Results of T4 Surgical Cases in the Japanese Lung Cancer Registry Study

Should Mediastinal Fat Tissue Invasion Really be Included in the T4 Category?

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Introduction: T4 lung cancer is a heterogeneous group of locally advanced disease. We hypothesized that patients in whom T4 lung cancer invaded only mediastinal fat tissue would show better prognosis after surgery than patients in whom T4 disease invaded other organs. The present study aimed to investigate how different invasive features of T4 disease impacted prognosis, and what types of patients with T4 disease could benefit most from surgical treatment.

Methods: A nationwide registry study on lung cancer surgical cases during 2004 was conducted by the Japanese Joint Committee of Lung Cancer Registry, including registries of 11,663 cases within Japan. The present study analyzed 215 of these cases involving T4 structures or with ipsilateral nonprimary lobe pulmonary metastasis (PM).

Results: Reasons for T4 classification included invasion of only mediastinal tissue in 32 cases (15%), invasion of other structures in 96 cases (45%), and ipsilateral different lobe PM in 87 cases (40%); among these three groups, there were no significant differences in survival, nodal status, and patterns of first recurrence. Multivariate analysis showed an age of 70 years or above ($p = 0.022$) and nodal status ($p = 0.004$) to be significant prognostic factors. T4N0 patients less than 70 years of age showed significantly better prognosis than those who were T4N1–2 and 70 years of age or older ($p = 0.0001$; 5-year survival rate 50.3 versus 19.9%).

Conclusions: There was no significant difference in survival between T4 patients with only mediastinal fat invasion and those with other T4 organ invasion and ipsilateral different lobe PM, demonstrating appropriateness of the T4 category definition in the current tumor, node, metastasis staging system. Age and nodal status were significant independent prognostic factors in T4 patients, and the best surgical candidates were shown to be T4N0 patients who were less than 70 years of age and had a 5-year survival rate of more than 50%.

Key Words: T4 lung cancer, Mediastinal tissue, Pulmonary metastasis.

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The T4 category of lung cancer is defined by invasion of the heart, mediastinal fat tissue, great vessels, trachea, recurrent laryngeal nerve, esophagus, vertebral body and carina, and additional nodules in ipsilateral different lobes.[1] In T4 cases, mediastinal fat tissue invasion is considered to be the last step before involving other mediastinal organs, such as the great vessels, esophagus, or trachea (Fig. 1).

We hypothesized that patients in whom T4 lung cancer invaded only mediastinal fat tissue would show better prognosis after surgery than those in whom T4 lung cancer invaded other organs. In the present study, we analyzed the outcomes of patients enrolled in the Japanese Lung Cancer Registry Study, who had T4 disease and underwent surgery. We also investigated whether surgery conferred different survival benefits on different types of T4 lung cancer cases.

PATIENTS AND METHODS

In 2010, the Japanese Joint Committee of Lung Cancer Registry conducted a nationwide retrospective registry study on surgical cases of primary lung cancer that had occurred during 2004. The study included registries of 11,663 cases from 253 teaching hospitals in Japan; each registry contained the previously described clinicopathologic profiles and

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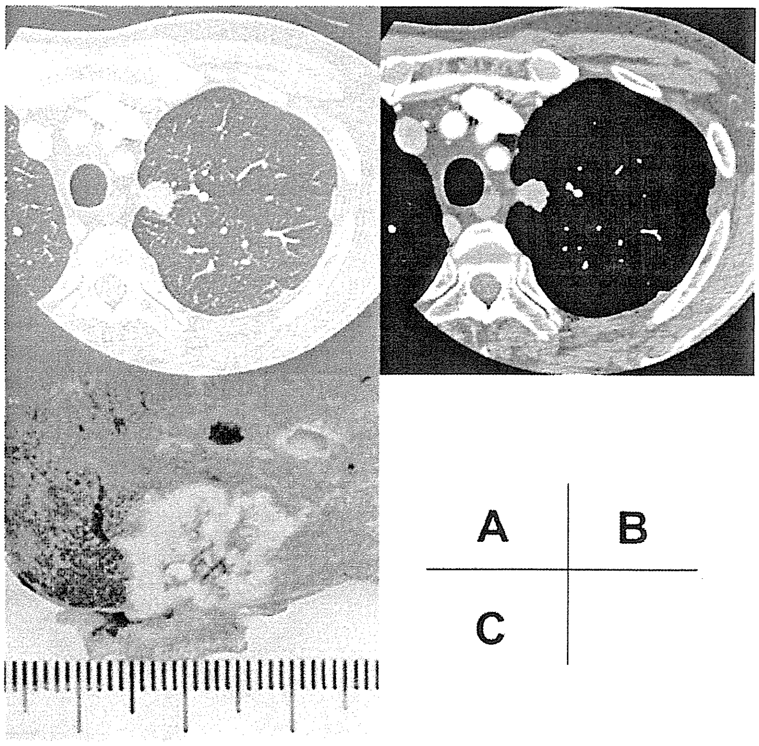

FIGURE 1. A case of pT4 disease invading the mediastinal fat tissue. *A*, CT scan (lung field window) showing a left upper lobe tumor with visceral pleura involvement. *B*, CT scan (mediastinal window) showing the tumor invading the mediastinal fat tissue. *C*, Photograph of the formalin-fixed resected specimen. CT, computed tomography.

prognoses.[2] The information collected about each tumor node metastasis (TNM) classification was used to reclassify each case according to the 7th edition of the International Union Against Cancer tumor, node, metastasis (TNM) staging system published in 2009.[1]

Of these cases, there were 218 surgical cases involving the neighboring T4 structures or ipsilateral nonprimary lobe pulmonary metastasis (PM). For the present study, three cases were excluded because the patients had both neighboring organ invasion and PM. The remaining 215 surgical cases were used in the present analysis.

Statistical Analysis

Survival was calculated by the Kaplan–Meier method, and differences in survival were determined by the log-rank test. Time zero was the date of surgery, and the terminal events were death because of cancer, noncancer, or unknown causes. Both univariate and multivariate analyses of prognostic factors were carried out using Cox proportional hazards regression models. Hazard ratios (HRs) and 95% confidence intervals were calculated. A p value less than 0.05 was considered to be statistically significant.

RESULTS

Patient Characteristics

Table 1 shows characteristics of the 215 patients enrolled in the study. The patients consisted of 166 men (77%) and 49 women (23%), with a mean age of 65.2 years and a mean tumor size of 4.5 cm. The reasons for T4 disease classification included neighboring organ invasion in 128 patients (60%) and ipsilateral different lobe PM in 87 patients (40%). Among the 128 patients with T4 disease invading neighboring organs, 32 cases (25%) invaded only mediastinal fat tissue and 96 (75%) invaded other anatomical structures. Six patients with T4 disease invading both mediastinal fat tissue and other structures were classified as other organs invasion group. The tumor cell types were adenocarcinoma in 99 (46%), squamous cell carcinoma in 77 (36%), and others in 39 patients (18%). R status was R0 in 123 (57%), R1 in 24 (11%), and R2 in 58 patients (27%). Pathologic N status was N0 in 107 (50%), N1 in 25 (12%), N2 in 79 (37%), and N3 in four patients (2%).

N and R Status Grouped by Reasons for T4 Category

Table 2 shows pathologic N status grouped by involved T4 organs. There were no significant differences in N status among the three groups ($p = 0.537$). Table 3 demonstrates R status grouped by involved T4 organs. Mediastinal fat invasion group showed significantly higher incidence of R0 than the other two groups ($p = 0.017$).

Univariate and Multivariate Analyses of Prognostic Factors

Univariate and multivariate analyses of prognostic factors were performed by means of Cox proportional hazard regression models. Univariate analysis showed age ($p = 0.02$), tumor size ($p = 0.007$), and pathologic nodal status ($p = 0.004$) to be significant prognostic factors; however, the reason for T4 disease was not a significant prognostic factor ($p = 0.949$) (Table 4). Multivariate analysis showed that ages 70 years and

TABLE 1. Patient Characteristics in Surgical Cases with Pathological T4 Disease in Japanese Lung Cancer Registry Study

No. of patients	215
Sex	
Male	166 (77%)
Female	49 (23%)
Age (yr)	
Range	32–84
Mean ± SD	65.2±10.4
Tumor size (cm)	
Range	0–15
Mean ± SD	4.5±2.4
Reasons for T4 disease	
Neighboring organ invasion	128 (60%)
Invading only mediastinal fat	32 (15%)
Invading other structures	96 (45%)
Great vessels	58
Heart	21
Esophagus	8
Vertebra	6
Carina	5
Trachea	3
Recurrent nerve	2
Ipsilateral different lobe PM	87 (40%)
Histological subtype	
Adenocarcinoma	99 (46%)
Squamous cell carcinoma	77 (36%)
Others	39 (18%)
R status	
R0	123 (57%)
R1	24 (11%)
R2	58 (27%)
RX (unclassified)	10 (5%)
Pathological nodal status	
N0	107 (50%)
N1	25 (12%)
N2	79 (37%)
N3	4 (2%)

PM, pulmonary metastasis; SD, standard deviation.

