new international standardization is in progress through a joint proposal by ISO and IEC, mainly for clinical electrical (thermistor) and ear thermometers. For this international standardization, the author is participating in an international working group activity as an expert member. The following committee draft document has been issued as of October 2007.

ISO/IEC CD.2 80601-2-56, "Medical Electrical Equipment Part 2-56, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement", ISO/IEC (2007).

4 Use of ear thermometer for preventing spread of infectious disease

Question (Akira Ono)

We've been warned that if bird influenza virus mutates and spreads around the world, it will be a major threat to humankind. When SARS epidemic occurred in 2003, the experiences of Taiwan, Singapore, China, and Hong Kong where the infection spread within the country may be valuable for Japan in the future. What do you think are the important points for body temperature measurement in public places? Also what role do you think ear thermometers will play?

Answer (Juntaro Ishii)

Immediately after SARS epidemic became a social problem in the Asian region in 2003, the author actually visited the metrology institutes in Singapore and Taiwan, and gathered information on case studies for screening infected patients with fever at such as international airports. All countries screened patients with fever of 38.0 °C or higher, and inspection using infrared thermographic instruments and ear thermometers were conducted.

From these case studies and discussion with persons involved, technical issues in public screening were: (1) maintaining stability of thermography and ear thermometer, and (2) efficient and reliable screening using combination of sensing devices. For (1), in contrast to laboratory with stable environmental condition, it was difficult to maintain reliability of the instrument (temperature reading) in places with severe fluctuations in environmental condition such as humidity and temperature. At the airport in Singapore, screening was done by installing improved thermography system in the passageway to the immigration counter, but the temperature reading of the thermograph image was not sufficiently stable. A simple BBR was placed behind the passageway, so people and blackbody cavity could be observed simultaneously by the thermography to make corrections of drifts of temperature scale of thermograph image. For (2), to conduct efficient and highly reliable screening on a large number of people, preliminary screening using thermography system was conducted, and full inspection using ear thermometer was conducted to people suspected of a fever, and this prevented giving stress to the travelers.

These cases and technical issues would be highly suggestive for operating public screening in Japan.

5 Shape and surface coating of standard blackbody cavity

Question (Akira Ono)

It is written that the blackbody cavity for ear thermometers

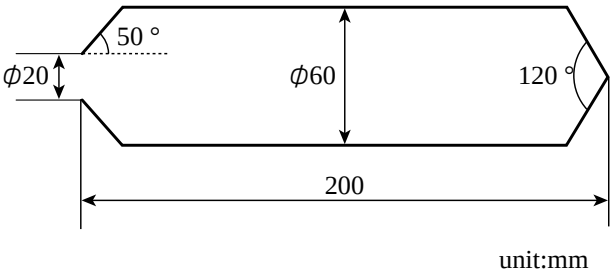

Fig. c Standard blackbody cavity for ear thermometer developed by AIST

having wide view angles was designed by conducting Monte Carlo simulation, but what is the shape of the cavity recommended by AIST and employed in JIS? Also, what material is used normally to coat the inner wall of cavity of the standard BBR, and what level of intrinsic emissivity does it have in the infrared region?

Answer (Juntaro Ishii)

Figure c shows the cross sectional view graph of the standard blackbody cavity for calibration of ear thermometer developed by AIST. The material of the blackbody cavity is oxygen-free copper with high thermal conductivity, and the wall of the cavity is designed so its thickness will be 0.5 mm or less. The inner wall of the blackbody cavity must be blackened so it will have high emissivity of 0.95 or more in the infrared wavelength region. AIST measured spectral emissivity for black paint and coating material commercially available in Japan and overseas in the infrared region using the FTIR spectrometer system, and we employed black paint (Nextel's velvet coatings) with spectral emissivity of 0.96 or more in the 5~12 μm wavelength region.

6 History of development of ear thermometer

Question (Naoto Kobayashi)

Ear thermometer is an innovative clinical thermometer that allows non-contact measurement in short time. You mentioned that it was developed by an American company in the 1990s, but was this type of thermometer developed in Japan or other countries at that time? If it was completely original creation by the American company, what is the reason that this company was able to make it while others couldn't? If it was a result of development competition, why couldn't the companies of Japan or other countries win this competition?

Answer (Juntaro Ishii)

The approach of determining temperature of skin and body surface by measuring infrared radiation from human body was a measurement technique available for a long time, and was applied to breast cancer diagnosis using thermography system. Also, measurement of temperature around the tympanic membrane was a subject of "basal body temperature (core temperature)" measurement that was medically important since it was close indication of brain temperature. However, in the conventional method, thin wire temperature sensor such as thermocouple or thermistor was pressed directly against the eardrum, so patients (subjects) felt pain and suffering, and it was a special body temperature measurement method done only by medical specialists.

Although I do not know the details of the history of development of current infrared ear thermometer, I guess that there were two technological points in product realization: development of highly sensitive and low cost infrared sensor, and technology for compensation of effect of temperature change in thermometer caused by the temperature fluctuation in surrounding environment and by contact with human body. I think the basic methodology for infrared ear thermometer was already known, and technical development for product realization was in progress not only in the US but also in Europe and Japan. In the US, state-of-art R&D were conducted for infrared sensor and precise infrared measurement as core technologies in defense and space fields, and I think the US was able to lead the world in producing highly practical ear thermometer using these advanced infrared technology. Although this is my guess, the clinical thermometer manufacturers of Japan and Europe, which had manufactured mercury-in-glass and thermistor thermometers but did not have technological foundation for infrared measurement, might have been thinking, "Product realization for low-cost highly reliable clinical infrared thermometer that can compete with thermistor thermometers was far ahead in time". Then, an American venture company actually developed competitive ear thermometer, and the product won support from users in the American market. I think, only after that, product development by Japanese and European manufacturers has accelerated.

