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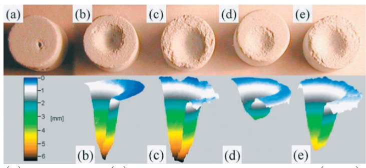
Extracorporeal Focused Ultrasound Lithotripsy — Cavitation Control Lithotripsy —

Yoichiro Matsumoto

Professor, Department of Mechanical Engineering, The University of Tokyo

Introduction

Ultrasound is widely applied in the clinical field today, such as ultrasound contrast agent imaging, High Intensity Focused Ultrasound (HIFU), Extracorporeal Lithotripsy, sonodynamic therapy. Some of these have a close relation to the dynamic behavior of micro bubbles and that of a bubble cloud. In an ultrasound imaging, micro bubbles are used as contrast agents.



(a) High 46 μs, (b) High 46 μs + Low 2 cycles (CCL), (c) High 46 μs + Low 5 cycles (CCL), (d) Low 2 cycles, (e) Low 5 cycles, (For all the cases, high frequency is 3.82 MHz, low frequency is 545 kHz.

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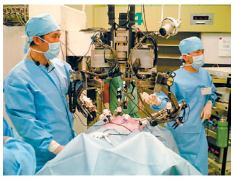
Development of a Remote Minimally-Invasive Surgical System with Operational Environment Transmission Capability

Mamoru Mitsuishi

Professor, Department of Engineering Synthesis, School of Engineering The University of Tokyo

1. Introduction

Tele-medicine is expected to contribute to teamwork medical care, emergency care, local medical service difference correction, home care, patient load reduction, doctor load reduction and high-level medical education. There are several kinds for the tele-medicine such as tele-radiology, tele-pathology, tele-mentoring, tele-surgery and tele-education. This paper describes the construction of a minimally invasive surgical system as an example of remote surgery, and its results.



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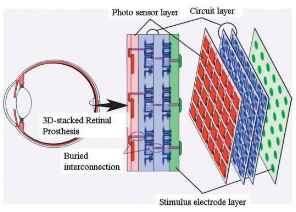
The 21st Century COE Program "Future Medical Engineering based on Bio-nanotechnology" in Tohoku University

Masaaki Sato

Professor, Program Leader Department of Bioengineering and Robotics, Graduate School of Engineering, Tohoku University

Introduction

The 21st century COE (Center of Excellence) program was firstly planned out in FY2002 by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) according the proposal reported by the University Council in 1998, "A Vision for Universities in the 21st Century and Reform Measures" to be Distinctive Universities in a Competitive Environment.



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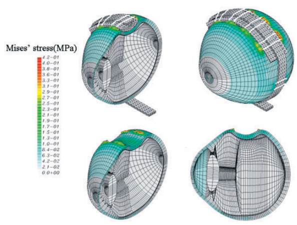
Human Simulator

Ryutaro Himeno

Director, Advanced Center for Computing and Communication Riken (The Institute of Physical and Chemical Research)

We started Computational Bio-Mechanics research project (CBM project, here after) in 1999 at RIKEN. This project is five-year project but the second CBM project will follow it from April, 2004. The ultimate goal of this project is developing a live human model on computer system. The human model should breath, have a beating heart and blood flows inside, and walk. He should become sick or be injured. Yes, we are going to develop a human simulator.



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Extracorporeal Focused Ultrasound Lithotripsy
− Cavitation Control Lithotripsy −

Yoichiro Matsumoto

Department of Mechanical Engineering, The University of Tokyo

Continued from page 1 In a HIFU treatment, micro bubbles are used to enhance the heating of the tissues. The acoustic cloud cavitation has a close relationship with the efficiency of Extracorporeal Lithotripsy. There is a need to understand more precisely the amplitude and the power spectrum of acoustic emission from micro bubbles to visualize the tissues and organs, to determine the heat deposition rate for the treatment of modeling tumors and to find the emitted shock pressure from the collapsing bubble cloud. In a HIFU application, high intensity ultrasound causes acoustic cavitation near the focal area. The violent collapse of cavitation bubble has a potential of causing tissue traumas, especially in the case in which the bubbles form a cloud. The maximum pressure in the cloud that reaches order of GPa is reported both in numerical and experimental studies. On the other hand in the study of ESWL (Extracorporeal Shock Wave Lithotripsy), the complex effect of cavitation has been known in the early stage of its research history and many researchers have investigated the role of the cavitation in ESWL. The studies were conducted both as the factor of tissue damage, and of stone comminution accelerator. In recently, cavitation control techniques by applying skillful shock wave combinations have been proposed and effective results have been achieved. However, the main force that breaks the stone is still considered to be the incident plane shock wave that has a 10～60 mm focal region. Moreover cavitation collapse is utilized only to accelerate the stone comminution.