TABLE 2. N Status by Reasons for T4 Category

Reasons for T4	No. of Patients	N Status			
		N0 (%)	N1 (%)	N2 (%)	*p*
Mediastinal fat invasion	31	18 (58)	4 (13)	9 (29)	0.537
Other organs invasion	95	44 (46)	14 (15)	37 (39)	—
Ipsilateral different lobe PM	85	45 (53)	7 (8)	33 (39)	—
Total	211	107 (51)	25 (12)	79 (37)	—

PM, pulmonary metastasis.

TABLE 3. R status by Reasons for T4 category

Reasons for T4	No. of Patients	R Status			
		R0 (%)	R1 (%)	R2 (%)	*p*
Mediastinal fat invasion	32	26 (81)	2 (6)	4 (13)	0.017
Other organs invasion	94	47 (50)	16 (17)	31 (33)	
Ipsilateral different lobe PM	79	50 (63)	6 (8)	23 (29)	
Total	205	123 (60)	24 (12)	58 (28)	

PM, pulmonary metastasis

TABLE 4. Univariate Analysis of Prognostic Factors Using Cox Proportional Hazards Regression Models

Factors	Hazard Ratio	95% CI	*p*
Age (per yr increase)	1.022	1.003–1.041	0.020
Sex			
Male	1.000	—	—
Female	0.675	0.441–1.032	0.069
Tumor size (per cm increase)	1.753	1.164–2.640	0.007
Reasons for T4 disease			0.949
Mediastinal fat invasion	1.000	—	—
Other organs invasion	0.980	0.581–1.653	0.939
Ipsilateral different lobe PM	1.042	0.619–1.753	0.877
Cell type			
Non-Sq	1.000	—	—
Sq	1.138	0.792–1.636	0.484
Pathological nodal status			0.004
N0	1.000	—	—
N1	1.561	0.890–2.739	0.121
N2	1.890	1.297–2.754	0.001

CI, confidence interval; Sq, squamous cell carcinoma; PM, pulmonary metastasis.

above ($p = 0.022$; HR = 1.516) and pathologic nodal status ($p = 0.004$; HR for N0 versus N1: 1.362; HR for N0 versus N2: 1.906) were significant prognostic factors (Table 5).

Survival Analysis

Figure 2 shows the overall survival curves of the 11,663 surgical cases in the Japanese Lung Cancer Registry Study grouped by pT factors. The 3- and 5-year overall survival rates of patients with T4 disease after surgery were 48.3% and 34.5%, respectively. Figure 3 presents survival curves grouped by three reasons for T4 category (invasion of mediastinal fat, invasion of other structures, and ipsilateral different lobe PM); the 5-year survival rates in these groups were 36.1%, 36.2%, and 33.0%, respectively, with no significant between-group differences in survival. The 30-day mortality was 0.47% (1 of 215).

Table 6 describes types of first recurrence grouped by three reasons for T4 category. There was no significant difference in patterns of first recurrence among the three groups ($p = 0.487$).

Figure 4 shows survival curves grouped by pathologic nodal status; the 5-year survival rates in pN0, pN1, and pN2

TABLE 5. Multivariate Analysis of Prognostic Factors Using Cox Proportional Hazards Regression Models

Factors	Hazard Ratio	95% CI	p
Age (yr)			
<70	1	—	—
≥70	1.516	1.061–2.167	0.022
Tumor size (per cm increase)	1.074	0.996–1.159	0.065
pN status			0.004
pN0	1	—	—
pN1	1.362	0.767–2.420	0.291
pN2	1.906	1.306–2.781	0.001

CI, confidence interval; pN, pathologic nodal.

patients were 45.0%, 27.0, and 25.0%, respectively. Patients with pN0 disease showed significantly better prognosis than those with pN2 disease ($p = 0.0006$). Figure 5 shows survival curves grouped by R status; the 5-year survival rates in R0, R1, and R2 patients were 41.2%, 33.3%, and 18.4%, respectively. Patients with R0 disease showed significantly better prognosis than those with R2 disease ($p = 0.0002$). However, there were no significant differences in survival between patients with R0 and R1, and those with R1 and R2 (R0 versus R1; $p = 0.5536$; R1 versus R2; $p = 0.0915$).

The survival curves and 5-year survival rates of the T4 surgical cases grouped by age (< 70 years or ≥ 70 years) and pathologic nodal status (N0 or N1–2) are shown in Figure 6. Patients without nodal involvement and less than 70 years of age showed significantly better prognosis than those with nodal involvement and were 70 years of age or older ($p = 0.0001$; 5-year survival rate 50.3% versus 19.9%).

DISCUSSION

According to the 7th edition of the TNM staging system, the T4 stage includes invasion of the following adjacent organs: heart, mediastinal tissue, great vessels, trachea,

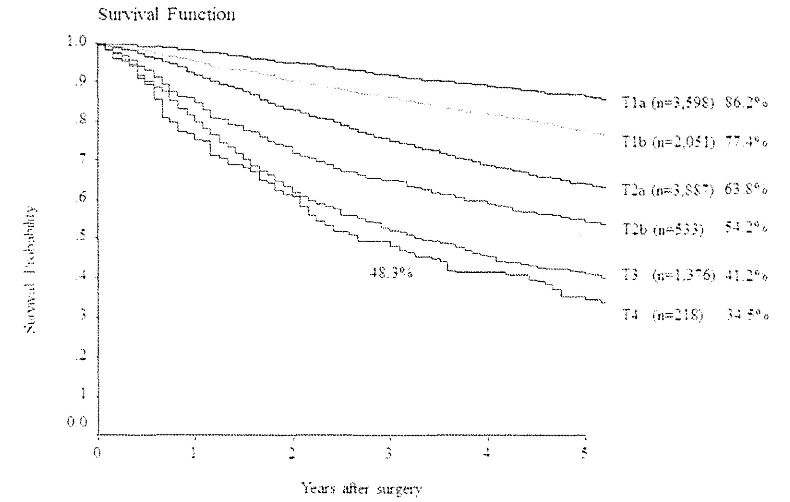

FIGURE 2. Survival curves of the 11,663 surgical cases in the Japanese Lung Cancer Registry Study grouped by pT factor International Union Against Cancer (IUCC)-Tumor Node Metastasis v. 7).

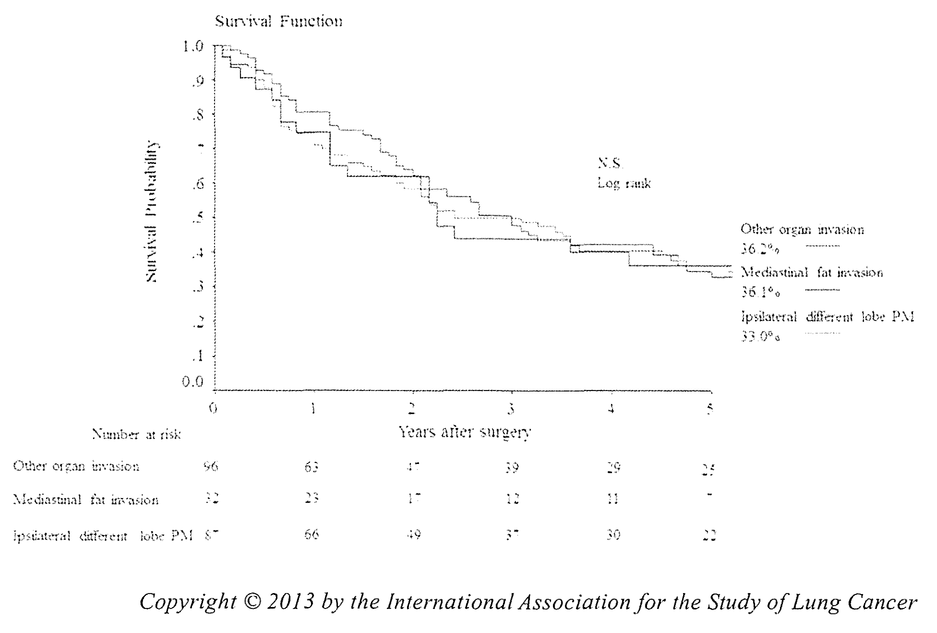

FIGURE 3. Survival curves of patients with pT4 disease grouped by reasons for being classified as T4. NS, not significant; PM, pulmonary metastasis.

TABLE 6. Types of First Recurrence by Reasons for T4 category

Reasons for T4	No. of Patients	First Recurrent Site: Local	Local + Distant	Distant	*p*
Mediastinal fat invasion	18	5 (28%)	4 (22%)	9 (50%)	0.487
Other organs invasion	46	8 (17%)	12 (26%)	26 (57%)	—
Ipsilateral different lobe PM	52	16 (31%)	8 (15%)	28 (54%)	—
Total	116	29 (25%)	24 (21%)	63 (54%)	—

PM, pulmonary metastasis.

recurrent laryngeal nerve, esophagus, body of vertebra, and carina.[1] Because of this great variety in neighboring organs, and the small number of resected T4 cases, there have been few review articles describing the prognosis of a substantial number of resected T4 cases.[3–6] Thus, the judgment for surgical indication is left to each institution.