7 Performance test of ear thermometer in market

Question (Naoto Kobayashi)

What is the level of reliability of current ear thermometer in market? In the comparison test (for FY2005) of ear thermometer conducted officially by the National Consumer Affairs Center, measurement variation of 0.5-0.7 °C was reported. Is this result unavoidable in the current situation where there is a maximum 0.4 °C fluctuation in temperature graduation due to insufficient long-term stability, or is it something that can be improved if the traceability for current ear thermometer gets better? These are points of interest and I would like to hear your thoughts.

Answer (Juntaro Ishii)

For user-level reliability of ear thermometer, I am aware of the fact that it does not completely satisfy the users. I think it is necessary to divide the issue into two parts for consideration: (1) performance of thermometer as a physical measurement instrument (thermometer), and (2) performance of thermometer as a medical equipment whose measurement subject is the human body.

For (1), as mentioned in the article, it is possible to verify the reliability of measurement and feed the result back to improve product performance by conducting calibration and conformity assessment using standard BBR traceable to international unit (SI) of temperature for infrared thermometer, and I believe that the result of R&D by AIST is contributing to the improvement of reliability. Some of the products do still have problems of long-term stability, but I think a more stable thermometer will be developed in the future along with verification and assessment using standard BBR and by maintaining traceability.

In contrast, (2) is a matter of obtaining reliability in measuring the human body, which is "measurement subject with variation", and a different approach is necessary from (1). As mentioned in the article, current ear thermometers have different measurement view angles by types, and the measured site is not necessarily "eardrum" itself, and in many cases it measures "interior of ear canal including eardrum". In general, a nonnegligible temperature difference (temperature distribution) may occur in the eardrum and the surrounding ear canal, and moreover, there may also be differences in emissivity between the eardrum and the skin surface of the surrounding ear canal. Therefore, even if the same subject is repeatedly measured with the ear thermometer, the measured data may show large variation depending on how the ear thermometer probe is inserted into the earhole. Moreover, occurrence of different temperature readings among ear thermometers with different measurement view angles is unavoidable in current circumstances.

These issues cannot be necessarily verified by engineering assessment using "physically correct BBR" as in (1), and it is necessary to increase reliability by conducting the clinical assessment with assumed medical knowledge. From the standpoint of developing the ear thermometer, "thermometer that selectively measures eardrum", and "method of taking repeated number of measurements in one measurement, and then using highest temperature value as measurement result" and "method of displaying values converted to temperature of armpit or oral by processing data based on the characteristics of thermometer and the clinical information rather than using measurement as it" are being researched and developed. On the other hand, in the international standardization (ISO/IEC) which is in progress now, the ear thermometer is categorized as a clinical thermometer

that requires clinical assessment, clinical assessment with subjects including patients with fever is conducted along with an engineering evaluation by standard BBR, and an assessment of clinical reliability using the statistical method is proposed. In this case, the achievement of uncertainty 0.2 °C is strictly required, as mentioned in the article, for the engineering assessment result, but for the clinical assessment, disclosure of assessment information to users is required rather than a specified numerical value of a tolerable level.

In the future, I think the two performance assessments will be conducted appropriately, and by feeding them back to product technology, higher reliability at user level can be achieved.

8 Possibility of introduction of future verification by the Measurement Law

Question (Naoto Kobayashi)

This is related to the question for Discussion 7, but ultimately, is it preferable to have all-product verification regulated by the measurement law for the ear thermometer? For this to be done, I think it is necessary for technological development to become matured fairly and start "to wilt", so to say, but when do you think that will happen? Or, to what level does the technology go for that?

Answer (Juntaro Ishii)

As mentioned in the article, verification is done to inspect the performance of measuring instrument according to law (Measurement Law) under the responsibility and authority of the government, and the measurement at a certain level or higher is maintained in Japan. Since it is a system with direct involvement of the government, user's confidence is high, but it may be a disincentive factor to product development and marketing for manufacturers. As mentioned in the previous section, product technology development to improve long-term stability as well as to improve reliability of clinical assessment is continued for the ear thermometer, so I think a shift to verification scheme with strong technological enforcement requires a period of about five years or more to study the trend of product technology. Moreover, new skin thermometer applying the principle of the ear thermometer is being developed, and technological consideration including such new thermometers will become an issue in the future.

This article discusses the consideration at the time when manufacture and sales of the ear thermometer grew rapidly in Japan from technological aspect. However in the future, if ear thermometers become a specified measuring instrument according to the Measurement Law, it will be necessary to consider not only the technological assessment, but also the economic effect on corporate activities by Japanese manufacturers, effect on the entry of overseas companies to Japanese market, and relationship with the Pharmaceutical Affairs Law (administered by Ministry of Health, Welfare and Labor). In the global flow toward free trade as exemplified by FTA, verification scheme under government large-scale auspice should be limited to absolutely necessary items to maintain safety of the citizens and reliability of trade, and creation of rules for maintaining traceability and conformity to international standards is strongly demanded internationally. Also, as mentioned in the previous Answer, clinical assessment including medical knowledge is necessary in addition to dissemination of measurement standard and establishment of engineering assessment method to obtain reliability at user level, so I think the important issue will be to consider more practical approach for both Measurement Law and Pharmaceutical Affairs Law.

Science and society, or research institution and journal: A historical retrospection

Motoyuki Akamatsu* **and Hiroyuki Iyama****

[Translation from *Synthesiology*, Vol.1, No.1, p.59-65 (2008)]

1 Introduction

For the publication of this new journal, we shall review the role of a journal in science and technology research from the perspective of history of science. In the age when there is a plethora of academic journals, it is necessary to state the significance of publishing yet another journal. We believe this will offer food for thought in seeking the direction the journal should take to make scientific and technological contributions to the society, which is our ultimate goal. For this purpose, we shall describe how academic journals, which we take for granted as places to report our research activities, were born.

