

3. 人材育成

平成 26 年度にはコアテック社員 2 名を含む民間企業人を主たる対象として岡山大学病院内の次世代医療機器開発プロフェッショナル育成プログラムアドバンスドコースにて計 10 回の講義を行い、民間企業人の人材育成を行った。人材育成の主たる責任者は岡山大学病院副院長兼国産医療機器創出促進基盤整備等事業進捗管理責任者の那須保友である。以下に実施状況や講義内容を提示する。

《岡山大学病院における研修内容》

(1) 講義形式

地元の医療関連企業の研究開発担当者に参加を求め、講義を重ねている。



《 講義の一場面 》 2014 年 12 月 9 日（土）開講

神戸大学大学院 山根 隆志 教授

『次世代医療機器開発ガイドライン』

岡山大学病院 中央診療棟 3F 多目的室

[表-2] 育成アドバンストコースの講義

講義期日	時間	講義タイトル名	講師	参加人数
平成 26 年 12 月 6 日 (土)	13:00-14:30	次世代医療機器開発ガイドライン	神戸大学工学研究科(機械系) 山根 隆志 教授	受講生 10 名 その他 6 名
	14:40-16:10	国際規格を踏まえた医療機器のリスクマネジメント	北里大学 医療衛生学部 中谷 敬 客員教授	
平成 27 年 1 月 17 日 (土)	11:30-13:00	新機能(C1)・新技術(C2)に位置付けされる医療機器開発について	ナカシマメディカル株式会社 石坂 春彦 薬事品証部部长	受講生 9 名 その他 2 名
	14:00-15:30 15:40-17:10	医学英語 I (医学英語の重要性の認識) 医学英語 II (疾患名・治療法に関する英単語と用法)	北里大学 医療衛生学部 中谷 敬 客員教授	
1 月 24 日 (土)	10:30-12:00	次世代医療機器評価指標について	中村MDオフィス代表 中村 雅彦 氏	受講生 12 名 その他 7 名
	13:00-14:30	医療ニーズに立脚した医療機器開発の重要性	早稲田大学 ナノ理工学 谷下 一夫 教授	
	14:40-16:10	ゴールを見据えた機器設計・研究開発、法規制対応計画の立て方	日本GE株式会社 大竹 正規 政策推進本部部长	
1 月 31 日 (土)	13:00-14:30	PMDA 講座	医薬品医療機器総合機構(PMDA) 医療機器審査専門員(臨床医学担当) 櫻井 淳 先生	受講生 10 名 その他 6 名
2 月 18 日 (水)	16:20-17:50	医療現場でのニーズ発掘	中央西日本メディカルイノベーション「岡山大学病院の医療現場からのニーズ」を受講することで出席に替える	受講者多数
3 月 22 日 (日)	14:00-15:30	医療用ロボット開発の歩み	岡山大学病院 放射線科 平木 隆夫 講師	

※参加人員の「その他」：学内教職員、運営スタッフを指す。

III. 学会等発表実績

1. 亀川哲志、松野隆幸、平木隆夫。CT 透視下針穿刺用医療ロボットの開発：ロボティック IVR の時代へ。岡山大学知恵の見本市 2014。岡山大学創立五十周年記念館。2014 年 11 月 14 日
2. 平木隆夫、亀川哲志、松野隆幸、北村浩基、井上卓也、難波孝文、中家寛貴、石井創、杉山晃平、桐田泰三、谷本圭司、三宅 徹、佐藤寿昭、難波喜弘。CT 透視下針穿刺用ロボットの開発。術者被ばくのない手技へ。中央西日本メディカルイノベーション 岡山大学鹿田キャンパス内 Junko Fukutake Hall、2015 年 2 月 17 日～18 日
3. 桐田泰三、亀川哲志、松野隆幸、平木隆夫。ロボティック I V R の開発に向けて 産学官連携学会関西中四国学会 愛媛大学 城北地区キャンパスメディアホール（総合情報メディアセンター内）、2014 年 12 月 5 日
4. 杉山晃平、井上卓也、中家寛貴、矢納陽、松野隆幸、見浪護、亀川哲志、平木隆夫、五福明夫，“肺がん治療における低侵襲 IVR のロボット化-第一報運動学の導出”，計測自動制御学会 システム・情報部門講演会 2014 (SSI2014)，SS6-9，pp. 585-590 (2014. 11)
5. 井上卓也、中家寛貴、松野隆幸、亀川哲志、平木隆夫、矢納陽、見浪護、五福明夫，“肺がん治療における低侵襲 Interventional Radiology 支援ロボットの開発”，第 15 回計測自動制御学会 システムインテグレーション部門講演会 (SI2014)，2M3-4，pp. 1773-1778 (2014. 12)
6. 難波 孝文，亀川 哲志，松野 隆幸，平木 隆夫，見浪 護，五福 明夫：“ロボティック IVR のための PHANTOM Omni を用いた遠隔操作システムの構築”，計測自動制御学会システム・情報部門学術講演会 2014 (SSI2014)，SS6-11，岡山 (2014. 11. 21)
7. 石井 創，亀川哲志，松野隆幸，平木隆夫，五福明夫：“CT ガイド下における針穿刺ロボットの開発-針穿刺ロボットの針先位置決め精度の測定-” ロボティクス・メカトロニクス講演会 2015 (投稿中)