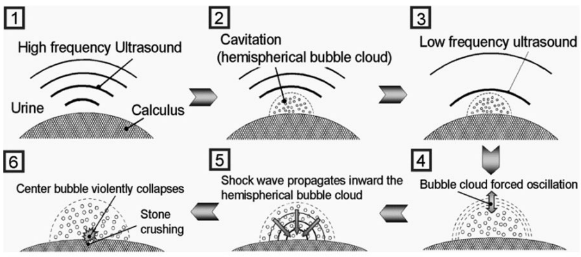


Fig.1 Schematic of cloud cavitation control

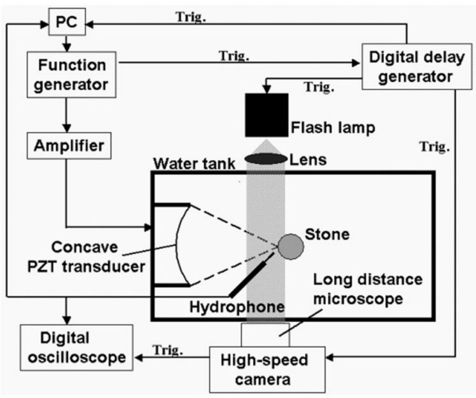


Fig.2 Experimental set-up

Cavitation Control Lithotripsy

By utilizing two frequencies focused ultrasound, extracorporeal lithotripsy method, Cavitation Control Lithotripsy (CCL) is being developed, that can erode and chip away the renal stone solely by the violent collapse of the cavitation that is induced by focused ultrasound. If the cavitation phenomena are well controlled in time and space only at the stone surface, the extremely high-energy and high-pressure concentration can be utilized as a main factor of renal stone disintegration. The concept of the method and the phenomena in the CCL protocol are explained and the results of the stone crushing are also discussed. Fig.1 shows the schematic of CCL. First, higher frequency ultrasound is focused at the stone surface (Fig.1-1). It has a range about 1～5 MHz in its frequency for a shorter wavelength than the characteristic length of the renal stone. It creates a hemispherical bubble cloud consisting of very tiny bubbles only at the stone surface (Fig.1-2). Immediately after the higher frequency is stopped, a short pulse of lower frequency ultrasound that has 100 kHz～1