The birth of modern science greatly owes to the exceptional works of people whom we call intellectual giants such as Galileo and Newton. However, in the background of their success in revolutionizing knowledge in the 17th century were the existences of research institutions and their vehicles or journals that disseminated scientific knowledge to the world. Isaac Newton wrote papers on classical mechanics and optics in *Philosophical Transactions*, the journal of the Royal Society of London, for which he later became chairman, and Antonie van Leeuwenhoek, woolen merchant and amateur biologist, sent a letter describing the world's first observation of microbes using his handmade microscope. The Royal Society of London and Accademia del Cimento of Rome encouraged active communication between the members, and published journals to deliver fresh, real-time information. Communalism, which is one of the important ethos (personalities and habits of a group) of scientific community advocated by sociologist Robert K. Merton in the 20th century, was already established during the age of scientific revolution, and gathering concentrated evidences and disclosure of these information were expected to become useful for the welfare of humankind.

The thinking that swift and active disclosure of knowledge will benefit mutual research exchange among scientists and will eventually contribute to the society originates from Francis Bacon's *Novum Organum* (1620). In the quarrel between the Ancients and the Moderns, the Ancients claimed that truth was revealed in classical knowledge exemplified by Aristotle, while Modernist Bacon emphasized the necessity of accumulating new knowledge or empirical knowledge obtained through experiments and observations, in order to look further in the distance "riding on the giant's shoulders". In his posthumous work, *New Atlantis*, he described the concept of a nation founded on science that will rise in a distant future, and discussed the model of a knowledge system for making contributions to the society. The principle of establishment of academic societies such as the Royal Society was influenced greatly by Bacon's new concept.

Although the system for promoting intellectual exchange among members by publishing the results of research in form of theses in journals was already established in the 17th century, most of them addressed natural historical oddities and extraordinary natural phenomena, and none focused on industrial significance of scientific products. Although facts were reported with honesty and candor, very few included deductive inference based on high-level logic, and hardly any addressed industrial application. The scientific journals started to address social issues only in the 19th century when disciplines matured and individual societies and their journals were published. The characteristic of scientific journals was totally transformed after the Industrial Revolution when discussion on the utility of knowledge became active. Two hundred years after Bacon's conceptualization, the perspective for evaluating knowledge with a measuring stick of "useful knowledge" was born. Later, through births of national support systems, research institutions, and universities of science, the scientific community was systematically organized into autonomous knowledge organization whose freedom of research was guaranteed, and science was eventually positioned at the core of the national plan. However, as symbolized by the establishment of Ig Nobel Prize in the end of the 20th century, knowledge for knowledge's sake was pursued and "useless" researches that lacked relevance to the real world were mass-produced. In this state of affairs, retracing the original purpose of scientific journals and their historical roots is an essential exercise in re-evaluating the relationship between modern science and society.

2 Usefulness of science to the society

One of the disciplines that were eagerly studied in ancient days was astronomy. For example, the oldest estimate of solar eclipse was done by Thales in 585 BC. Since rituals

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were important in the ancient world, accurate observations were essential. In Egypt, it was known that embalming and preservation technologies were used from fragments of papyrus. Unparalleled, advanced surveying technology was used to build the pyramids. In all early civilizations, metallurgy, the technology for refining metal, was established as core technology. Of course, military technologies were fervently developed in ancient times. Crane and catapult designed by Archimedes were used successfully in the Punic Wars between Rome and Sicily, and Zhuge Liang of Three Kingdom Period, China invented the south-pointing compass and overwhelmed the Wei army. Ancient science and technology were linked closely to national needs. In other words, only knowledge that was useful to the state was nurtured and systematized.

The origin of pre-modern science and technology was generally incidental, and the research system for obtaining new and useful knowledge was not organized, except in some exceptions like the study of medicinal herbs. Although useful scientific knowledge existed, there was no system to retrieve them in organized and systematic manner. In the Middle Ages, research was primarily storage of the ancient heritage and passing them on to the successors.

In modern times, the thinking that scientific knowledge brings benefit to people's lives started from a philosopher, Francis Bacon (1561-1626). In *Novum Organum* written in 1620, he described the public interest and innovation of scientific research and its effect on people's lives, as well as the benefit of technology and knowledge of craftsmen. In a utopian novel, *New Atlantis*, written in 1627, Bacon imagined a national research institute called "Solomon's House" where scientists convened to conduct research, claimed that knowledge contributed to expanding power, and asserted that the domain of human empire can be expanded by natural philosophy. This was the germination of philosophy of science and technology with objective to contribute to society.

From where did the philosophy of social contribution of natural sciences arise? Science as we know now was called natural philosophy at the time, and was considered as one of the studies to acquire knowledge, along with theology and humanities. Since God created nature, knowing nature created by God was to know the act of God, so nature was considered to be the second Bible. The foundation was Christian philanthropy: knowing nature and knowing God by natural philosophy will bring happiness to all humankind. Due to the Inquisition against Galileo's heliocentric theory, science and religion are often considered to be antagonistic, but in Bacon's philosophy, natural philosophy or natural science was an effort to know God.

We must not forget another point in Bacon's philosophy that greatly affected science. Bacon stated that deduction, where inference is made from general principles, tended to fall into error of prejudice and preconception (*idola*), and so one should use induction, where a principle is reached from observation of evidences (empiricism). That was the reason for pushing natural philosophy. Also, basic methodology for science rested on thinking that accumulation of evidences obtained from observations and experiments will expose the principles hidden in nature.

3 Establishment of societies and science academies

In the 17th century when modern science was established, societies and science academies arose in major western cities, as places to exchange and accumulate knowledge of natural science. Universities had only three departments for theology, mathematics, and law. It had no department that specialized in natural science, and subjects such as geometry and astronomy were sometimes taught under the category of liberal arts, which is equivalent to the modern general education curriculum. Natural science here was learned through Classics, and the works of ancient philosophers had authority inscribed in gold. Empirical approach of learning new facts by experiments and observations was not taken. Therefore, a stance of collecting objective evidence and extracting general theory or law was not nurtured, and as a consequence, the university was not an appropriate place to present scientific findings.