IV. 研究成果の刊行物・別刷

1. 平木隆夫、亀川哲志、松野隆幸、金澤 右。CT透視下針穿刺用ロボット開発の歩み：術者被ばくゼロのIVRを目指して。IVR会誌 2014; 29:375-381.
2. Hirotaka Nakaya, Takayuki Matsuno, Tetsushi Kamegawa, Takao Hiraki, Takuya Inoue, Akira Yanou, Mamoru Minami, Akio Gofuku, "CT Phantom for Development of Robotic Interventional Radiology", 2014 IEEE/SICE International Symposium on System Integration (SII2014), SaA1C.5, pp. 82-87(2014.12)

学 会 等 発 表 実 績

委託業務題目「医療機器開発推進研究事業」

CT透視下針穿刺用医療ロボットの開発～ロボティックIVRの時代へ～

機関名 国立大学法人岡山大学

1. 学会等における口頭・ポスター発表

発表した成果（発表題目、口頭・ポスター発表の別）	発表者氏名	発表した場所（学会等名）	発表した時期	国内・外の別
CT透視下針穿刺用医療ロボットの開発：ロボティックIVRの時代へ（ポスター）	亀川哲志、松野隆幸、平木隆夫	岡山大学知恵の見本市（岡山）	2014年11月14日	国内
CT透視下針穿刺用ロボットの開発。術者被ばくのない手技へ（口頭・展示）	平木隆夫、亀川哲志、松野隆幸、北村浩基、井上卓也、難波孝文、中家寛貴、	中央西日本メディカルインノベーション（岡山）	2015年2月17日～18日	国内
ロボティックIVRの開発に向けて（口頭）	桐田泰三、亀川哲志、松野隆幸、平木隆夫	産学官連携学会関西中四国学会（愛媛）	2014年12月5日	国内
肺がん治療における低侵襲IVRのロボット化-第一報運動学の導出	杉山晃平、井上卓也、中家寛貴、矢納陽、松野隆幸、見浪護、亀川哲志、平木隆夫、五福明夫	計測自動制御学会 システム・情報部門講演会（岡山）	2014年11月21日	国内
肺がん治療における低侵襲 Interventional Radiology 支援ロボットの開発	井上卓也、中家寛貴、松野隆幸、亀川哲志、平木隆夫、矢納陽、見浪護、五福明夫	第15回計測自動制御学会システムインテグレーション部門講演会（東京）	2014年12月16日	国内
ロボティックIVRのためのPHANTOM Omniを用いた遠隔操作システムの構築	難波 孝文、亀川 哲志、松野 隆幸、平木 隆夫、見浪 護、五福 明夫	計測自動制御学会システム・情報部門学術講演会（岡山）	2014年11月21日	国内
CTガイド下における針穿刺ロボットの開発-針穿刺ロボットの針先位置決め精度の測定-	石井 創、亀川哲志、松野隆幸、平木隆夫、五福明夫	ロボティクス・メカトロニクス講演会（京都）	投稿中	国内