Among the T4 diseases with neighboring structure invasion, mediastinal fat tissue invasion is considered to be the last step before involving other T4 organs, including mediastinal vessels, esophagus, or trachea (Fig. 1). The complete combined resection of mediastinal fat tissues adjacent to the primary tumor is technically much easier than that of other T4 organs. Therefore, we hypothesized that T4 patients with only mediastinal fat invasion might have a better prognosis than those with other T4 organ invasion or ipsilateral nonprimary lobe PM. However, the results of the present study found no significant differences in survival among these three groups with T4 disease. Although the number of patients in each T4 subset is small, these findings confirm the appropriateness of the definition of the T4 category in the current TNM staging system.

Two points constitute the prime criteria in determining the indication for resecting the neighboring organs in T4 lung cancer patients,. One is whether complete resection is possible, and the other is the length of survival that can be expected for the T4 patient even after complete resection. The presence or absence of complete resection is an absolute prognostic factor in lung cancer surgery. Although many previous reports have suggested the technical feasibility of surgery for T4 disease, fewer series have demonstrated long-term results after the extended resection.[3–6] Grunenwald et al.[7] suggested that the T4 category includes two types of disease, calling one *potentially resectable T4* and the other *definitively unresectable T4*. The potentially resectable T4 group includes cases where complete resection seems possible, based on the degree of invasion, and a better prognosis is anticipated; this group includes invasion of the carina, left atrium, superior vena cava (SVC), and mediastinal tissue. For example, in patients having tumor that directly invades the SVC, the prognosis after combined resection of the SVC is relatively good,[8–11] with a 5-year survival rate of 36%.[12] However, cases with invasion of the trachea, vertebra, and esophagus are considered to be definitively unresectable T4 because reconstruction is difficult, surgical stress is unreasonable, the operative morbidity and mortality are high, and a good prognosis cannot be expected after the resection. Grunenwald et al.[7] reported the clear identification of esophageal invasion as the worst prognostic factor,[4] and most surgeons consider invasion of the esophagus, vertebral bodies, or trachea as contraindications to surgery.

The present study was based on a nationwide registry that collected 11,663 cases during 2004 from 253 major teaching hospitals in Japan; however, only an extremely small number of surgical cases involved invasion of the esophagus, vertebra, and trachea ($n = 8$ [0.07%], $n = 6$ [0.05%], and $n = 3$

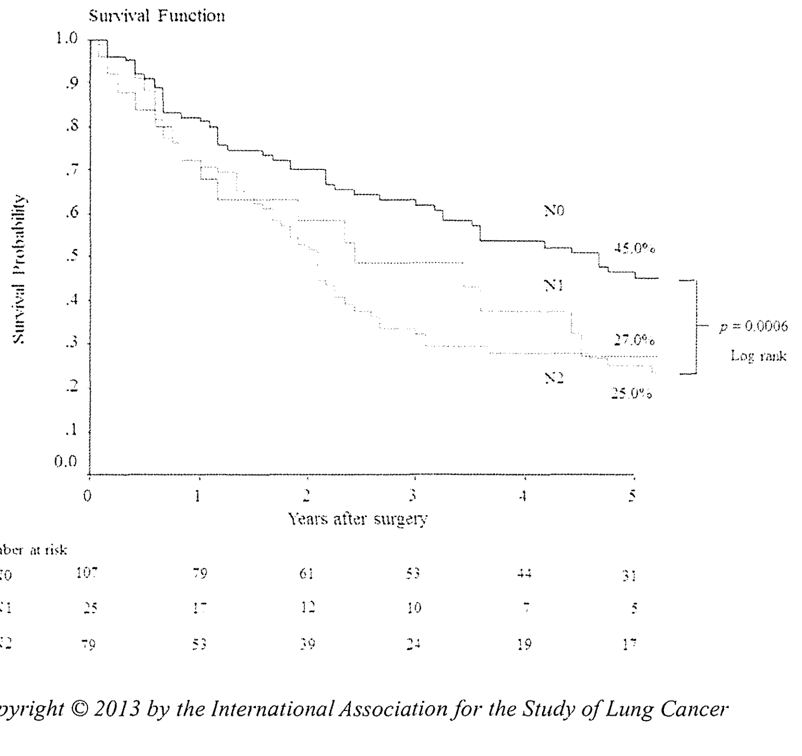

FIGURE 4. Survival curves of patients with pT4 disease grouped by pN status.

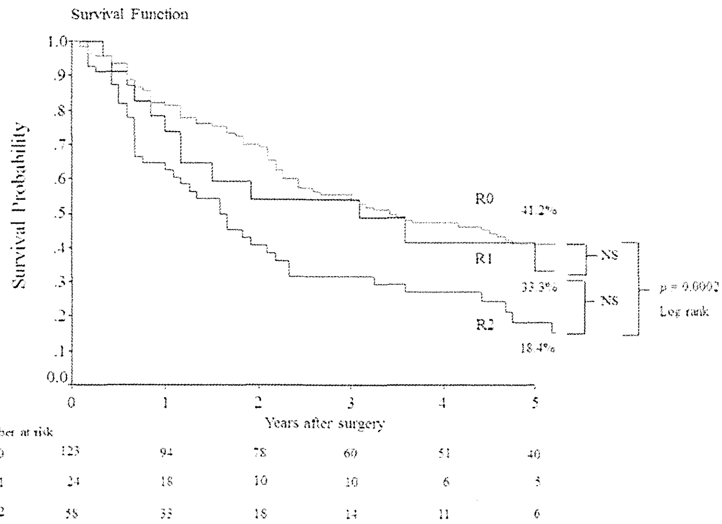

FIGURE 5. Survival curves of patients with pT4 disease grouped by R status. NS, not significant.

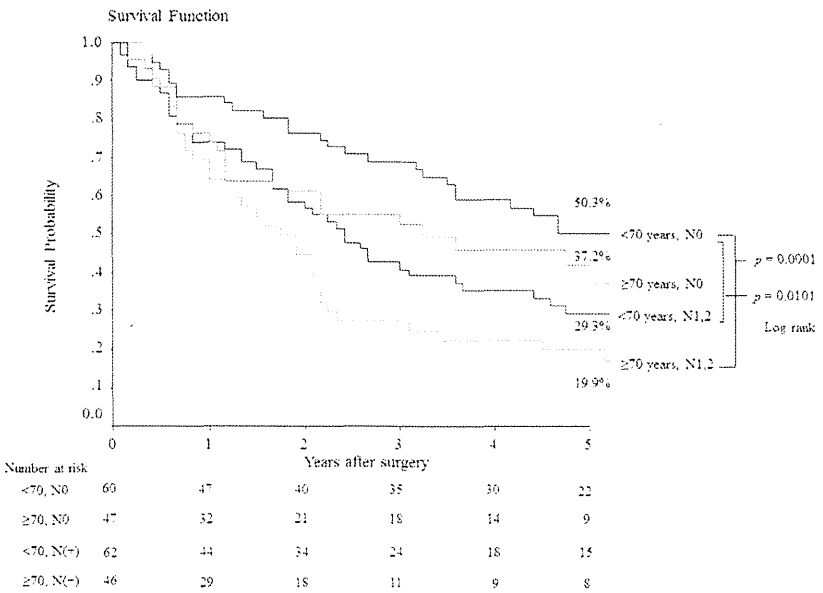

FIGURE 6. Survival curves of patients with pT4 disease grouped by age and nodal status.

[0.03%], respectively; Table 1). Overall survival of T4 surgical cases in this registration study showed better prognosis, with a 5-year survival rate of 35.4% (Fig. 2) compared with a 5-year survival rate of 22% reported in the International Association for the Study of Lung Cancer[13] staging article in 2007. These relatively good results for T4 surgical cases were probably because of the recent changes in how Japanese surgeons select T4 disease patients as surgical candidates, in accordance with the results of previous reports to determine the prognosis of resected T4 disease.[3–7] This patient selection bias may be one of the reasons why there was no significant difference in survival among the three subgroups of T4 category in our study (Fig. 3). Very low surgical mortality of these T4 patients in this registry (1 of 215; 0.47%) may support this hypothesis.