In this age, natural scientists continued their study as a hobby while either engaging in proper trade or receiving patronage of aristocrats and royalties. Societies started as places to conduct experiments, to discuss, and to publicize the discoveries and inventions of these natural scientists. Accademia dei Lincei and Accademia del Cimento of Italy to which Galileo belonged were first societies. Royal Society of London (1662-), in which Newton and Boyle participated as members, and Académie Royale des Sciences (1666-) in Paris, France followed. The Royal Society of London is the oldest society that exists to this day. When Japanese hear the word "society", they may think of an organization with an office in a university or a research institution, but these science academies not only served as places to present research results, but also had experimental facilities where the members could conduct experiments (Figure 1). As it can be seen from this, the science academies from which modern societies originated were research institutions or centers.

The science academies created as places where researchers convened to conduct experiments and present research reports were realizations of Bacon's "Solomon's House", and the Royal Society of London, to which Lord Chancellor

Bacon belonged, was greatly influenced by him. Although the Royal Society was "royal" because it was chartered by the King, it did not receive financial sponsorship. It was "private" in the sense that it was operated by financial support of the membership. On the other hand, Académie Royale des Sciences of Paris succeeded in obtaining support from Louis XIV, and became the world's first national research institute where researchers were paid salaries from the royal treasury to carry on their researches.

It was necessary to accumulate scientific discoveries and inventions to seek principles of natural science, and for accumulating scientific discoveries and inventions, a research institution, where accumulation of knowledge was done from a standpoint that scientific findings were equal, was more appropriate than a university, which is a place of authoritarianism (although in reality power play also occurs in society).

4 Publication of academic journal

The societies and academies published journals for their members. They became academic journals to publish the results of natural science studies. The oldest journal which continues to this day is *Philosophical Transactions of Royal Society of London* (1665-) (Figure 2). Henry Oldenburg, secretary of the Royal Society established in 1662, started this journal as voluntary activity.

Oldenburg wrote why he decided to publish the journal in the introduction of the first issue.

The Introduction.
Whereas there is nothing more necessary for promoting the improvement of Philosophical Matters, than the communicating of such, as apply their Studies and Endeavours that way, such things as are discovered or put in practise by others; it is therefore thought fit to employ the Press, as the most proper way to gratifie those, whose engagement in such Studies, and delight in the advancement of Learning and profitable Discoveries, doth entitle them to the knowledge of what this Kingdom, or other parts of the World, do, from time to time, afford, as well of the progress of the Studies, Labours, and attempts of the Curious and learned in things of this kind, as of their compleat Discoveries and performances: To the end, that such Productions being clearly and truly communicated, desires after solid and usefull knowledge may be further entertained, ingenious Endeavours and Undertakings cherished, and those, addicted to and conversant in such matters, may be invited and encouraged to search, try, and find out new things, impart their knowledge to one another, and contribute what they can to the Grand design of improving Natural knowledge, and perfecting all Philosophical Arts, and Sciences. All for the Glory of God, the Honour and Advantage of these Kingdoms, and the Universal Good of Mankind.

Oldenburg stated that complete understanding of natural science can be achieved by collecting scientific knowledge (discoveries and ideas) by scientists and geniuses around the world using the magazine medium, and the scientific knowledge contributes to the state and brings prosperity. The journal was published to put into practice Bacon's empiricism or the attempt to understand a common principle through accumulation of evidences.

After Gutenberg invented the printing technology in the 15th century, book became the medium for communicating scientific knowledge by the 17th century. On the other hand, magazine as communication medium began with *Journal des Savants*, an information magazine for publication of books published in Paris in the 17th century. Oldenburg thought, instead of books that were complete in one volume, the printed medium of magazine, which is a regular collection of various findings, was the most appropriate for accumulating research results of scientists working around the world.

5 Peer review system and originality

The current peer review system to determine the eligibility of placement of article in academic journal was a system adopted by the *Philosophical Transactions* of the Royal Society. Although Oldenburg selected articles that might be interesting to the members, the article had to be approved

Fig. 1 Activities by members of Académie Royale des Sciences in Paris.
The figure on top shows members doing research in the royal library, and bottom figure shows experiments in the laboratory. From *Macmillan Album of Science* (Hara Shobo) [14].

by certain members to be included in the *Philosophical Transactions*. This might have been due to the fact that Oldenburg himself was not a natural scientist, but it was also necessary to determine the validity of some of the articles with pseudoscience and occult contents as well as hearsays of strange creatures not observed directly.

Natural philosophy, after taking the form of journal and also introducing peer review, took on a format for gaining knowledge different from conventional scholasticism in which truth was pursued from heritage of Aristotle's naturalism and through deduction by propositional logic. The basic stance of natural philosophy became "empirical evidence" first rather than "demonstrative legitimacy". However, it should not be forgotten that the peer review system also had conservative and authoritarian aspects where things that could not be understood by the reviewers were not included.