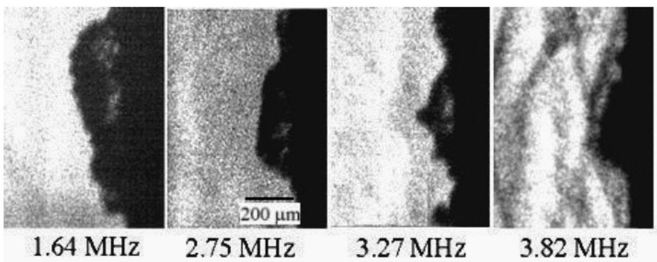


Fig.3 Stable bubble cloud at different frequencies

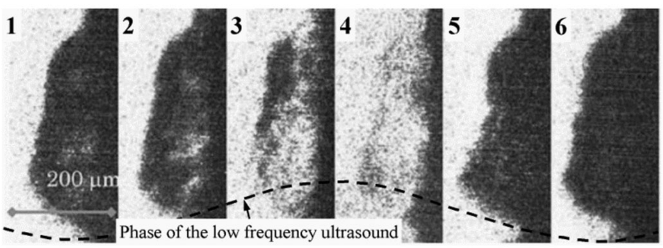


Fig.4 A forced cloud cavitation collapse

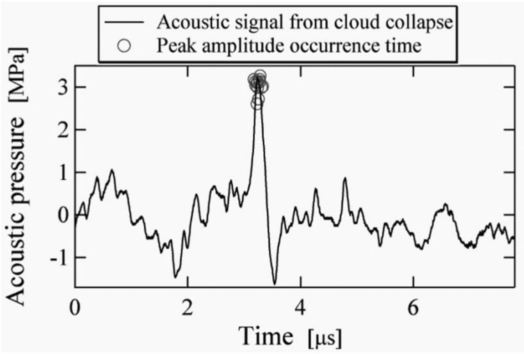
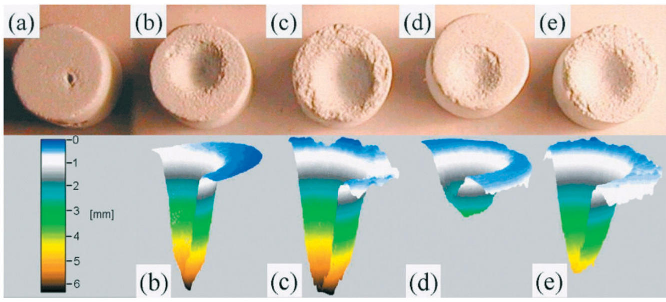


Figure5 Shock wave signal and peak amplitude occurrence time of the cloud cavitation collapse



(a) High 46 μs, (b) High 46 μs + Low 2 cycles (CCL), (c) High 46 μs + Low 5 cycles (CCL), (d) Low 2 cycles, (e) Low 5 cycles, (For all the cases, high frequency is 3.82 MHz, low frequency is 545 kHz.

Figure 6 Model stone crushing test and the surface plot of the erosion shape

MHz in its frequency is focused at the hemispherical bubble cloud (Fig.1-3). The lower one resonantly forces the bubble cloud to oscillate (Fig.1-4). Accompanied with the bubble cloud forced oscillation, shock wave propagates inward from the hemispherical bubble cloud (Fig.1-5). At the center of the bubble cloud, the bubbles near the center collapse violently while they emit an extremely high-pressure wave that reaches order of GPa. Therefore, only at the stone surface the stone is crushed resulting in scoop-like indentations, with a high-energy concentration and also with the minimum amount of cavitation. The typical cavitation control ultrasound waveform is as follows : As indicated previously, high frequency ultrasound (bubble cloud creator) is immediately followed by low frequency ultrasound (cloud collapse inducer). The interval time should be long enough to dissolve all of the cavitation bubble into liquid. If this scheme can be finely controlled within cavitation area in space and the occurrence time of the bubble cloud collapse, a lithotripsy method utilizing only cavitation erosion can be developed that produces less tissue damage and more tiny fragments than conventional ESWL.

Behavior of the bubble cloud in CCL method

The experimental set up is shown in Fig.2. The concave PZT ceramic diaphragm that have the natural frequencies of 500 kHz is used for the ultrasound transducer. It transmits higher amplitude of ultrasound at the frequencies of (2n+1) times of the fundamental frequencies than the other frequencies. Appropriate higher order harmonics coupled with fundamental frequency is used to realize CCL waveform by one PZT transducer. The aluminum ball or artificial stone, which is used as the crushing test material of the ESWL machine, is fixed at the focus point. The cavitation phenomena at the focal point of the ultrasound are photographed by the ultra high-speed camera. Needle type hydrophone is placed near the focal region to detect the synchronized signal of the shock wave emitted by the cavitation collapse.

High frequency focusing phase : Stable bubble cloud

Fig.3 shows the stable bubble clouds made by the single frequency ultrasound at the focal point. After 100 - 200 μs irradiation of the single frequency ultrasound, stable bubble clouds are observed. With the bubble cloud growing in size, at its surface, almost the entire pressure wave is scattered and pressure wave does not proceed into the bubble cloud. At some point, the bubble cloud stops growing and becomes stable size. Then, there is a strong relationship between the size and the ultrasound wavelength. At the focal point, because the standing wave field that is created by the incident and reflected ultrasound wave determines the pressure field, the size of stable bubble cloud is considered to be dependent on the wavelength. Fig.3 shows that the sizes of the area generated by the bubble cloud can be controlled with respect to the ultrasound frequency in the area restricted within some 100 μm, i.e., in the focused ultrasound field, acoustic cavitation at the solid surface can be well controlled in space.