2. 学会誌・雑誌等における論文掲載

掲載した論文（発表題目）	発表者氏名	発表した場所（学会誌・雑誌等名）	発表した時期	国内・外の別
CT透視下針穿刺用ロボット開発の歩み：術者被ばくゼロのIVRを目指して	平木隆夫、亀川哲志、松野隆幸、金澤 右	IVR会誌	2014年12月	国内
CT Phantom for Development of Robotic Interventional Radiology	Hiroataka Nakaya, Takayuki Matsuno, Tetsushi Kamegawa, Takao Hiraki, Takuya Inoue, Akira Yanou, Mamoru Minami, Akio Gofuku	IEEE/SICE International Symposium on System Integration	2014年12月	国内

CT Phantom for Development of Robotic Interventional Radiology

Hiroataka Nakaya, Takayuki Matsuno, Tetsushi Kamegawa, Takao Hiraki,
Takuya Inoue, Akira Yanou, Mamoru Minami, Akio Gofuku

Abstract— There is a surgical method called Interventional Radiology (IVR) as one of lung cancer treatments. It has a problem that doctors are exposed to radiation because IVR is conducted in CT apparatus. In order to avoid the problem, a robotic IVR system that doctors conduct the puncture with a robot is developed. An operation test is necessary to develop the robotic IVR system, however, an experiment with real patients is rejected based on ethic regulation. Therefore, a phantom is used for experiments instead of patients. A phantom is a model of human used for both evaluation and adjustment of medical imaging equipments such as CT and MRI. However, ready-made phantoms can not be punctured, because they are only aimed to radiography and their surface are hard. Therefore a phantom for CT-IVR which can be punctured is developed.

I. INTRODUCTION

In recent years, medical technologies are progressing. As one of them, Interventional Radiology (IVR) is paid much attention. IVR is a surgical method that a doctor inserts a needle for treatment in the body while observing medical images which scanned by roentgenoscopy, ultrasound imaging apparatus and Computed Tomography (CT) apparatus. This surgical method is applied to treatment of cancer and blood vessel widely. Compared to general surgical treatment, IVR has low invasiveness to patients, because there is no need to incise an abdomen. And time to get out from hospital becomes short, because a scar after surgery is minimized. Moreover urgent correspondence is possible, and it is possible for patients whose physical status are severe to be treated under local anesthesia. Because of these advantages, the number of IVR increases in recent years [1].

There is a treatment method called radiofrequency ablation (RFA) as one of IVR treatment methods for liver cancer and lung cancer. RFA is the medical procedure which cauterizes a tumor by inserting a needle and generating radiofrequency waves. By completely cauterizing a cancer cell, IVR has a high complete recovery ratio [2].

At the lung cancer treatment, a tumor is hard to distinguish at medical images by roentgenoscopy and ultrasound imaging, because there is range of air in lungs. Therefore CT apparatus which has high spatial resolution is used at the lung cancer treatment. But CT apparatus has higher radiation

This work was supported by MEXT KAKENHI Grant Number 13233919
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T. Hiraki is with Department of Radiology , Okayama University Hospital, Okayama, Japan



Fig. 1. IVR with observing CT images

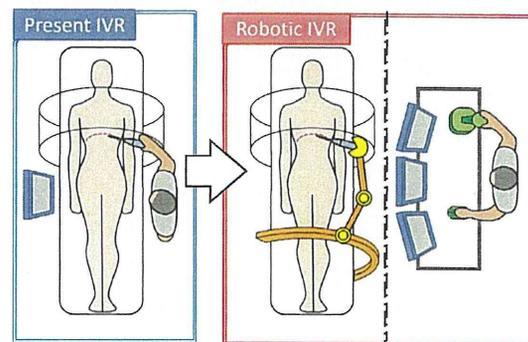


Fig. 2. Concept of IVR robot

than other devices. In the current IVR, doctors puncture a needle in the gantry of CT apparatus which generates a radiation (Fig.1). So it is a problem that doctors are exposed to radiation.

There are some researches about medical robot system for IVR such as CTbot and AcuBot. CTbot is aimed to IVR for abdomen, it has an automatic positioning system in order to insert into abdomen with needle [3]. AcuBot is a compact six-degree-of-freedom robot for manipulating slender surgical instrument in the confined space of medical imaging apparatus such as gantry of CT apparatus without inducing artifacts on the CT images [4]. On the other hand, an IVR robot that doctors conduct the IVR of lung cancer treatment at the position away from gantry of CT apparatus is developed in order to solve the problem [5]. Our robot is conceived as shown in Fig.2. And the produced IVR robot is shown in Fig.3.