Another factor that was introduced by academic journals and still has great influence on research today is the preemption of discovery and invention. The regularly published journal stamped time at the moment discoveries and invention were reported therein. The concept of originality appeared around the Renaissance, and the fact that the word "origin" or source developed into "originality" which meant personal capacity expresses well the shift to individualism during the Renaissance. However, there was no method for time stamping back then, so there were many condemnations of plagiarism. The preemption of discovery and invention became clear through publication of research in journals that began in the 17th century, and provided proof of research ability of the individual scientist. While this may be a

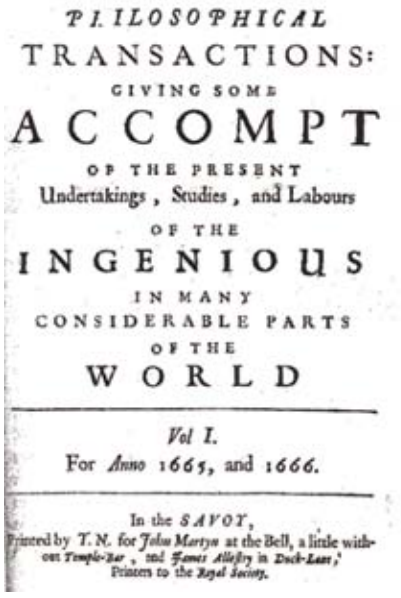
PHILOSOPHICAL
TRANSACTIONS:
GIVING SOME
ACCOMPT
OF THE PRESENT
Undertakings, Studies, and Labours
OF THE
INGENIOUS
IN MANY
CONSIDERABLE PARTS
OF THE
WORLD
Vol I.
For Anno 1665, and 1666.
In the SAVOY,
Printed by T. N. for John Martyn at the Bell, a little without Temple-Bar, and James Allestry in Duck-Lane,
Printers to the Royal Society.

Fig. 2 Cover of the first issue of *Philosophical Transactions of the Royal Society of London.*

demonstration of individualism, it was also related closely to the employment of scientists. As mentioned earlier, although some scientists were employed by the academy or held professorship at university, many subsisted on patronage of aristocrats. Leonardo da Vinci during the Renaissance, and Galileo and Kepler of the Modern age were under patronage. Therefore, showing one's ability as scientist was necessary to finding good patrons.

Although academic journals were started for the collective interest of providing a place of accumulation of scientific knowledge for the good of all humankind, they also took on the character of individualism with expressions of originality and further advanced to show expressions of self-indulgence, and thus inconsistency developed.

6 Segmentation of scientific knowledge

Returning to the *Philosophical Transactions of the Royal Society of London*, Oldenburg who was secretary of the Royal Society not only transcribed the oral presentations and published them in the journal, but also translated the reports of discoveries and inventions sent from all over the world into English. Oldenburg was a German, and before he became secretary of the Royal Society, he created connections throughout Europe through his job as a tutor for children of British aristocrats accompanying them on the grand tour of Europe to broaden their knowledge. After becoming secretary of the Royal Society, he was able to make the journal successful by collecting discoveries and inventions of natural science with his fluency in language and through his personal connections.

Looking at the articles of the *Philosophical Transactions*, it included stories of some plant discovered somewhere, how to make lens, and stories on Jupiter. The articles were not limited to specific fields. From our current viewpoint, Oldenburg's abilities to read such wide-ranging contents and to translate them are absolutely amazing. However, "knowledge" initially meant full knowledge. Since natural science was a discipline to understand the truth of nature, it was necessary to look at many different natural phenomena to fully understand the workings of nature.

In his writings, Bacon did not think mere collection of evidence was sufficient. He encouraged the stance of carefully inspecting the subject and classifying them by creating lists of present and absent. His information classification system resulted in the segmentation of the natural world and promoted specialization of scientific knowledge. In the knowledge system where natural phenomenon is broken down into the simplest element inevitably assumed the characteristics of reductionism. To clarify law and theory that govern the reduced element, it

was necessary to organize the evidences within a detailed classification system, as much as the accumulation of sufficient amount of knowledge. Therefore, elementalism accompanied segmentation of knowledge, and as a result, academic journals became necessary for each segmented region of nature as places for accumulating knowledge. In the 19th century, societies for different scientific disciplines were established and academic journals for each discipline were published one after the other, as Baconian knowledge classification system solidly took hold.

To pursue knowledge, researches were conducted by dividing the subject into elements, and drifted away from full knowledge that was the original goal of natural philosophy. An English scholar, William Whewell, created the word "scientist" with which we are very familiar in the 19th century. It was a word created by combining the Latin "scientia" which meant "knowledge" and Greek "ist" which meant person with special ability. Unlike a philosopher who aimed for full knowledge, a "scientist" was knowledgeable only in his specialized field, but the term was accepted by natural scientists and continues to be used to the present. There is a long history behind the attitude often seen among science and technology researchers who think it is perfectly okay to be content in the water of their specialization only.

Segmented scientific research is only targeted to part of the whole that is composed by the elements. However, researchers conduct researches believing that that element is the essential to the whole. However, as elements increase, it seems that there is a long road before research of individual elements can make contributions to society.

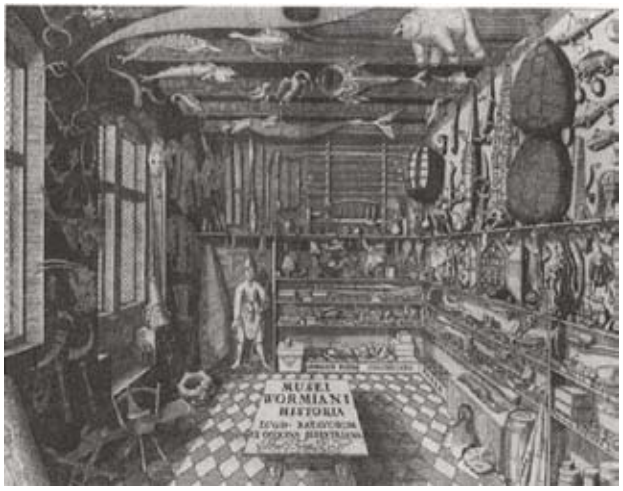

Fig. 3 Interior of the Worm's Museum.[14]
The museum was established in the 17th century by Ole Worm, a physician of Copenhagen. It contained stuffed animals as well as collection of artifacts such as stone tools. The collection seems random but actually is classified according to Worm's thinking.