Low frequency focusing phase : Collapse of bubble cloud

The photographs of the bubble cloud forced into oscillation are shown in Fig.4. Immediately after 100 μs irradiation of 2.75 MHz ultrasound, 545 kHz pulse ultrasound is focused upon the cloud. The stable bubble cloud is forced to oscillate by 545 kHz ultrasound. The bubble cloud shrinks at the positive phase of 545 kHz ultrasound decreasing each bubble radius, and then at the 4th frame, the bubble cloud is forced to collapse. Fig.5 shows the acoustic signal that is taken 1.6 mm away from the focal point. In Fig.5, 4 points of peak amplitude against the occurrence time that overlap the acoustic signal time history are shown. This figure shows the CCL method triggers the bubble cloud collapse with a very high reproducibility. The standard deviation of the occurrence time is 65 ns. The maximum pressures are about 3 MPa at 1.6 mm away. It is shown that cloud cavitation collapsing phenomena can be well controlled in time with a high pressure and energy concentration at the solid surface.

In vitro stone crushing tests

The crushing tests of model stone (diameter 10 mm, height 10 mm), which are used as the test material of ESWL machine, are conducted. The PRF (Pulse Repetition Frequency) of the ultrasound pulse and the amplifier voltage are fixed at 20 Hz and 1.6 kV (peak-to-peak). The irradiation time of the each waveform is 3 minutes. Fig.6 shows the picture and the plot of the indentation shape of model stones. The waveforms, high frequency only, (a), erode the stones a little, 1 mm in depth. In the case low frequency only waveforms, (d) and (e), erodes the stone more. 2 cycles and 5 cycles of low frequency erode the stone 2.5 mm and 4.3 mm. In case (c) and (d), high and low frequency combination waveform, CCL waveform, the depth of the scoop indentation reaches 6 mm by cloud cavitation collapse. Especially in case (b), very acute hole is created, and there seems to be no damage at the surrounding surface of the stone. These results show by controlling acoustic cavitation phenomena, high-pressure and high-energy concentration is realized within a fine spatial and timing resolution, in case (b). The estimated total break up time by CCL is comparable to the conventional ESWL methods. Also the resulting fragments are sufficiently small to pass through the urethra.

Concluding Remarks

An extracorporeal lithotripsy method, Cavitation Control Lithotripsy (CCL) is being developed utilizing two frequencies focused ultrasound. By controlling cloud cavitation phenomena, high-energy and high-pressure concentration only at the stone surface is obtained. Cavitation phenomena are well controlled both in time and space. The occurrence time of the bubble cloud collapse can be controlled within 65 ns, and the cavitation area that is generated by high frequency ultrasound can be controlled within 100 μm in space. A model stone is efficiently chipped away. The stone comminution mechanism is attributed solely to the cavitation erosion. Compared with conventional ESWL, cavitation spatial range is narrower and total input energy is also smaller. The CCL method has the potential to provide a less invasive and more controllable lithotripsy system.

Development of a Remote Minimally-Invasive Surgical System with Operational Environment Transmission Capability

Mamoru Mitsuishi

Professor, Department of Engineering Synthesis, School of Engineering

The University of Tokyo

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2. Overview of the developed system

The developed remote minimally invasive system consists of surgery site, multi-media cockpit and communication system. Images from the endoscope, the whole operation room, and of vital sign are displayed on the large display and the small display located close to the operator in the multi-media cockpit. Master manipulators for the left and right hands were also developed (Fig.1). They are equipped with multi-axis force sensors to feedback the force information detected at the slave manipulator. Position and orientation information from the master manipulator is transmitted to the slave manipulator in the surgical site. The foot pedal is used to switch between the endoscope control and the forceps control modes. Using the master manipulator, it is possible to change the viewing direction of the endoscope. The slave manipulator has three arms; the left and right arms hold the forceps and the middle one holds the endoscope (Fig.2). Each arm is designed to hold the insert position of the trocar mechanically fixed for safety. During the operation, the insert position is fixed as the first step. Then three rotational, one translational and the grasping degrees of freedom are controlled.

3. Operational environment transmission and display

To perform the tele-surgery, visual information of the whole operational room as well as visual information from the endoscope should be transmitted to the multi-media cockpit. The information of the assistant at the surgical site, status of the slave manipulator and the vital signs of the patient should also be transmitted.

Therefore, in our system, the combination or the selection of the visual information from the endoscope, visual information of the abdominal region of the patient, visual information from the assistant and the slave manipulator and vital signs, such as an electrocardiogram (ECG), can be transmitted (Fig.3). The transmitted visual information of the total operation room environment is displayed on the large display behind and the small display close to the operator.