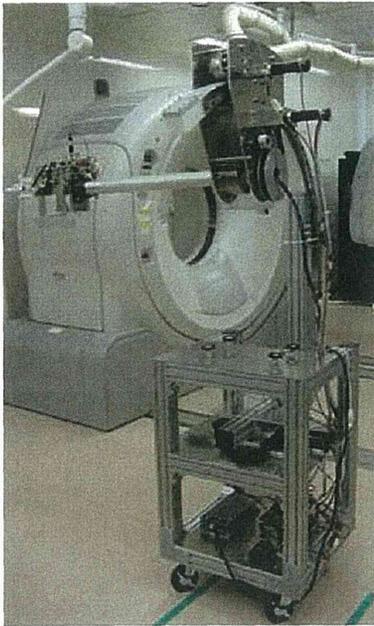


Fig. 3. IVR robot



Fig. 4. Ready-made phantom

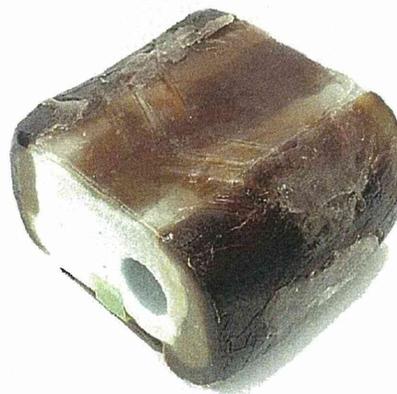


Fig. 5. CT-IVR phantom

In a process to develop the robot, operation tests are necessary to evaluate operability of the robot. However, an experiment with real patients is rejected based on ethic regulation. Therefore, we use a phantom in experiments instead of patients. The phantom is a model of human used for evaluation and adjustment of medical imaging apparatus such as CT apparatus or Magnetic Resonance Imaging (MRI) apparatus. The phantom shown in Fig.4 is sold by Kyoto Kagaku Co.,Ltd. [6]. This phantom is used for not only evaluation and adjustment of apparatus but also training of radiographers. However, it cannot be punctured, because it is made of acrylic resins. So we cannot use this phantom in our experiments. Also there is a simulator for blood vessel IVR called EVE which is commercialized by FAIN-Biomedical Co., Ltd. [7]. This is aimed for training of doctors, and simulation of IVR with a catheter is possible. However, we cannot use this simulator in experiment, because this is not aimed for lung cancer treatment.

Therefore a phantom for IVR of lung cancer treatment can be punctured is required. There are two requirements for development of phantom. First, a reaction force, as doctor punctures the phantom, is similar to the human body. Secondly, medical image which is scanned by CT apparatus is similar to human body. At all a phantom for CT-IVR which can be used in experiments is developed (Fig.5).

II. PHANTOM FOR CT-IVR

CT images of phantom for CT-IVR is necessary to be similar to CT images of human body, because doctors conduct IVR treatment while observing CT images. And reaction force to puncture phantom with a needle is necessary

to imitate sensation to puncture human body, in order to conduct an experiment as a real operation environment. The phantom is made of materials which satisfy these requirements.

1) *Artifact*: At developing IVR robot, an artifact on the CT images becomes a problem. An object which does not exist may appear on the CT images as a virtual image. This virtual image is called artifact. A radial line occurring from the object in a red frame in Fig.6 is artifact. If an artifact overlaps a cancer tumor on CT images, distinguishing boundary between artifact and cancer tumor becomes difficult. So it may be difficult to conducted treatment cause of an artifact. There are some kinds of artifact such as a metal artifact and beam hardening artifact. The metal artifact caused by metal part absorbs X-rays highly. The beam hardening artifact appears because of the large difference of X-rays absorption between a measured object and its surrounding. The proposed of phantom does not consist of metallic materials, so the metal artifact does not appear. The phantom is developed with attention to the beam hardening artifact.