7 Integration of scientific knowledge

Segmentation of knowledge was unavoidable if the reductionist methodology of science was followed, and at the same time, segmentation of subjects was promoted to warrant originality of research, or in other words, as proof of research ability. To maintain originality of the papers sent to the journals, one must claim novelty of knowledge, but that also meant segmentation of the subject. Pushed by the social behavior of scientists who submitted several papers to journals to present their research ability, science followed the path of segmentation.

The word "system", which had the opposite meaning to segmentation, was used in the 17th century. However, a knowledge system here was how to neatly classify or categorize, and it was an understanding by classification or how to position knowledge as encouraged by Bacon (Figure 3). Although it was difficult to understand unclassified knowledge as a whole, it could be understood as knowledge organized as small classification β in medium classification *A* belonging to large classification *I*.

Although systematizing knowledge would help understanding, understanding here meant to understand positioning (Figure 4). However, understanding of knowledge by systematization was, after all, understanding of segmentation, and was not a bridge connecting scientific knowledge for the good of society. Classification and organization of phenomena were to collect things with equivalent quality, and was not to clarify relationship among phenomena. To create things that will be useful to people and society, it is necessary to seek relationship among evidences and phenomena, and integrate and compose them. However, hardly anything can be learned from the history of science so far concerning activities to obtain "useful knowledge" and "making knowledge useful". The knowledge that natural science pursued was knowledge of evidences of nature, and basic scientific methodology for gaining evidential knowledge was reductionist de-composition of elements. Understanding of evidential knowledge is understanding of "what it is", and is not functional or compositional understanding of "what it can do". For scientific knowledge to be useful to society, it is necessary to understand what can be done with the knowledge. Yet in the process of pursuing evidence by elemental de-composition, de-composition was conducted according to specific functional characteristic of the phenomenon, so there was no accumulation of what kind of functional and compositional characteristics a phenomenon had in the form of scientific knowledge.

Since functional and compositional characteristics of the phenomenon were diverse, expectation and delusion may occur in the process of converting them into knowledge.

As it can be seen in the product realization cases, they are romanticized as success stories, and the processes of integration and composition as evidence are often lost. It is the battle against *idola* of which Bacon warned. However, in the modern world where principles of how to utilize scientific knowledge in society has not yet been discovered, what can be done is to accumulate knowledge of "what ought to be done". This method must be sought without falling into segmentation that was the method for accumulating evidential knowledge in conventional natural science.

8 Conclusion

In the new publication of an academic journal to fill the gap between science and technology and society, we discussed the significance of academic journals by looking through the history of science. Many people may question why a public research institution publishes an academic journal rather than an academic organization, but we hope that people now understand that there is no mystery in a research institution, which can produce results as well, publishing an academic journal to accumulate research results, considering the history that academies and research institutions share the same origin. Moreever, contribution of science and technology to society is the philosophy of Bacon who advanced modern science, marking the starting point of science, and academic journals were started for this purpose. However, if there are reasons for the inability to fill the gap called "valley of death" or "period of nightmare" between science and society in the conventional activities of science including elemental reductionism, we must build new methodology for science and technology to bridge the gap. Rather than depending on approaches from the society side of looking for technological potential, it is the responsibility of the community of science to establish methodology and make approaches from our side. The attempt to publish this journal is an attempt to return to our origin.

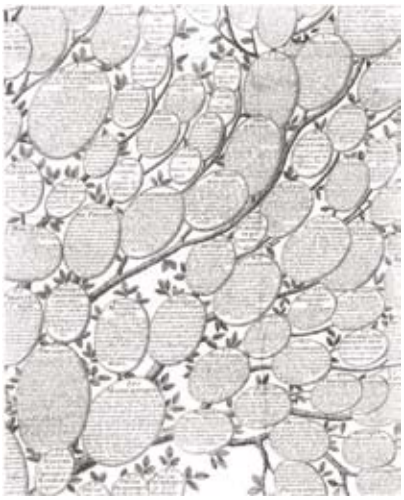

Fig. 4 Tree of Knowledge from Diderot's *Encyclopédie*[14].
Edited by Denis Diderot in the 18 th Century, the *Encyclopédie* is a grand dictionary that covered all sorts of knowledge including art and history as well as science and technology in a systematic manner. This tree of knowledge expresses the classification of knowledge. The branches of the tree show that "science of nature" was divided into mathematics and physics, and physics was further broken down into individual disciplines such as astronomy, climatology, botany, zoology, and others.

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Editorial Policy

Synthesiology Editorial Board

Objective of the journal

The objective of *Synthesiology* is to publish papers that address the integration of scientific knowledge or how to combine individual elemental technologies and scientific findings to enable the utilization in society of research and development efforts. The authors of the papers are researchers and engineers, and the papers are documents that describe, using "scientific words", the process and the product of research which tries to introduce the results of research to society. In conventional academic journals, papers describe scientific findings and technological results as facts (i.e. factual knowledge), but in *Synthesiology*, papers are the description of "the knowledge of what ought to be done" to make use of the findings and results for society. Our aim is to establish methodology for utilizing scientific research result and to seek general principles for this activity by accumulating this knowledge in a journal form. Also, we hope that the readers of *Synthesiology* will obtain ways and directions to transfer their research results to society.

Content of paper

The content of the research paper should be the description of the result and the process of research and development aimed to be delivered to society. The paper should state the goal of research, and what values the goal will create for society (Items 1 and 2, described in the Table). Then, the process (the scenario) of how to select the elemental technologies, necessary to achieve the goal, how to integrate them, should be described. There should also be a description of what new elemental technologies are required to solve a certain social issue, and how these technologies are selected and integrated (Item 3). We expect that the contents will reveal specific knowledge only available to researchers actually involved in the research. That is, rather than describing the combination of elemental technologies as consequences, the description should include the reasons why the elemental technologies are selected, and the reasons why new methods are introduced (Item 4). For example, the reasons may be: because the manufacturing method in the laboratory was insufficient for industrial application; applicability was not broad enough to stimulate sufficient user demand rather than improved accuracy; or because there are limits due to current regulations. The academic details of the individual elemental technology should be provided by citing published papers, and only the important points can be described. There should be description of how these elemental technologies are related to each other, what are the problems that must be resolved in the integration process, and how they are solved (Item 5). Finally, there should be descriptions of how closely the goals are achieved by the products and the results obtained in research and development, and what subjects are left to be accomplished in the future (Item 6).