4. Active forceps with multi-axis force sensor

The active forceps developed in this paper has the functions of rotating the forceps around its axis and grasping an object at the tip. It is possible to separate the actuation and sensing, and the tool part. The tool part can be changed, for example from forceps to a radio knife.

The tool part is inserted in the human body. The tool part consists of only mechanical elements for easy sterilization and washing. The attachment unit was developed using a thrust bearing where the rotational motion around the forceps and grasping motion at tip can be independently transmitted. Translational motion of the rod for grasping is realized using a rack and pinion and a linear guide.

The grasping motion of the forceps is realized by pushing and pulling the rigid rod attached with the link mechanism at the forceps tip. A force sensor is located between the rod and the actuator (Fig.4). The pulling force is detected to estimate the grasping force. In the developed system, a 1-axis force sensor based on a parallel plate structure is attached between the attachment unit and the linear actuator.

A torque sensor where 4 thin plates are radially located is attached between the attachment unit and the motor for the rotation. It is possible to detect the torque around the forceps axis.

A 6-axis force sensor is attached between the active forceps and the slave manipulator. It is possible to detect the 3 directional forces and 3 moments. In the implemented system, all force sensors were originally developed using strain gauges.

5. Experiment and results

In the experiment, the multi-media cockpit and the surgical site were located at the University of Tokyo and the animal experiment institution located in the Shizuoka, respectively. The distance between the sites is approximately 150km. In the experiment, the gallbladder of a pig was removed. 3 ISDN lines were used in the experiment. 2 ISDN lines (256kpbs) and 1 ISDN line (128kbps) were used to transmit the visual and auditory, and control information including force information, respectively.

In the experiment, after trocars were inserted at the surgical site, the endoscope and forceps were inserted. Then the operation was executed from the remote multi-media cockpit. At first, the gallbladder was grasped using the left hand forceps. Then it was exfoliated using the right hand forceps. The following operations were executed subsequently : cutting off the cystic duct and gallbladder, and collecting it. A radio knife was attached to the right slave manipulator while the cystic duct and gallbladder were cut off (Fig.5).

Using the developed system, it was possible to accomplish the series of operations. The measured time delays were approximately 350ms and 50ms, for the visual and auditory information, and control information transmission, respectively.

6. Conclusions

(1) Construction method of the remote minimally invasive surgical system was presented. The system was actually implemented.

(2) Using the developed system, a cholecystectomy for a pig was successfully executed over a distance of approximately 150km.

(3) Time delay for the various information transmissions was measured.