Multivariate analysis showed that nodal status was the most important prognostic factor in T4 disease (Table 5), similar to other lung cancer patients. Surgery seemed to be contraindicated in patients with mediastinal metastasis because of their poor prognosis (HR = 1.906; $p = 0.001$), as previously reported. In the TNM 7th edition, T4N0-1M0 was downstaged from stage IIIB to stage IIIA. However, the indication for N1 disease is still controversial, as some reports suggest a very poor prognosis for patients with hilar metastasis (N1). A T4N0M0 case where complete resection is possible is a good candidate for surgical treatment, as shown in Figure 4, and to perform a meticulous evaluation of the N factor through computed tomography scan, positron emission tomography scan, endobronchial ultrasound, or mediastinoscopy before any judgment is indispensable.[4–16]

In the present study, age and nodal status were revealed to be independent prognostic factors. T4 patients 70 years of age or more with any nodal involvement (N1, 2) showed poor prognosis, whereas T4 patients less than 70 years of age without nodal involvement (N0) showed good prognosis, with a 5-year survival rate of more than 50%. There was no significant difference in the distribution of involved T4 organs between the group of patients who were 70 years of age or older and that group in which patients were less than 70 years of age, in the present study (data not shown). Because the risk–benefit ratio for extended surgical resection is very high in older T4 patients,[3] special care must be taken to decide the surgical indication, especially in node-positive T4 patients who are more than 70 years old. In particular, the outcomes after resection in patients with carinal involvement reportedly show a high average operative mortality of 17% (range, 7%–29%).[17–21] According to the evidence-based clinical practice guidelines of the American College of Chest Physicians,[17] it is recommended that surgical candidates with T4 disease should be very carefully selected, and surgical resection should be carefully undertaken only at a specialized center because of the limited survival and the high mortality. It is necessary for surgeons to collectively consider the patient's nodal status, age, quality of life after resection, the presence of alternative treatment, the extent of surgery, and subsequent morbidity and mortality before performing surgery for T4 disease.

CONCLUSION

Although T4 patients with only mediastinal fat invasion showed high incidence of R0 resection, there was no significant difference in survival between T4 patients with only mediastinal fat invasion and those with other T4 organ invasion, or ipsilateral different lobe PM, which demonstrates the appropriateness of the T4 category definition in the current TNM staging system. Patients with involvement of T4 structures should be very carefully selected for surgical resection because of the limited survival. Before undergoing surgery, patients should be subjected to careful assessment of hilar and mediastinal nodal involvement, particularly for those who are 70 years of age or older. On the basis of the findings obtained to date, the best prognosis for T4 disease is found for T4N0 patients who are less than 70 years of age and have a 5-year survival rate of more than 50%.

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The Concept and Feasibility of EXPERT: Intelligent Armrest Using Robotics Technology

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BACKGROUND: Continuous precise motions are required in microneurosurgery to provide high-quality surgical results. Stabilizing the surgeon's arm and reducing fatigue during surgery are expected to improve the precision of microsurgical procedures. We have developed an intelligent armrest, EXPERT, that follows the surgeon's hand and fixes at an adequate position automatically using robotics technology.

OBJECTIVE: To understand the feasibility of EXPERT by using the system in laboratory experiments and clinical situations.

METHODS: EXPERT has an arm holder and acts as a passive controlled robot with 5 degrees of freedom. The system has 3 modes: transfer, arm-holding, and arm-free mode, which are selected automatically. In the transfer mode, the arm holder follows the surgeon's arm. In the arm-holding mode, EXPERT supports the surgeon's arm weight by fixing the arm holder. The surgeon can move his/her arm away from the arm holder in the arm-free mode. The surgeon can change the position of armrest while looking through the microscope and can continue the microsurgical procedure while holding surgical instruments. Since 2010, EXPERT has been applied in 13 surgeries.

RESULTS: The EXPERT system decreased surgeon fatigue and reduced difficulty in performing surgical procedures. The EXPERT system markedly reduced surgeon hand tremor. There were no complications related to the use of this system.

CONCLUSION: EXPERT is a useful tool for holding the surgeon's arm comfortably and following the surgeon's arm automatically.

KEY WORDS: Movable armrest, Microneurosurgery, Robotics surgery, Surgeon supporting device

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In microneurosurgical procedures, continuous precise procedures are required to provide high-quality surgical results. Stabilizing the surgeon's arm with an armrest during surgery is expected to improve the precision of microsurgical procedures.[1] A freely movable armrest (FMA) was developed to support the surgeon's hand during surgery[2]; however, it has not been widely used because it requires continuous manual user interaction.[1,2] We have developed a new intelligent armrest using robotics technology. This system was designed so that the arm holder follows the surgeon's arm and fixes in the adequate position automatically. Here, we describe this system in detail and present preclinical and clinical results.

ABBREVIATION: FMA, freely movable armrest

METHODS

Concept of the Arm-Holding Device

We produced a prototype model to fulfill our requirements, which we called EXPERT (Figure 1). EXPERT consists of an arm holder, a holder support, and a base. The arm holder is made from the thermoplastic polymer Ortholen, which is widely used in prosthetic limbs. It has a curved shape and holds the surgeon's forearm. Three small electric magnets are set in the arm holder. A 6-axis force sensor is set between the arm holder and the holder support. The holder support has 5 degrees of freedom. No electric motors are used in the holder support. Each joint has springs and/or counterweights, electric brakes, and encoders. The base has 3 wheels to stand and move the EXPERT system. The system is attached to the operator's chair (Micro Chair, Mizuho Ikakogyo Co, Ltd, Tokyo, Japan) at the base; it is independent of the height adjustment of the chair but follows the forward/backward movement of the chair.

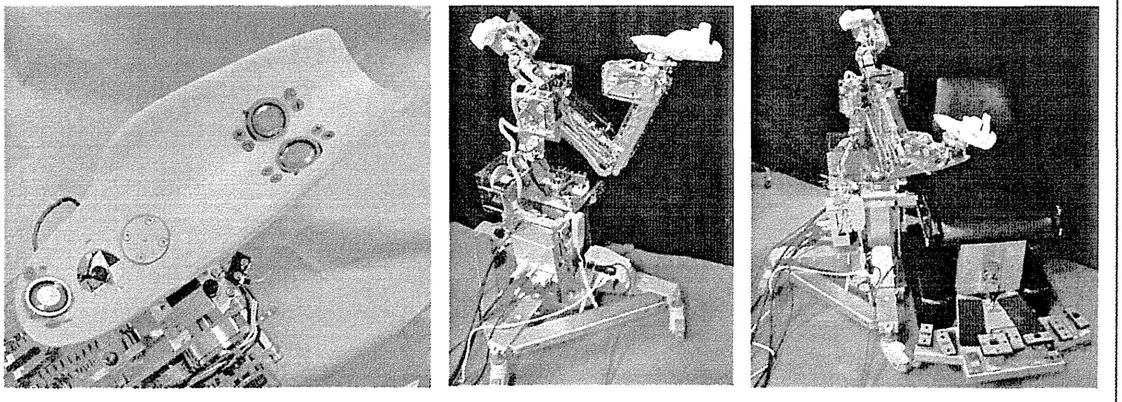

FIGURE 1. Left, *photograph of the arm holder made of Ortholen with 3 electromagnets installed.* Center, *photograph of EXPERT. The arm holder is indicated by the yellow circle; the holder support, by the green circle; and the base, by the red circle.* Right, *EXPERT is fixed to the operative chair. The holder support moves independently of the operative chair.*

EXPERT has 3 working modes: the transfer, arm-holding, and arm-free modes, which are converted automatically by analyzing the signals from 6-axis force sensor and the encoders in each joint. There is no need to press any buttons or switches to change modes. The surgeon wears a ferromagnetic wristband that connects to the electric magnets in the arm holder beneath sterile clothing. In the transfer mode, the electric brakes are released and electromagnets are active, so that the arm holder follows the surgeon's arm from below. The movement is achieved by the magnetic force between the surgeon's arm and the arm holder. The power required to move the arm holder is < 50 N. Most of the power is transferred to the upper side by springs, and the system reduces the surgeon's arm weight in the transfer mode. The force to move horizontally is < 50 N. In the arm-holding mode, the arm holder maintains the position by locking the electric brakes and supports the surgeon's arm weight. When the surgeon moves his/her arm away from the arm holder, eg, to change surgical instruments or to move the operating microscope, it is in the arm-free mode. The arm holder maintains its position by locking the electric brakes. When there is no arm on the arm holder and the unit is in transfer mode, the arm holder moves away from the patient.

Laboratory Experiment

Simulated microneurosurgery, involving suturing a thin piece of rubber, was used to examine the use of EXPERT. One quarter of a 10-mm circle was incised in thin pieces of rubber 4 cm in diameter. This circle was placed in a bowl at a depth of 60 mm. The conical working space was formed by plastics in the center of the bowl, which was 55 mm in diameter at the surface and a 10- to 20-mm ellipse at greater depths. Five sutures with 10-0 nylon were put in the incised rubber at even intervals using an operating microscope with conventional surgical instruments (Figure 2). EXPERT was set on the right side of the operator's chair. Six experienced neurosurgeons were registered as test candidates. Three of the 6 evaluating neurosurgeons (T.G., K.H., T.Y.) are included as authors; the others are colleagues in our department. They practiced the task and use of EXPERT adequately beforehand. The task was carried out once with and once without EXPERT. In each task, performance time to complete suturing was recorded, and each test candidate was asked to give 3 subjective evaluations regarding hand tremor, fatigue, and impression of maneuverability. Subjective evaluations were scored on a visual analog scale in which 1 is the minimum fatigue and the worst to perform and 100 is the maximum fatigue and the best to perform.

Statistical Analysis

The data were analyzed by paired t test. $P < .05$ was taken to indicate statistical significance.