Subject of research and development

Since the journal aims to seek methodology for utilizing the products of research and development, there are no limitations on the field of research and development. Rather, the aim is to discover general principles regardless of field, by gathering papers on wide-ranging fields of science and technology. Therefore, it is necessary for authors to offer description that can be understood by researchers who are not specialists, but the content should be of sufficient quality that is acceptable to fellow researchers.

Research and development are not limited to those areas for which the products have already been introduced into society, but research and development conducted for the purpose of future delivery to society should also be included.

For innovations that have been introduced to society, commercial success is not a requirement. Notwithstanding there should be descriptions of the process of how the technologies are integrated taking into account the introduction to society, rather than describing merely the practical realization process.

Peer review

There shall be a peer review process for *Synthesiology*, as in other conventional academic journals. However, peer review process of *Synthesiology* is different from other journals. While conventional academic journals emphasize evidential matters such as correctness of proof or the reproducibility of results, this journal emphasizes the rationality of integration of elemental technologies, the clarity of criteria for selecting elemental technologies, and overall efficacy and adequacy (peer review criteria is described in the Table).

In general, the quality of papers published in academic journals is determined by a peer review process. The peer review of this journal evaluates whether the process and rationale necessary for introducing the product of research and development to society are described sufficiently well.

In other words, the role of the peer reviewers is to see whether the facts necessary to be known to understand the process of introducing the research finding to society are written out; peer reviewers will judge the adequacy of the description of what readers want to know as reader representatives.

In ordinary academic journals, peer reviewers are anonymous for reasons of fairness and the process is kept secret. That is because fairness is considered important in maintaining the quality in established academic journals that describe factual knowledge. On the other hand, the format, content, manner of text, and criteria have not been established for papers that describe the knowledge of "what ought to be done." Therefore, the peer review process for this journal will not be kept secret but will be open. Important discussions pertaining to the content of a paper, may arise in the process of exchanges with the peer reviewers and they will also be published. Moreover, the vision or desires of the author that cannot be included in the main text will be presented in the exchanges. The quality of the journal will be guaranteed by making the peer review process transparent and by disclosing the review process that leads to publication.

Disclosure of the peer review process is expected to indicate what points authors should focus upon when they contribute to this journal. The names of peer reviewers will be published since the papers are completed by the joint effort of the authors and reviewers in the establishment of the new paper format for *Synthesiology.*

References

As mentioned before, the description of individual elemental technology should be presented as citation of papers published in other academic journals. Also, for elemental technologies that are comprehensively combined, papers that describe advantages and disadvantages of each elemental technology can be used as references. After many papers are accumulated through this journal, authors are recommended to cite papers published in this journal that present similar procedure about the selection of elemental technologies and the introduction to society. This will contribute in establishing a general principle of methodology.

Types of articles published

Synthesiology should be composed of general overviews such as opening statements, research papers, and editorials. The Editorial Board, in principle, should commission overviews. Research papers are description of content and the process of research and development conducted by the researchers themselves, and will be published after the peer review process is complete. Editorials are expository articles for science and technology that aim to increase utilization by society, and can be any content that will be useful to readers of *Synthesiology.* Overviews and editorials will be examined by the Editorial Board as to whether their content is suitable for the journal. Entries of research papers and editorials are accepted from Japan and overseas. Manuscripts may be written in Japanese or English.

Required items and peer review criteria (January 2008)

	Item	Requirement	Peer Review Criteria
1	Research goal	Describe research goal ("product" or researcher's vision).	Research goal is described clearly.
2	Relationship of research goal and the society	Describe relationship of research goal and the society, or its value for the society.	Relationship of research goal and the society is rationally described.
3	Scenario	Describe the scenario or hypothesis to achieve research goal with "scientific words".	Scenario or hypothesis is rationally described.
4	Selection of elemental technology(ies)	Describe the elemental technology(ies) selected to achieve the research goal. Also describe why the particular elemental technology(ies) was/were selected.	Elemental technology(ies) is/are clearly described. Reason for selecting the elemental technology(ies) is rationally described.
5	Relationship and integration of elemental technologies	Describe how the selected elemental technologies are related to each other, and how the research goal was achieved by composing and integrating the elements, with "scientific words".	Mutual relationship and integration of elemental technologies are rationally described with "scientific words".
6	Evaluation of result and future development	Provide self-evaluation on the degree of achievement of research goal. Indicate future research development based on the presented research.	Degree of achievement of research goal and future research direction are objectively and rationally described.
7	Originality	Do not describe the same content published previously in other research papers.	There is no description of the same content published in other research papers.

Instructions for Authors

Synthesiology Editorial Board
Established December 26, 2007

1 Types of contributions

Research papers or editorials should be submitted to the Editorial Board.

2 Qualification of contributors

There are no limitations regarding author affiliation or discipline as long as the content of the submitted article meets the editorial policy of *Synthesiology.*

3 Manuscripts

3.1 General

1) Articles may be submitted in Japanese or English.
Accepted articles will be published in *Synthesiology* (ISSN 1882-6229) in the language they were submitted in. All articles will also be published *Synthesiology - English edition* (ISSN 1883-0978). The English edition will be distributed throughout the world approximately four months after the original *Synthesiology* issue is published. Articles written in English will be published in English in both the original *Synthesiology* as well as the English edition. Authors who write articles for *Synthesiology* in Japanese will be asked to provide English translations for the English edition of the journal.
2) The manuscript should be prepared using a word processor or similar device, and printed on A4-size portrait (vertical) sheets of paper. The category of article (research paper or editorial) should be stated clearly on the cover sheet.