Here, a flow to constitute CT images is described simply

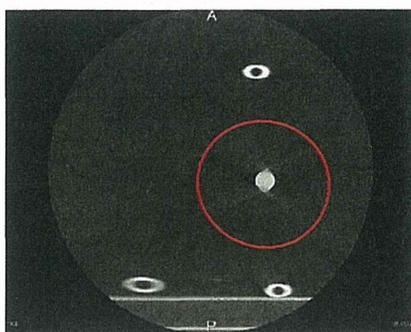


Fig. 6. Example of beam hardening artifact

(Fig.7). Firstly, a X-rays generator of CT apparatus radiates X-rays. X-rays penetrated a human body are received by a detector. Because some X-rays are absorbed by internal tissues of human, the X-rays quantities detected are varied. Then values which subtract radiated X-rays quantities from detected X-rays quantities are acquired as detected data. A value of this data is called absorption coefficient. A difference of absorption coefficients of internal human tissues is very small, so it is need to enhance edges in order to visualize human tissues well. Then edges of absorption coefficients are enhanced by filter processing. A value detected by this processing is called CT number. These processes are conducted while a X-ray generator revolve once on the circumference, and data in one revolution are acquired. Finally, CT images are constituted by superposing these data.

CT image constitution system has nonlinearity. Detected data of internal human tissues are low contrast because a difference of absorption coefficients of internal tissues of human is very small. Therefore, when human body is scanned, CT image constitution system has pseudo-linearity. On the nonlinear system, it is kept that a characteristic which an output is proportional to an low contrast input. This characteristic is a pseudo-linearity. However, when human body is scanned with an object whose absorption coefficient is very large such as metals, detected data become high contrast and it collapses a pseudo-linearity of CT image constitution system. Therefore, an artifact appears on the CT image caused by collapse of pseudo-linearity.

Next, the beam hardening artifact is described. X-rays have various wavelengths. After penetrating objects which absorbs X-rays, X-rays qualities are varied because some X-rays are absorbed. This variation of X-rays causes collapse of pseudo-linearity. Then these X-rays collapsed pseudo-linearity are received by detector. Then CT images are constituted by CT apparatus without desirable data of X-ray. The beam hardening artifact appears cause of wrong process like this. X-rays which is radiated from X-ray tube include various wavelengths. Low energy X-rays with short wavelength have a property that is easy to be absorbed. On the other hand, high energy X-rays with long wavelength have a property that is difficult to be absorbed. So there are only high energy

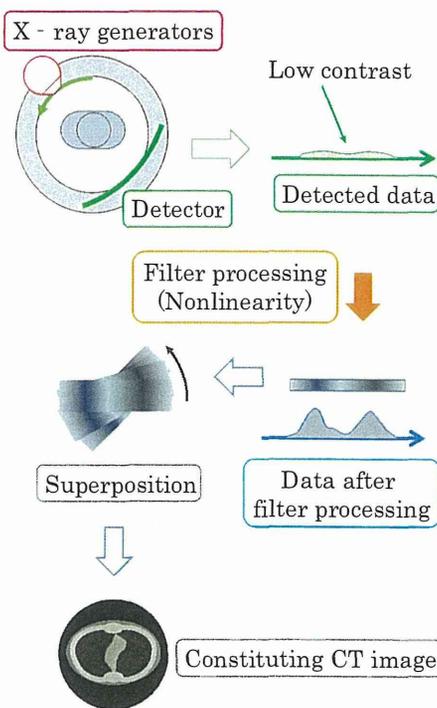


Fig. 7. Flow to constitute CT image

X-rays with long wavelength as penetration to absorption objects. This phenomenon where energy domain of X-rays becomes high is called hardening. Like this, an artifact appears because a detector receive wrong data which is varied after X-rays penetrate an absorption object. An artifact appears well in case that there is an object which absorbs X-rays highly in an object where absorbs X-rays too lowly. This artifact hardly appears in case human body scanned by CT apparatus. Therefore, it is required to prevent what the beam hardening artifact appears on the CT images of the developed phantom.

An incidence of artifact is influenced by a ratio of objects which absorb X-rays on the section of CT scan. This is similar to the condition to appear the beam hardening artifact well. In particular the ratio of air on the section of CT scan becomes high, an artifact appears well. Because air does not absorb X-rays almost. So an artifact appears well when an object which absorbs X-rays highly is dotted. It was confirmed that an artifact appeared when there is only part of simulated cancer tumor on the section of CT scan by basic experiment. The cause of this result is considered that the ratio of the objects which can absorb X-rays on the section of CT scan was small. Therefore, the phantom whose size should be like human is developed in order to conduct the operation test such as real IVR treatment. So the appearance of artifact can be prevented.