RESULTS

All tasks were performed successfully without mechanical error of the EXPERT system. The performance time and subjective evaluation score are summarized in Figure 3. Four of 6 test candidates showed shorter performance time with EXPERT. The performance time was not different with and without the EXPERT for the remaining 2 test candidates. All 6 test candidates reported lower scores of fatigue when using EXPERT. The maneuverability score was higher with EXPERT. Recorded video showed that hand tremor of each test candidate was reduced and manipulation was more stable with EXPERT.

Clinical Use

Since March 2010, EXPERT has been clinically applied in 13 surgeries at Shinshu University Hospital. Before surgery, clinical application of EXPERT had been approved by the ethics committee of Shinshu University School of Medicine, and informed consent was obtained from all patients and their families. After the usual preparation of craniotomy and dura opening, EXPERT, covered with a sterile sheet, was introduced into the operative field. A surgeon performed the operation with routine microneurosurgical procedures supported by the EXPERT system (Figure 4). The surgeons did not always use EXPERT because rapid procedures without stringent accuracy requirements could

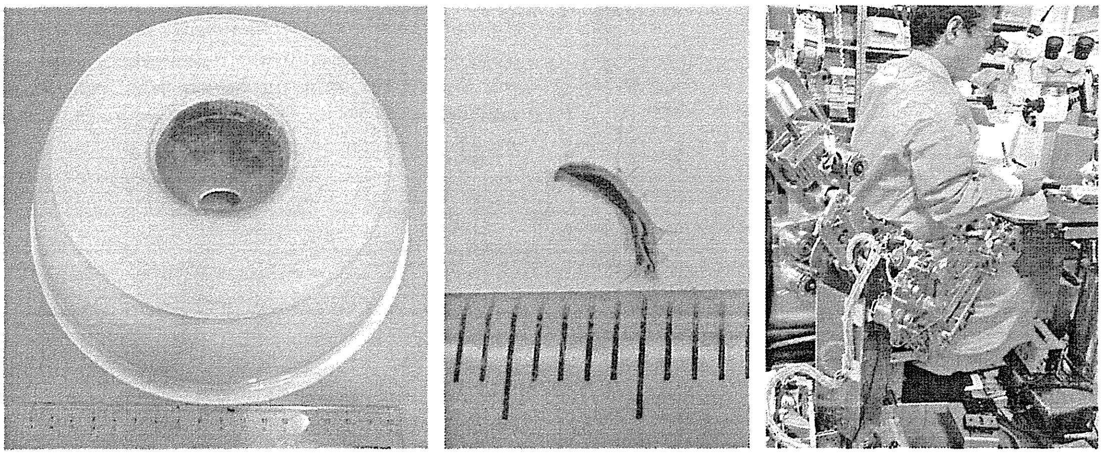

FIGURE 2. Left, *photograph of task field in laboratory experiment: 60-mm depth from surface, surface hole 55 mm in diameter, and elliptical deeper hole measuring 10 to 20 mm.* Center, *suture task. Five sutures were made with 10-0 nylon in a quarter-circle cut 10 mm in diameter on the thin piece of rubber* Right, *photograph of a laboratory experiment. An experienced neurosurgeon performed the task using EXPERT to support the right hand under an operating microscope.*

be performed easily without the system. There were no complications related to the use of EXPERT.

DISCUSSION

To provide high-quality surgical results, continuous precise motions are required in microneurosurgery. Precise movements can be achieved by maneuvering the surgical instruments with adequate stabilization of the surgeon's arm at the appropriate position. This has been achieved in conventional microneurosurgery by resting the surgeon's arm, hand, or finger on the patient's body or craniotomy edge and on the armrest of the surgical chair and a part of the head fixation frame.[3-10] The rigid, fixed-type armrest can be introduced easily but cannot completely cover the work space because many factors limit the surgeon's hand position. The brain surface cannot be touched or compressed by the surgeon's hand or arm. It is necessary to change the positions of brain spatula and self-retaining brain retractors frequently during surgery. The direction and angle of surgical instruments restricted by surrounding structures also limit the surgeon's hand position.

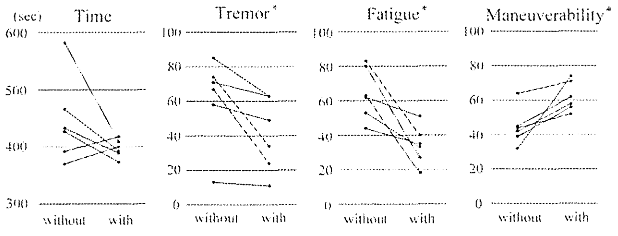

FIGURE 3. *Graph of the result. Fine lines indicate results for each test candidate without the EXPERT and with the EXPERT.* *P < .05.

An armrest with positions that can be changed as required is called an FMA and is considered effective. Ohta and Kuroiwa[2] developed the FMA (Smartarm, Mizuho Ikakogyo Co, Ltd, Tokyo, Japan) and reported its usefulness in neurosurgery. There is no doubt that the use of an FMA reduces operator fatigue and improves surgical maneuverability. We had also reported that the use of an FMA gave the operator a more relaxed posture and reduced both muscle stress and hand tremor compared with the use of a conventional armrest system.[1] Use of the FMA will reduce tremor when fine microsurgical movement is performed and thus will provide a good surgical result. Even if the surgeon can perform fine microsurgical movement without assistance of the FMA, more precise procedures can be performed with the FMA.

Despite its advantages for precise procedures, FMA-assisted surgery has not been widely adopted because its use is time-consuming and adjustment can be difficult. When the surgeon wishes to adjust the position of the FMA, eg, the Smartarm, it is necessary to put down the surgical instrument, push the button to change from locking to moving mode, adjust the position at which the arm is held, release the button to return from locking mode to moving mode, and retrieve the surgical instrument. These actions are time-consuming and troublesome. The optimal position of the surgeon's arm changes frequently, so real adjustment of the armrest to the optimal position may be impossible. The surgeon can identify the optimal position of the armrest while holding the surgical instrument in his/her hand and watching the operative view. When the position of armrest is incorrect, the adjustment action must be repeated. Therefore, the surgeon may continue

FIGURE 4. *Photographs of the operating room. The surgeon sits on the Micro Chair with the right hand supported by EXPERT.*

the procedure even if the position of the arm holder is not adequate.

EXPERT is classified as a type of FMA. However, EXPERT differs from an FMA in that it automatically follows the surgeon's arm. The surgeon can change the position of the armrest while using the microscope and can continue the microsurgical procedure while holding the surgical instrument. There is no need to push any buttons to convert between the lock and free modes. We believe that most disadvantages associated with the use of previous FMAs can be reduced by these functions of the EXPERT system.

Cost-effectiveness is also an important factor in widespread adoption. EXPERT is a surgeon support system and does not touch the patient. EXPERT is in the same equipment category as operating bed and operating chair and thus has no need for a clinical trial before commercial production. The potential commercial cost of EXPERT should be reasonably low.

Further improvement of EXPERT is necessary. The usefulness of EXPERT has been confirmed with only the right hand; however, using EXPERT with both hands may yield better results in microneurosurgery. The space occupied by EXPERT is also a problem because many surgical tools such as the operative microscope, navigation systems, drilling system, and coagulation system must be set near the surgeon. The base of EXPERT is large and heavy to prevent the system from falling or toppling over. Reducing the size of the EXPERT system while maintaining its functionality is a necessary future development. There is a tight feeling during transposition of the surgeon's arm because the supporting part must move automatically with the surgeon's hand motion.

The success of da Vinci surgical systems incited a dream to apply master-slave configured surgical robots in all surgical fields. Thus, the NeuRobot was developed for microneurosurgery.[11-13] From the experience with NeuRobot, we determined the difficulty of using surgical robots for microneurosurgery. Microneurosurgery is a fine art that only the human hand can produce. EXPERT provides support for a surgeon's art by allowing smooth and steady movement.

CONCLUSION

The intelligent armrest EXPERT held the surgeon's arm comfortably and followed the surgeon's arm automatically. EXPERT represents a useful tool for microneurosurgery. However, several modifications are required for commercial development of this system.

Disclosures

This project was supported by the Japanese Ministry of Education, Culture, Sports, Science and Technology Grant-in-Aid for Scientific Research No.19200043 (Dr Hongo). The arm holder was made by Arizonoseisakusyo Co, Ltd Japan. The holder supporting part and basal part was made by Hitachi JTE Co, Ltd, Japan. The surgical drape was made by Hogi Co, Ltd, Japan. There was no financial support from any companies. The main features of this system were already opened for patent in Japan No. 2008-151906 L0800004. Shinshu University and Waseda University preserve all rights without relevant company and individual persons. The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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Intelligent Operating Theater: Technical Details for Information Broadcasting and Incident Detection System

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Abstract

This paper introduces an intelligent operating theater equipped with a magnetic resonance imaging (MRI) scanner and video recording and broadcasting system to enhance the quality of surgery. To reduce error, intraoperative incidents are detected and dealt with using semi-automatic computer algorithm. A multiple-channel video recording and broadcasting system was installed in an operating room and the surgical procedure was recorded. The supervising surgeon monitored the operation in real-time from outside the operating room. Information sharing via the intra-hospital network improved the work efficiency of staff. The amount of motion was estimated from recorded file size based on the principle of inter-frame video compression. A time period for which the file size significantly increased compared to those for neighboring time periods was chosen and the majority voting technique was applied to detect events using six channels of the video. A change in file size indicated a phase change of the surgical procedure. The proposed method is promising for future daily clinical procedure.