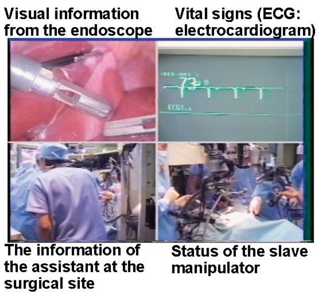

Fig.3 Operational environment transmission

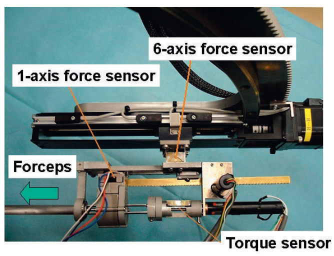

Fig.4 Force sensors at the slave manipulator

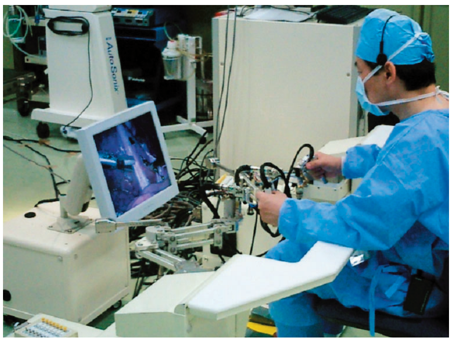

Fig.1 Master manipulater

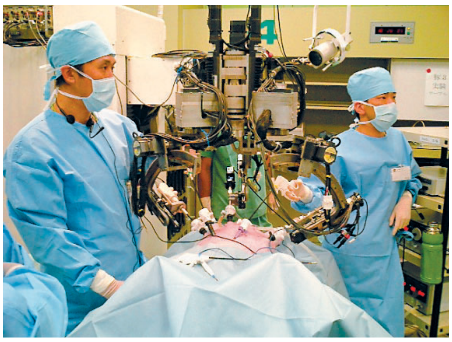

Fig.2 Slave manipulator

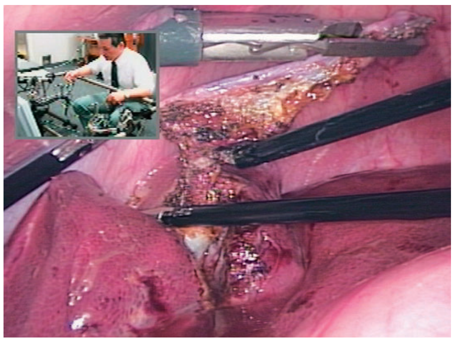

Fig.5 Cholecystectomy for a pig

The 21st Century COE Program "Future Medical Engineering based on Bio-nanotechnology" in Tohoku University

Masaki Sato

Professor, Program Leader

Department of Bioengineering and Robotics, Graduate School of Engineering, Tohoku University

Continued from page 1 In FY2002 applications were done in five different major fields, 1. Life Sciences, 2. Chemistry, Material Sciences, 3. Information Sciences, Electrical and Electronic Engineering, 4. Humanities, and 5. Interdisciplinary, Combined Fields, New Disciplines. Superb 113 proposals were in total selected for promoting advanced education and research in Japanese universities. Only our program was selected from purely engineering-oriented proposals in the field of life sciences. The main aim of our program is to promote the advanced education for students in Ph.D. course through advanced high technologies in biomedical engineering by supporting them financially as well as educationally.

Backgrounds

Technology is widely expected to provide answers to some of the medical and other problems faced by people in our aging society. Traditionally, Tohoku University has developed new technologies for the life sciences through cooperative research that has been undertaken by its engineering and medical schools. Advanced research at Tohoku University has led the way in the fields of cell function and biomolecular technology, nanomedicine, imaging and structure of biomolecules, and medical informatics. It is now crucial that we combine these advanced research activities into a systematic approach so that future biomedical engineering can be applied to sophisticated medical research and practice. This program aims to unite various technologies in order to develop the ultimate in prophylactic measures for age-dependent diseases, using tailor-made diagnostic and therapeutic procedures. The overall objective of this program is to form a global center of excellence in biomedical engineering. The active 18 members of this program widely belong to various departments from engineering to medical schools. To facilitate this process, the program will be rigorously assessed by an independent committee composed of external members.

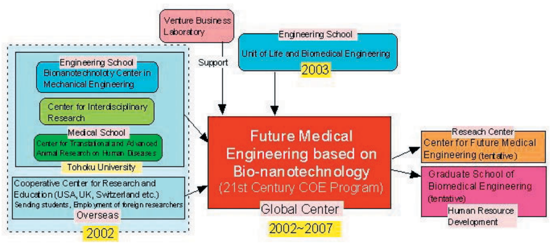

Fig.1 Centers for researches and education, and the future plan

Plan for Formation of Research Center

a. *Start-up*: The Administrative Center. In the first fiscal year, the Bionanotechnology Research Center in Mechanical Engineering, the Center for Translational and Advanced Animal Research on Human Diseases in the Graduate School of Medicine, and the Center for Interdisciplinary Research, formed the basis for the new center as shown in Fig.1. The Unit of Life and Biomedical Engineering in the Graduate School of Engineering will constitute the base for this center in the second year. Cooperative research centers will be established abroad.

b. *Steering committee*: Members include a chairperson, four vice-chairs, and several active members. This committee deals with important issues concerning the administration.

c. *Assessment committee*: The members (five persons) of this committee are experts from other universities, and from related institutions or companies, who assess our activities at the end of each fiscal year.

d. *Employment of foreign researchers*: Active researchers, professors (full, associate or assistant) will be invited to undertake cooperative research at Tohoku University, as well as to discuss subjects of mutual interest and to teach students through conference presentations and debates.

e. *Research groups*: Four research groups were implemented and cooperative research between the groups will be actively encouraged. The groups will study Cell function and biomolecular technology, Nanomedicine, Imaging and structure of biomolecules, and Medical informatics as shown in Fig.2. As one of the research projects in the nanomedicine group, a 3D-

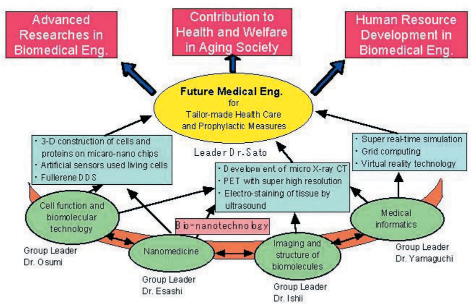

Fig.2 Research groups, their themes and cooperative structure

stacked retinal prosthesis has been developed (Fig.3).