3.2 Structure

1) The manuscript should include a title (including subtitle), abstract, the name(s) of author(s), institution/contact, main text, and keywords (about 5 words).
2) Title, abstract, name of author(s), and institution/contact should be provided.
3) The length of the manuscript should be, about 6 printed pages including figures, tables, and photographs.
4) The title should be about 10-20 Japanese characters (5-10 English words), and readily understandable for a diverse readership background . Research papers shall have subtitles of about 15-25 Japanese characters (7-15 English words) to help recognition by specialists.
5) The abstract should be about 200 Japanese characters (75 English words).
6) The main text should be about 9,000 Japanese characters (3,400 English words).
7) The article submitted should be accompanied by profiles of all authors, about 200 Japanese characters (75 English words) for each author.
8) Discussion with reviewers regarding the research paper content shall be done openly with name of reviewers disclosed, and the Editorial Board will edit the highlights of the review process to about 3,000 Japanese characters (1,200 English words) or a maximum of 2 pages. The edited discussion will be attached to the main body of the paper as a part of the article.

3.3 Format

1) The text should be in formal style. The section and subsection chapters should be enumerated. There should be one line space at the start of paragraph.
2) Figures, tables, and photographs should be enumerated. They should have a title and an explanation (about 20-40 Japanese characters or 10-20 English words), and the position in the text should be clearly indicated.
3) For figures, clear originals that can be used for printing or image files (resolution 350 dpi or higher) should be submitted. In principle, the final print will be 15 cm x 15 cm or smaller, in black and white.
4) For photographs, clear prints (color accepted) or image files should specify file types: tiff, jpeg, pdf…explicitly (resolution 350 dpi or higher) . In principle, the final print will be 7.2 cm x 7.2 cm or smaller, in black and white.
5) References should be listed in order of citation in the main text.

Journal – [No.] Author(s): Title of article, *Title of Journal*, Volume(Issue), Start page-End page (Year of publication).
Book – [No.] Author(s): *Title of Book*, Start page-End page, Publisher, Place of Publication (Year of publication).

4 Submission

One printed copy or electronic file of manuscript should be submitted to the following address:

Synthesiology Editorial Board Office
Public Relations and Publishing Division, National Institute of Advanced Science and Technology(AIST)
Tsukuba Central 2, 1-1-1 Umezono, Tsukuba, Ibaraki 305-8568, Japan
E-mail: synthesiology@m.aist.go.jp

The submitted article will not be returned.

5 Proofreading

Proofreading by author(s) of articles after typesetting is complete will be done once. In principle, only revisions or correction of printing errors are allowed in the proofreading stage.

6 Responsibility

The author(s) will be solely responsible for the content of the contributed article.

7 Copyright

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Letter from the editor

We are publishing a new type of journal for research papers. The name of the journal is *Synthesiology*, and the equivalent word in Japanese is "kohseigaku". Since the journal accepts research papers and articles written either in Japanese or in English, the editorial board decided to publish an equivalent, translated edition following the original one where all materials are written in English for better international circulation. That is this journal, *Synthesiology-English edition*.

The word *Synthesiology* is a coined word made by joining "synthesis" with the meaning of integration and "-logy" with the meaning of learning. As is well known, "synthesis" is a word of Greek origin, with *syn* (meaning 'with') + *the* (meaning 'put') + *sis* (meaning 'process, condition'), and "-logy" also originated from the Greek word *logos* (meaning 'Word of God') and has the same word origin as "logic". With the thought that, in order to make full use of science in society, how one "integrates" elemental, scientific knowledge is important, the word, "synthesis", was used as the basis; and "-logy" was added because the purpose of the journal is to find a common method or logic by accumulating congregative, constructive work in order to pass the research development results to society. Thus *Synthesiology* was born. The meaning of "*Synthesiology*" is discussed in detail in the Preface of this issue.

As opposed to "synthesis", the word, "analysis", naturally came into mind. In the 17th century, science came into existence and the academic society was established, and thereafter, reductionism has brought about success in sciences. However, today the limitations of reductionism are strongly felt and the importance of integration and constitution is talked of in the academic community. There is this sentiment to go back to the point of origin of science, and to review its relationship with society. The general historical background is discussed in the Article of this issue.

In publishing this new journal, the significant problem was envisioning the readership. Although almost all the present academic journals are circulated within individual, segmented academic fields, this journal aims to transcend discipline boundaries to reach people from all areas of society with interest in research development and the application of scientific knowledge. This covers scientific researchers to engineers and managers of research development and people in all technological domains and related humanities and social science areas. We would like to ask you to see whether this aim is effectively achieved by reading the 6 research papers published in this issue. As seen from the view point of the editor, I think that the goals have been achieved to a respectable degree.

Another point to notice is the motives of the authors. The authors of the research papers of this issue have all been producing notable basic research results and their papers have been published in various academic journals. These authors have told me that there was something significant they were able to write about for the first time in this particular journal.

The difficulty in editing was that, the research papers of this journal being completely different in form than those in the existing other academic journals, the authors and reviewers had to exchange views many times and collaboratively produce the new journal. The manuscript guidelines and review criteria are described in the Editorial Policy of this issue. It needs to be pointed out, however, that the style of paper is still being developed, and it is hoped that several styles will come together after gradual refinement through trial and error. There is no other way to verify the originality of research papers and demonstrate high quality standards on an ongoing basis.

I hope that many researchers and engineers of a broad domain related to scientific research and its applications to society will be interested in and actively contribute to this journal.

Editor in Chief
Akira Ono

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