Keywords: Neurosurgery, Intraoperative magnetic resonance imaging (MRI), Surgical information, Incident detection, Video recording, Motion tracking, Digital forensics

1. Introduction

Sophisticated operating suites equipped with intraoperative imaging modalities have been introduced in a lot of hospitals. Intraoperative imaging enables in-situ visualization of the target lesion and the evaluation of surgical treatment results, allowing surgeons to modify the surgical plan in real-time in the operating room, especially in brain tumor surgery, which requires very precise resection of the target lesion. Intraoperative imaging can only optimize the surgical procedure, but total optimization of the whole surgical process can enhance the total quality of the surgery. In the operating room, surgical devices such as intraoperative imaging modalities (ultrasonography, fluoroscopy, C-arm, X-ray computed tomography, magnetic resonance imaging (MRI)) and surgical microscopes are used. Staff includes surgeons, anesthesiologists, clinical engineers, scrub nurses, and supporting nurses. Operating room and operative procedures are thus complicated.

Around 98,000 people die per year from medical errors in the United States [1]. Complicated medical care may be one of the reasons for such errors. Serious accidents and errors are investigated to find their causes to prevent future accidents. The best way to prevent medical error is the identification of potential risk factors and practical countermeasure for the risks [2]. This methodology was established for aircraft accidents [3]. Similar approaches are used in industrial companies, especially in the assembly of automobiles and ships. Assembly consists of small procedures, and can be disassembled into small pieces. If the relationship among the small pieces is clear, the complex procedure can be described using a flowchart, which facilitates the finding of the cause of error.

Surgical procedures also comprise small tasks, but they are not repetitive. A surgery, for example a brain tumor resection in the left frontal cortex, has a basic routine, but details differ depending on patient's clinical history, lesion location, operative approach, and so on. In other words, surgeons never perform the exact same operation. Only a rough flow chart of surgery can be created. The present study reviewed many clinical cases to find risk factors. As shown in Heinrich's triangle and Reason's organizational model (Swiss cheese model) [4,5], a lot of risk factors and small incidents exist behind a serious error. Such small incidents should be detected and mitigated before a serious error occurs.

Medical error is a critical issue in medical practice. A web-based adverse event reporting system for surgical patients has been developed [6] and incident analysis is conducted in the

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scenario of surgical setting [7]. As reporting systems largely depend on clinical staff input, the results can be subjective and there is a risk of intentional concealment. Surgical staff may consider a small incident not worth reporting. However, such an incident is a key to finding risk factors and reduces medical errors.

Several studies have recorded all events in an operating theater. Recorded data is objective and can be scientifically analyzed. In [8,9], a video camera and microphone were installed to record audio-visual information. Special sensors have been installed to record numerical data in the operating room [9,10].

An exact preservation of intraoperative information has advantages in its completeness and objectivity. However, raw time-series data needs to be analyzed and comprehended to extract meaningful information. The most simple method is visual observation by a surgeon, but it is time-consuming and boring. If a surgeon has time to watch a video of the whole operation, it would be better for him to observe the operation directly in the operating room. Automatic recognition using a computer algorithm has been proposed. If a computer can find intraoperative incidents automatically, the surgeon can spend less time and effort finding incidents from a video file or sensor log. For this purpose, an incident or error has to be defined. However, defining a medical incident is difficult because incidents are not identified as an action, but the result of an action. Incidents are identified in the context of surgical procedure.

The identification of incidents by a medical doctor is time-consuming, and artificial intelligence is insufficient for surgical workflow analysis. This study thus uses the hypothesis that the movement of surgical staff increases when an incident occurs in order to compensate for the problem or when the surgical phase changes [11]. If the motion of surgical staff can be measured in a video and time periods with a relatively large amount of motion can be found, the time periods can represent candidate events that contain medical errors.

In this study, a video recording and broadcasting system is installed in an intelligent operating theater in Tokyo Women's Medical University, Japan. The results of video analysis for detecting the candidates of surgical incidents are reported.

2. Materials and methods

2.1 Intelligent operating theater equipped with intraoperative MRI

An intelligent operating theater was built in 2000 at Tokyo Women's Medical University Hospital, mainly for image-guided neurosurgery [12]. Brain tumor resection requires precise operation, so image-guided surgical navigation technology using pre-operative images is widely adopted. The brain, however, is soft tissue floating in cerebral fluid and its shape changes easily when cerebral fluid overflows from the cranium after craniotomy. The deformation of the brain in shape is called a brain shift. The deformed shape is different from the preoperative image. Thus, re-planning for the surgical approach is necessary using the latest images acquired after craniotomy in the operating room. For this purpose, an open configuration MRI system (AIRIS II, Hitachi Medical Corporation, Japan) is set up in the operating theater (Fig. 1).

The MRI system uses a permanent magnet to generate a vertical static magnetic field, whose strength is 0.3 T [13]. A lower magnetic field has various merits. One of them is its narrower area of magnetic field leakage. Since, outside the area, effect of magnetic field is negligible and the surgeon can use conventional surgical instruments, he does not have to use unfamiliar magnetic resonance (MR)-compatible surgical instruments. The surgeon can also operate near the MR scanner, and does not have to move the patient a long distance to take MR scan, which is a risk factor in the handling of various tubes for medication and lines for patient monitoring. In the intelligent operating theater, several MR-compatible devices were adopted, namely a special surgical table and surgical microscope, which are located very close to the MR scanner, and a patient monitor and anesthesia machine which work during MR scanning without electromagnetic interference.

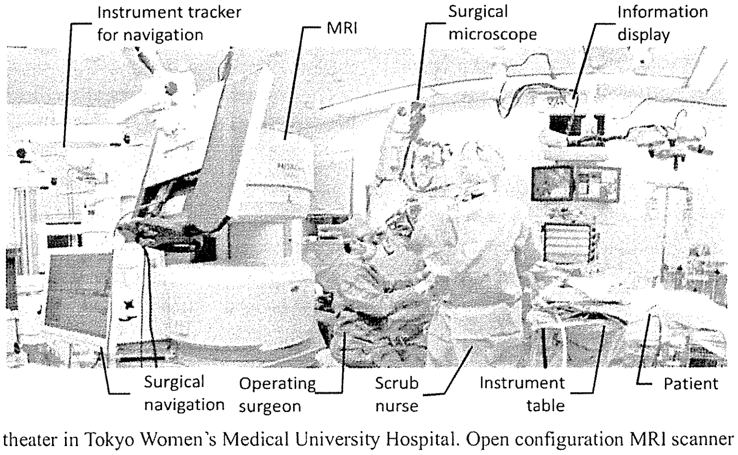


Figure 1. Intelligent operating theater in Tokyo Women's Medical University Hospital. Open configuration MRI scanner is installed in the operating room to acquire intraoperative images for more precise surgery.

A surgical navigation system that utilizes the latest intraoperative images was installed. More than 1000 operations had been conducted by the end of August 2011. The present research including system implementation and evaluation was conducted on this platform.

2.2 Multiple-channel video recording

For the exact recording of intraoperative visual information, a video recording system consisting of multiple video cameras was installed in the intelligent operating room. Since electromagnetic interference degrades the quality of MR images, electromagnetic noise filtering box and noiseless data transferring system using optical fibers were also installed. The system configuration is shown in Fig. 2.

2.2.1 Intraoperative information acquisition

Several cameras were mounted in the operating room to shoot the motion of surgical staff [11]. Figure 3(a) shows four cameras mounted on the surgical light. The cameras shoot the surgical field because the surgical light always faces it. A compact camera was mounted on a rack to give an overview of the operating room (Fig. 3(b)). Other cameras and a networked camera were mounted on a shelf in the operating room (Fig. 3(c)). The operating room has electromagnetic shielding to reduce the noise caused by exogenous noise, so the video signal inside the operating room cannot be transferred directory to the outside. The authors previously used a noise filter box connected to the shielding wall. Here, a device was adopted to convert the video signals to be sent over an optical fiber cable (Fig. 2), which does not create electromagnetic interference. Networked pan/tilt cameras were installed. Their Ethernet cable signals were converted to be sent over optical fiber using a media converter.

Neurosurgery is usually conducted using a surgical microscope, which records hand operation in the surgical field. The video output of the surgical microscope is transferred using metal cable via noise filter box to video recording system outside operating room. The screen image of the surgical navigation was transferred as a video signal via metal cable directly to video recording system. Surgical navigation is not used during MR scanning, so it does not affect MR image quality. The video cable thus runs through the door of the operating room without any electromagnetic interference measures taken.