Education Implementation Plan

a. *Faculty meetings*: Educational policy, self-assessment, and an advisory system for students are discussed and implemented.

b. *New curriculum*: A new curriculum for students was developed to enable students to acquire the necessary experience and knowledge of biomedical engineering.

c. *Education center*: An administration office for educational purposes was built where faculty and students can conduct research and further their education.

d. *Nomadic education system*: By means of competition, students will be selected to participate in cooperative research at universities abroad. Students from overseas universities will also be selected and invited to our center.

e. *Itinerant education system*: By means of competition, self-reliant students will be selected and trained individually under a special apprenticeship program with individual professors.

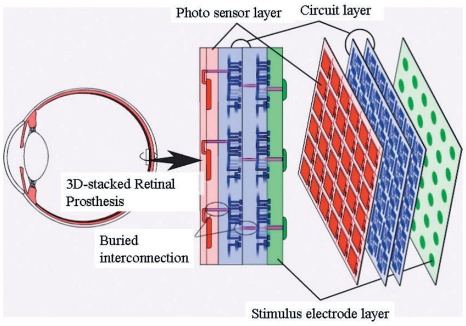

Fig.3 3D-stacked retinal prosthesis

Summary

Advanced research in the field of biomedical engineering is undertaken in four areas: 1. Cell function and biomolecular technology, 2. Nanomedicine, 3. Imaging and structure of biomolecules, and 4. Medical informatics. Students in the doctoral program are able to obtain funds, including funds to study abroad, by means of a competition among applicants. Students are expected to undertake original research and to be self-motivated in their work. Through this program, we intend to establish a unique, high-level center for research and education in biomedical engineering.

Human Simulator

Ryutaro Himeno

Director, Advanced Center for Computing and Communication

Riken (The Institute of Physical and Chemical Research)

Continued from page 1 Of course, we do not know much about human physiology. We started the development in subjects of which governing equations we have already known. Those are 1) soft and hard tissue simulation, 2) circulatory system simulation and 3) human motion simulation based on kinematics.

1) Soft and hard tissue simulation

Eye ball and bone are our current targets of simulation. A silicone band is fitted onto the wall of eye ball in the retina detachment operation. The band squeezed the eyeball. This process is simulated to tell doctors to choose optimum properties of the band (Fig.1) For this simulation, we have developed not only simulation software system but also a high-resolution geometry measurement system: 3-D

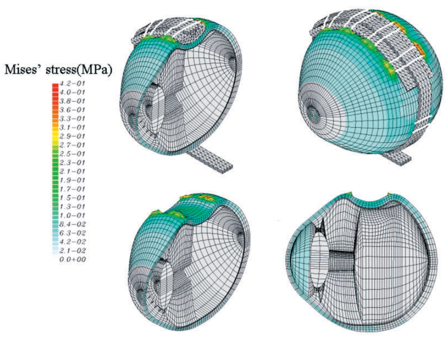

Fig.1 Simulation of retina detachment operation

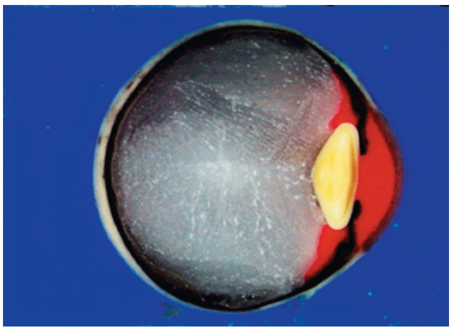

Fig.2 Three dimensional internal structure microscope and an output sample image with 20micron resolution

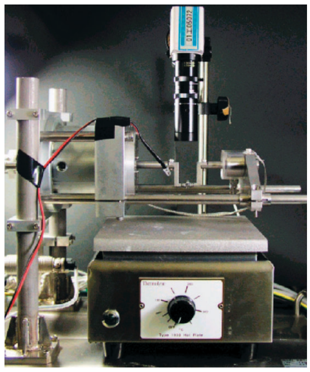

Fig.3 Strength testing device for medical materials

Internal Structure Microscope (Fig.2) and a strength testing device (Fig.3).

