Personalized 3D-Printed Model for Informed Consent for Stage I Lung Cancer: A Randomized Pilot Trial

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We conducted a preliminary evaluation of the usefulness of personalized 3D-printed models for improving patient comprehension in informed consent for surgical resection of stage I lung cancer. From January through March 2018, we enrolled a total of 20 adult patients who were suspected to have stage I lung cancer on a preoperative multidetector chest computed tomography and decided to undergo elective surgical resection. The patients were randomly assigned to 3D printing and control arms. Informed consent was obtained before surgery with or without a half-life-size patient-specific 3D-printed model depending on the assigned arm. The patients evaluated the quality of the informed consent process in a 5-point scale using a questionnaire regarding patient knowledge, benefit, risk, alternative treatments, and satisfaction. The patient knowledge score was significantly higher in the 3D-printing group than in the control group (13.6 ± 1.5 vs 11.8 ± 1.6; *P* = 0.02), while the total score and the scores of the other 4 categories did not significantly differ between the groups: total score, 61.3 ± 7.8 vs 55.4 ± 7.3 (*P* = 0.12); benefit, 13.1 ± 0.9 vs 11.6 ± 2.1 (*P* = 0.10); risk, 11.3 ± 2.1 vs 11.7 ± 1.7 (*P* = 0.73); alternative treatment, 10.3 ± 3.1 vs 9.0 ± 2.7 (*P* = 0.40); and satisfaction, 13.0 ± 2.2 vs 11.3 ± 2.5 (*P* = 0.10). Personalized 3D printing was technically implementable and had the potential to improve patient comprehension in informed consent for surgical resection in patients suspected of having stage I lung cancer.

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3D-printed RUL lung cancer (dark blue) model within transparent flexible lung parenchyma.

Central Message

A personalized 3D printing had the potential to improve patient comprehension in informed consent for surgical resection in patients suspected of having stage I lung cancer.

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Informed consent must be provided before surgical treatment of lung cancer. The patient's understanding is the key component of appropriate informed consent, but is often inadequate.[1] Patient-specific 3D-printed models have the potential to improve patients' presurgical comprehension.[2] The aim of this study was to conduct a preliminary evaluation of the usefulness of personalized 3D-printed models for improving patient comprehension in informed consent for surgical resection of stage I lung cancer.

This study was approved by our institutional review board. Informed consent for participation was obtained, with a target sample size of 20 patients in this pilot study. From January through March 2018, we enrolled a total of 26 patients at our institution who met the following inclusion criteria: (1) adult patients who were 20 years old or older; (2) patients who were suspected to have stage I lung cancer and decided to undergo

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Table 1. Baseline Characteristics of Patients and Pulmonary Lesions

	3D-Printing Arm	Control Arm	*P* Value
Age (years)	65.8 ± 8.1	63.0 ± 12.3	0.481
Male: female	4:6	5:5	0.656
Medium to high socioeconomic status	30.0% (3/10)	60.0% (6/10)	0.370
High school or higher education	50.0% (5/10)	80.0% (8/10)	0.350
Lesion location			0.826
Right upper lobe	25%	33%	
Right middle lobe	8%	8%	
Right lower lobe	17%	25%	
Left upper lobe	25%	17%	
Left lower lobe	25%	8%	
Multiplicity	20.0% (2/10)	10.0% (1/10)	1.000
Lesion diameter (cm)*	2.4 ± 1.2	2.3 ± 0.9	0.912
Lesion composition on computed tomography			1.000
Solid lesion	30.0% (3/12)	20.0% (2/11)	
Subsolid lesion	70.0% (9/12)	80.0% (9/11)	
Pathology			0.303
Primary lung adenocarcinoma	100.0% (12/12)	80.0% (9/11)	
Chronic granulomatous inflammation		10.0% (1/11)	
Metastasis from pancreatic adenocarcinoma		10.0% (1/11)	
T category			
T1	62.5% (5/8)	70.0% (7/10)	1.000
≥T2	37.5% (3/8)	30.0% (3/10)	

*The largest dimension of invasive component was measured for T category according to the 8th edition TNM staging.

(A) (B) (C)

Figure 1. Representative computed tomography and 3D-printed model images of a 54-year-old woman with primary lung adenocarcinoma (T1cN0M0). (A) A computed tomography image shows a 2.1-cm part-solid ground glass nodule in the posterior segment of the right upper lobe. A subsegmental pulmonary vein passes through the nodule. (B, C) A 3D-printed model shows the nodule (dark blue) within transparent flexible lung parenchyma. The pulmonary vessel passing through the nodule (pink) is located at the center of the tumor and the tracheobronchial structures are colored in green.

elective surgical resection; (3) patients who had a preoperative multidetector chest computed tomography (CT) scan. A total of 20 patients were included and randomly assigned to 3D printing and control arms (Table 1 and Fig. 1; Supplemental Figure 1).