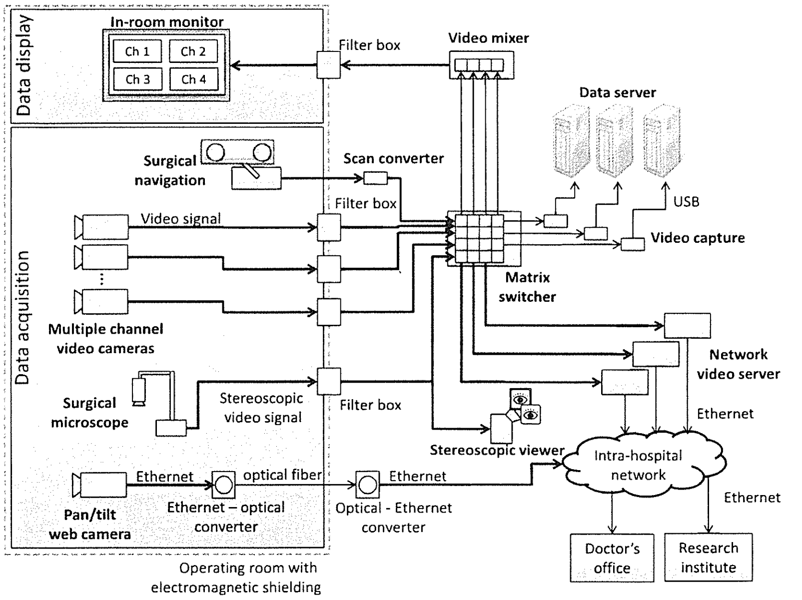
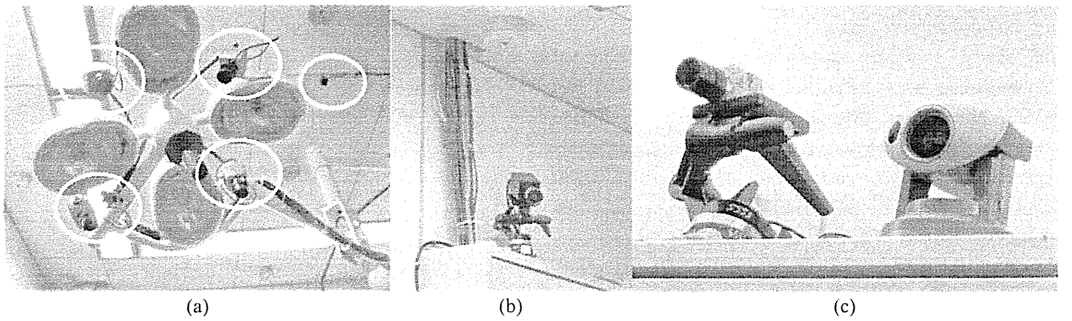


Figure 2. Configuration of video recording and broadcasting system in intelligent operating theater. All video signals are fed to the matrix switcher and broadcast to various devices.



(a) (b) (c)

Figure 3. Examples of video cameras mounted on the ceiling and wall in the operating room; (a) four cameras mounted on the surgical light and one camera mounted on the ceiling; (b) compact camera and networked camera, and (c) telecamera on the shelf.

2.2.2 Information broadcasting and in-room information display

The video sources in the intelligent operating room are fed to a video matrix switcher (SWX-1010, Imagenics, Japan) and broadcast to various devices. Some of the streams are recorded on computers through USB-connected video capture devices, and some are broadcast to a doctor's office and the research institute using a networked video server via the intra-hospital network. In this study, six channels of video were recorded simultaneously using a developed system [11]. Several channels of video are integrated using a video mixing device (TAHOMA LE-16 multiviewer, Apantac LLC, USA), and shown on the in-room monitor (CELL REGZA 55X2, Toshiba, Japan).

2.3 Incident detection algorithm for post-operative surgery analysis

In this study, the hypothesis is that the movement of surgical staff increases when an incident occurs because surgical staff works busily to compensate for the problem, or when a surgical phase changes [11]. Thus, the amount of motion is quantified to find candidate incidents.

Automatic motion analysis from video data usually requires motion recognition using algorithms such as face recognition, motion detection, or fiducial marker detection. In the operating room, the surgical staff wears identical uniforms, masks, and caps, and everything is pale blue or green. This makes surgical staff look similar. Face recognition is not easy because only the eyes and eyebrows are visible. In addition, surgical staff watches the surgical field or operating surgeon; they do not look at the video cameras. Automatic computation process such as face recognition is difficult in an operating room.

Optical flow [14] is a commonly used method for motion detection, but it has a high computational cost. Since the precise motion of each pixel is not necessary in the proposed system, optical flow is not optimal. Fiducial markers are a robust method for tracking the motion of a target. The tracking systems adopted in commercial surgical navigation systems use infrared light to track targets. Their performance is well established, but such systems are expensive and reflective marker must be attached to every tracking target. In addition, the fiducial markers must be sterilized. Fiducial markers can also be hidden behind surgical staff or devices. Fiducial markers are thus not a good choice.

In this study, a simple algorithm is implemented for detecting busy situations in recorded video files without any additional devices or cost. The algorithm makes use of the video compression algorithm. In video compression, two kinds of compression are applied, namely intra-frame compression and inter-frame compression. Intra-frame compression uses the current frame to reduce the file size, whereas inter-frame compression uses the subtraction of sequential frames. When the subtraction result between two frames is small, the video data is compressed efficiently. However, when the subtraction result is large, the video is not optimally compressed and the file size increases. Thus, a video file with a lot of motion is large. This principle is used here to estimate the amount of motion from the video size. As a result, the time period with a lot of motion can be determined.

In the developed system, six channels of video are recorded in a short time period (every minute in this study), and then the file size is checked. This requires no additional computer process. When the file size in a time period is larger than those in other time periods, the time period is marked as a candidate incident.

3. Results

3.1 Broadcasting of intraoperative information from intelligent operating theater

Intraoperative information is transmitted to the research institute or a doctor's office via the intra-hospital network in real-time (Fig. 4). The supervising senior surgeon can observe the operation without entering the operating room as well as join the intraoperative re-planning of the surgical approach and decision-making during the surgical procedure. The supervisor can thus assist the operating surgeon, improving his efficiency.

Unexpected merit of broadcasting system was found in pathologist laboratory. The pathological results of a stereotactic biopsy are important in brain tumor resections to determine the unclear boundary between normal tissue and tumor lesion. If the biopsy result does not show the presence of tumor cells, surgeon can know that tumor lesion is completely resected. As a pathologist cannot know when an operating surgeon requests instant pathological examination during surgery, he has to patiently wait for the request by the surgeon. Now the pathologist watches the operational process through broadcasted video information and can expect the time of biopsy. Pathologist can utilize his time resource.

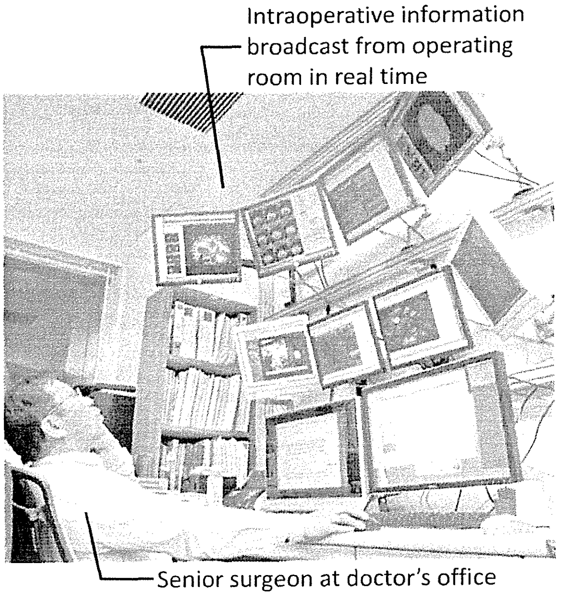


Figure 4. Broadcast video information of surgical microscope view, surgical navigation system, and views of web camera.

3.2 Intraoperative video information analysis for incident detection

The multiple-channel video recording system was applied to a clinical case (brain tumor resection, recurrent case of glioma at right occipital lobe). The operation started at 8:54 and ended at 16:30, for a total operation time of 7 hours and 36 minutes. Six channels of video were utilized (Fig. 5). The videos were recorded simultaneously, creating 6 channels of video of a given event from various angles. The video data was recorded with permission by the ethical committee and agreement of the patient and surgical staff. Offline analysis of the recorded video data was conducted after surgical operation. No adverse event associated with the video recording was observed.

In our previous study, only one channel [15] was observed or six channels were separately analyzed using time-series file size and increasing ratio of file size compared to the average size of neighboring files [16]. The increasing ratio is defined as the variation ratio of the file size compared to the average file size of neighboring files, as shown in Eq. (1) and (2). When file size is $f(t)$ at time t, the average file size of N minute neighboring files is given as $g(t,N)$ and the file size variation is $v(t)$ at time t, where N is initially set to 5.

$$g(t,N) = \frac{f(t-N)+...+f(t)...+f(t+N)}{2N+1} \quad (1)$$

$$v(t) = \frac{f(t)}{g(t,N)} \quad (2)$$

The focus here is the increase in file size, which is caused by the motion of the surgical staff. When $v(t)$ is less than 1 (i.e., $f(t)$ is smaller than the average file size of neighboring files $g(t,N)$), $v(t)$ is set to 1.