TABLE I
MATERIAL OF CT-IVR PHANTOM

body tissue	material
muscle and lungs	melamine form
ribs	acrylic pipe
backbone	acrylic pipe
cancer tumor	carrageenan
skin	carrageenan

III. DEVELOPMENT OF PHANTOM

A. Overview

A produced IVR robot is aimed to only conduct IVR for treatment of lung cancer. So a phantom does not need to imitate whole body. Therefore, a produced phantom is made from a chest to an abdomen including lungs. The phantom consists of body tissues, ribs, backbone, skin, cancer tumor, muscle and lungs. Materials of phantom for CT-IVR are selected from two requirements. One is that they are suitable hardness that can be punctured with a needle. The other is that their rates of X-rays absorption are suitable. Materials selected for each tissues are shown in Table 1. Melamine form is spongiform material used with commercial cleaning tools. Carrageenan is one of gelling agents used for foods.

B. Part of simulated cancer tumor

A part of simulated cancer tumor is made of carrageenan gel. Carrageenan is one of gelling agents and used for food processing such as commercial jelly. There are three types of carrageenan such kappa and iota and delta. And these three types have different characteristics each. Compared with other two types, kappa type carrageenan can get enough hardness and stickiness. Therefore, kappa type carrageenan is adopted for making part of simulated cancer tumor. How to make gel is described. Firstly, liquid gel having high viscosity is made by completely dissolving carrageenan powder in water with applying heat. This liquid gel hardens as it gets colder.

The density of carrageenan is important to make gel, because hardness of gel is varied by the density of carrageenan in the gel. Then, some samples whose densities are different were made. It is verified which sample is suitable from the view of both points of hardness and rate of X-rays absorption. The densities of prepared samples are 4 % , 5 % and 6 % . The verification result of CT image is shown in Fig.8. From this result, it was found out that each samples are same in the rate of X-rays absorption. Next, the verification of hardness was conducted by a doctor. The doctor punctured the samples as shown in Fig.9, and it was found out that the gel whose density is 4% is suitable. Therefore, 4% density is adopted for making part of simulated cancer tumor.

C. Part of skin

A part of skin is made of carrageenan gel like part of simulated cancer tumor. The density of carrageenan is decided as 3% by considering the reaction force at puncture. The carrageenan gel is necessary to keep refrigerated because it

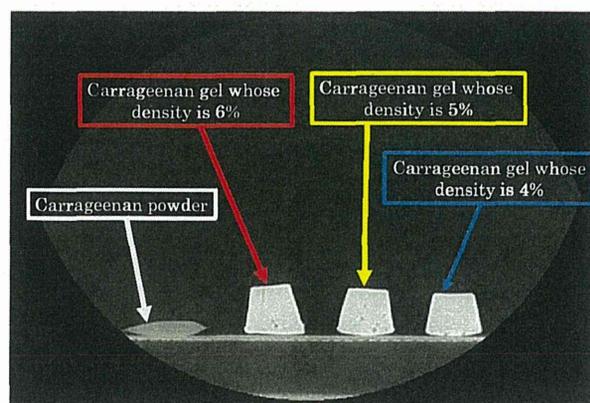


Fig. 8. CT image of carrageenan gel



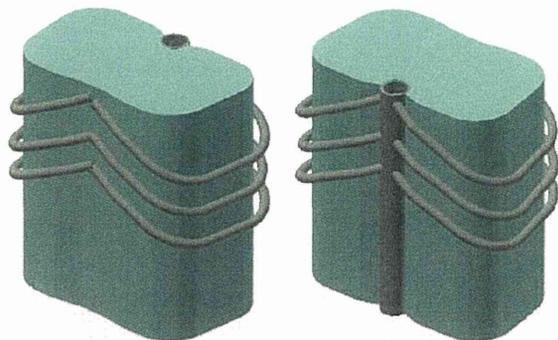
Fig. 9. Puncturing carrageenan gel

is perishable. However, a part of skin has many volume, so it is difficult to keep refrigerated. Then iodine solution is mixed as a preservative with carrageenan gel. This carrageenan gel is hardened around an inside of phantom which is made of melamine form and acrylic pipe. The inside of phantom is shown Fig.10. The state of making part of skin is shown in Fig.11.