The unilateral lung where a suspected lung cancer existed was extracted from Digital Imaging in Communications and Medicine data, and commercially available software (MEDIP, MEDICALIP, Seoul, Korea) was used for segmentation and postprocessing of the following structures: the lung cancer, normal lung parenchyma, interlobar fissure, proximal pulmonary vessels, and tracheobronchial structures. A half-life-size patient-specific 3D-printed model was created based on the segmented areas with a combination of 4 different photopolymer materials, including transparent flexible material for the lung parenchyma. The interlobar fissure was expressed as a slit-like gap between lobes. The median interval between patient enrollment and materialization of the 3D-printed model was 13 days (interquartile range, 11−15.5 days). The price per printing was approximately 1000 dollars. Informed consent was obtained by an attending surgeon 1 day before surgery with or without a 3D-printed model depending on the arm the patient had been assigned to. In control arm, the surgeon explained verbally about suspected lung cancer and surgical procedure using a standardized institutional document for informed consent of lung cancer surgery, along with letting patients see cross-sectional CT images of lung cancer. The document contained a simplified diagram of lung anatomy and written general information about lung cancer, benefit, complication, alternative of surgical procedure. Those materials were also provided for 3D-printing arm. Immediately after providing informed consent, the patients evaluated the quality of the informed consent process in a 5-point scale using a questionnaire that consisted of 15 items regarding patient knowledge, benefit, risk, alternative treatments, and satisfaction (Supplemental Table 1). The Mann-Whitney test was performed to compare the results between groups.

The patient knowledge score was significantly higher in the 3D-printing group than in the control group (13.6 ± 1.5 vs 11.8 ± 1.6; $P = 0.02$), while the total score and the scores of the other 4 categories did not significantly differ between the groups: total score, 61.3 ± 7.8 vs 55.4 ± 7.3 ($P = 0.12$); benefit, 13.1 ± 0.9 vs 11.6 ± 2.1 ($P = 0.10$); risk, 11.3 ± 2.1 vs 11.7 ± 1.7 ($P = 0.73$); alternative treatment, 10.3 ± 3.1 vs 9.0 ± 2.7 ($P = 0.40$); and satisfaction, 13.0 ± 2.2 vs 11.3 ± 2.5 ($P = 0.10$).

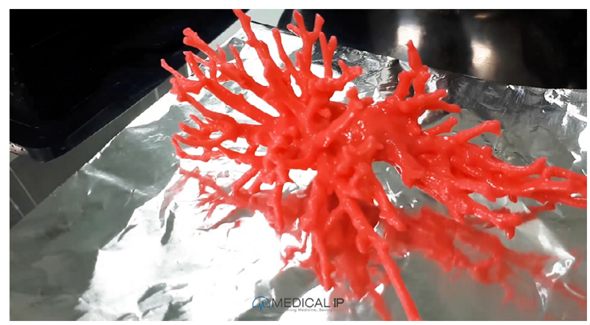
The quality of informed consent can be improved through ensuring that patients have a proper understanding of the basic anatomy of lung structures, the lung cancer, and the relationships thereof. The enrolled patients and surgeons could freely touch, rotate, and see through the transparent flexible hand-held 3D-printed models, leading to straightforward anatomic comprehension of lung structures and the location and extent of lung cancer. As a consequence, surgeons could more effectively convey a personalized explanation to patients about the planned extent and method of surgical resection. Interestingly, the questionnaire scores for benefit and satisfaction were higher in the 3D-printing group than in the control group, although the between-group difference did not reach statistical significance. Thus, 3D-printed models may be a promising tool for improving patient satisfaction, which potentially enhances surgeon-patient rapport and surgical outcomes.[3]

This study had several limitations. The number of participants was small, as it was as a pilot feasibility study confined to early-stage lung cancer, which can be easily segmented. We plan to perform a subsequent study including operable patients with advanced lung cancer, which may have a more complex shape and mediastinal lymph node metastasis and 3D-printing of more sophisticated case seems technically feasible.[4] In addition, the quality of the informed consent process was assessed based on patients' subjective perceptions, requiring further validation regarding whether the difference of patient knowledge score is clinically meaningful. The price and time spending for 3D-printing were not sufficiently practical. Nevertheless, those would decrease when optimized, and be much shorten by producing a personalized online 3D model without real printing (http://147.47.229.147:8080/STLRendering/180914_submission_low.html).

In conclusion, personalized 3D-printing was technically implementable and had the potential to improve patient comprehension in informed consent for surgical resection in patients suspected of having stage I lung cancer.

SUPPLEMENTARY MATERIAL

The following is the supplementary data to this article:



Video 1. Summary of procedures for 3D printing of personalized lung cancer model.

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