It is essential to know detailed inside structure of the bone for precise prediction of its strength. We have developed a micro CT device to get fine 3-D inside structure of the bone (Fig.4). Fig.5 shows a result of an implant simulation.

Fig.4 Micro CT device to capture 3D structure of Cancellous bone

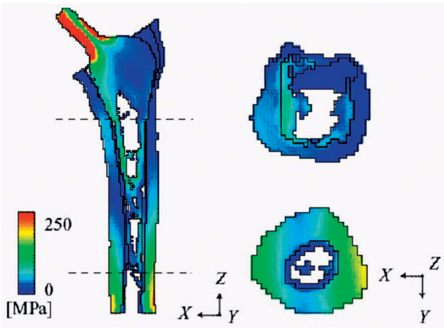

Fig.5 Implant simulation

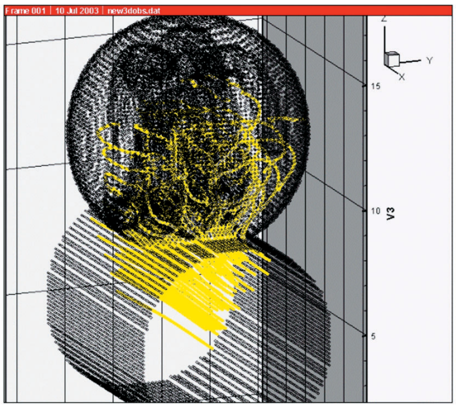

Fig.8 Flow around the coil in an aneurism.

2) Circulatory system simulation

We are developing not only basic algorithm for fluid-structure coupling model (Fig.6) but also practical blood flow simulation system from medical images by MRA, CT or Ultrasonic imaging devices. Fig.7 shows flows in the left ventricle whose changing geometry was taken by a ultrasonic imaging device. Fig.8 shows a simulation of inserted coil in aneurism of cerebral artery.

3) Human motion analysis

A musculoskeletal model is used for simulating human motion. Fig.9 shows a simulation of human gate motion when a muscle of the leg is damaged. This kind of simulation will help rehabilitation of patients.

We will start the second CBM project from April, 2004. We will integrate above three simulation to achieve a whole human body with various organs, bones, muscles, blood vessels and skins.

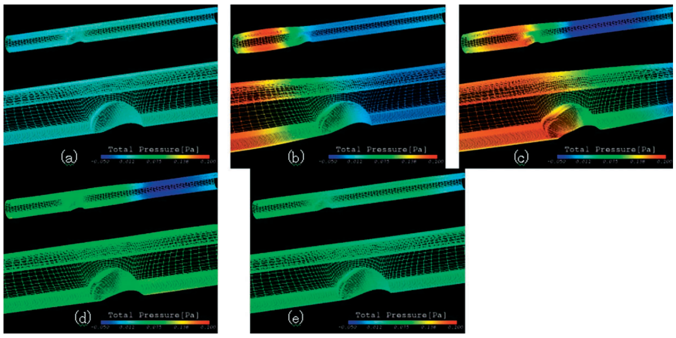

Fig.6 Fluid-structure coupling simulation for blood vessel and stenosis.

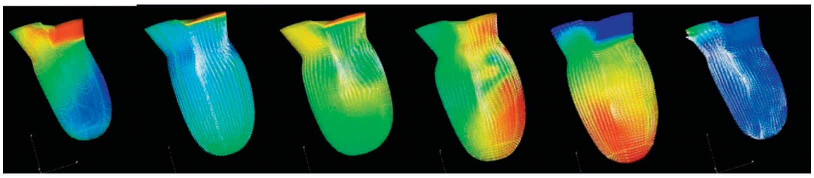

Fig.7 Flow vectors and pressure distribution in the left ventricle

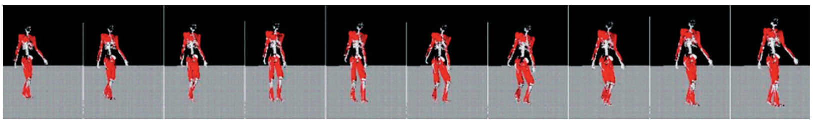

Fig.9 Human gait motion

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