IV. CT SCANNING OF PHANTOM

The developed phantom was scanned by CT apparatus in Okayama University Hospital as shown in Fig.12. The CT image of developed phantom is shown in Fig.13. For comparison, CT image of ready-made phantom is shown in Fig.14. Two problems were found out through the experiment.

First, when the part of skin was made by pouring carrageenan gel, carrageenan gel soaked into melamine form. And the soaked carrageenan gel appeared on the CT image. If this part overlaps the part of simulated cancer tumor, puncture becomes difficult because it is hard to distinguish them. Therefore, the production process of part of skin is necessary to review. Secondly, it becomes clear that to distinguish parts of bones from skin is difficult, because the X-rays absorption coefficients of acrylic pipe and carrageenan gel were almost the same. In the case of human, it is



(a) Front (b) Back

Fig. 10. Inside of CT-IVR phantom



Fig. 11. Making skin of CT-IVR phantom

easy to distinguish bones from other body tissues on the CT images. Distinguishing bones from other tissues is very important. Because doctors have to puncture while avoiding bones. So the position starting puncture must be decided before puncturing. However, in the case of phantom, it is difficult to decide the position starting puncture because part of bones and skin are similar on the CT images. Therefore, the materials of bones should be changed because it is easier to change the material of bones than the material of skin.

V. PHANTOM PUNCTURE EXPERIMENT

Puncture experiment was conducted with the phantom developed. A doctor controlled the IVR robot and puncture the phantom with a needle. The experimental environment is shown in Fig.15. The CT images when the phantom was punctured are shown Fig.16. In this experiment, the doctor punctured a phantom by remote control of the IVR robot while observing a CT image of phantom for CT-IVR. The result of phantom puncture experiment is described.

Parts of ribs performed the function which was expected as an obstacle when the phantom was punctured. Therefore, parts of ribs maintain a shape and position, however, change of the materials which was described in previous section is

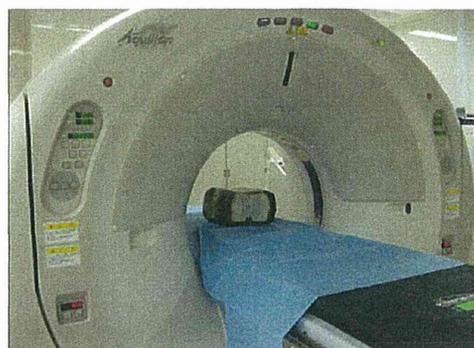


Fig. 12. Environment of CT photography

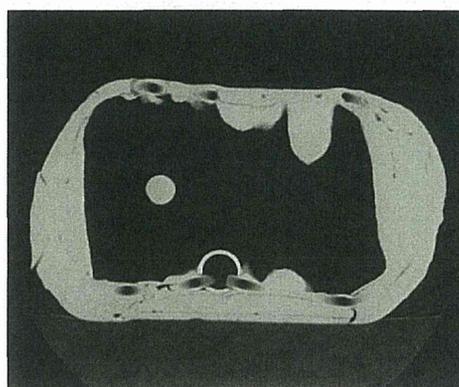


Fig. 13. CT image of CT-IVR phantom

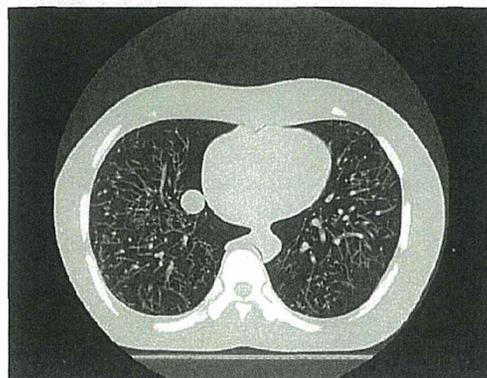


Fig. 14. CT image of ready-made phantom

the future problem. And it was made out that if there are more areas where puncture is impossible such as a sternum and heart, a more practical experiment can be conducted. So it is necessary to add these two organs into the phantom.

Considering about part of lungs, there is flexibility of a needle in the real human lungs while puncturing, because a ratio of air in the lungs is high. However, parts of lungs of this phantom were filled with melamine form, a needle punctured was fixed and had no flexibility of operating. Therefore,