Obvious incidents were not found by human visual observation in this experiment, but various events were detected using file size analysis. Time-series file size showed typical patterns (Fig. 6). Since during MR scanning all power supply is shut down to not cause electromagnetic interference, which degrades MR image quality, video was not recorded during this time period. Time-series file sizes of channels (a) to (e) show time periods without data shown as gaps during MR scanning, except channel (f), which worked only between the 1st and 2nd MR scanning. Other time periods showed a slight file size change, but it was not significant. When the file size variation was calculated, channels (a) to (e) showed significant increases before and after MRI scanning. The MR scanning phases can thus be detected using multiple video sources.

In this study, the results were comprehensively analyzed by majority voting in addition to the time-series file size (Fig. 6) and file size variation (Fig. 7) analysis. As shown in Fig. 8, the threshold value was dynamically changed to extract incident candidates from file size variation data, and the top 10, 20, 30, and 40 events showing a high value of file size variation in each channel of video were extracted. The number of events extracted at a time period was counted. The number shown in right y-axis means the sum of video sources indicating the time period with high variation ratio.

In Table 1, time periods were extracted when two or more channels were selected as top 10 - 40 events. With 40 events detected, it takes 240 minutes (40 events × 6 channels) to check the recorded video files, which is thought to be the limit of time required for checking the video from the discussion with

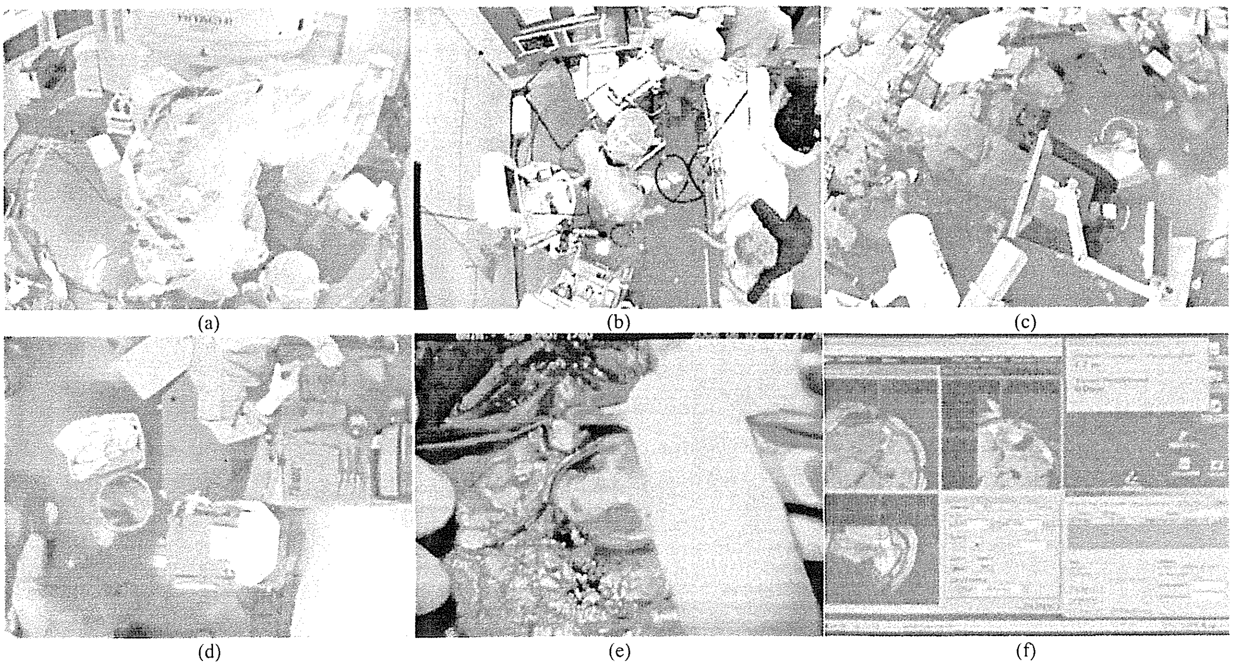


Figure 5. Field of view of each camera [16]; (a) around surgeon, (b) around anesthesiologist, (c) whole view of the operating room, (d) around scrub nurse and assisting nurse, (e) microscope view of surgical field, and (f) surgical navigation window.

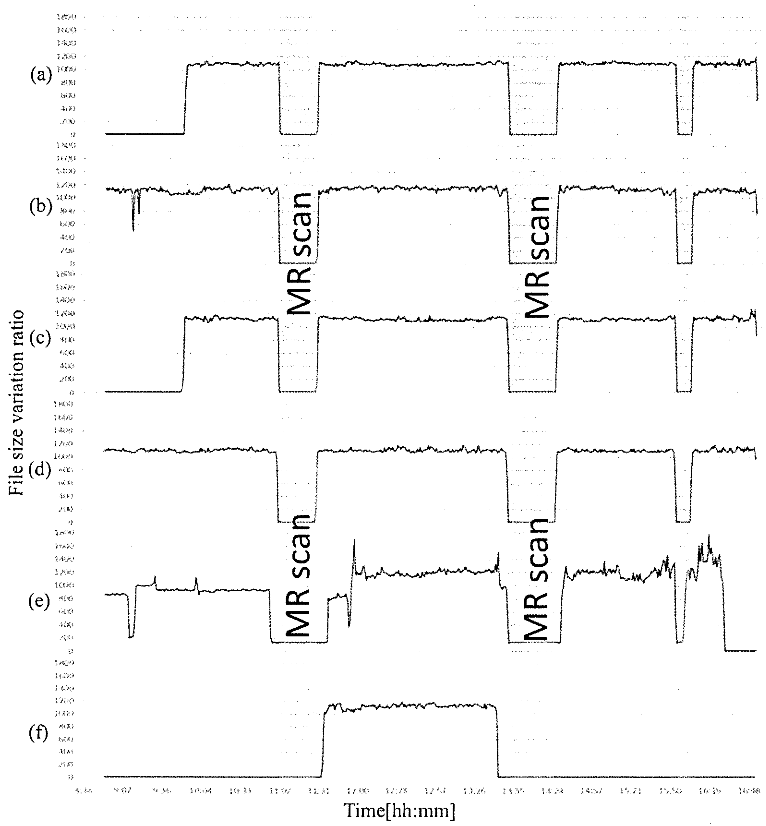


Figure 6. Time series (1-minute intervals) of file size for six video channels [16]. (a) to (f) correspond to the video images shown in Fig. 5. Around 11:30, 14:00, and 16:00, measured value of each channel is constant at low level. During this time period, MR images are taken and power supply is shut down to prevent electromagnetic interference, so blue screen is recorded. Recording of channels (a) and (c) started late, and channel (f) was recorded only two hours because surgical navigation system was used for a limited time period in this case.

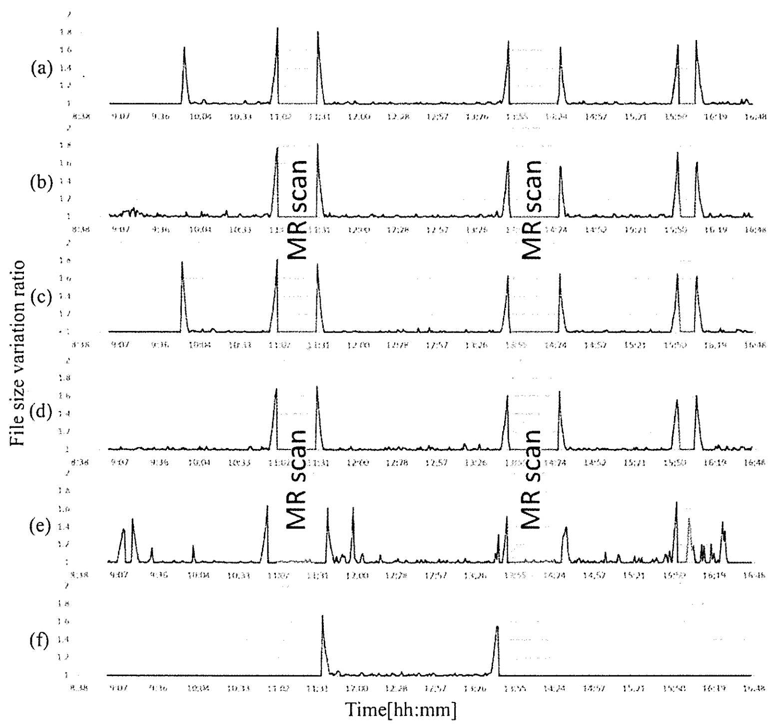


Figure 7. Time series of file size variation rate among 5 minute neighboring files for six video channels [16]. (a) to (f) correspond to the video images shown in Fig. 5. Before and after MR scanning, variation rate has peaks because during MR scanning the recorded file size is constant at a low value.

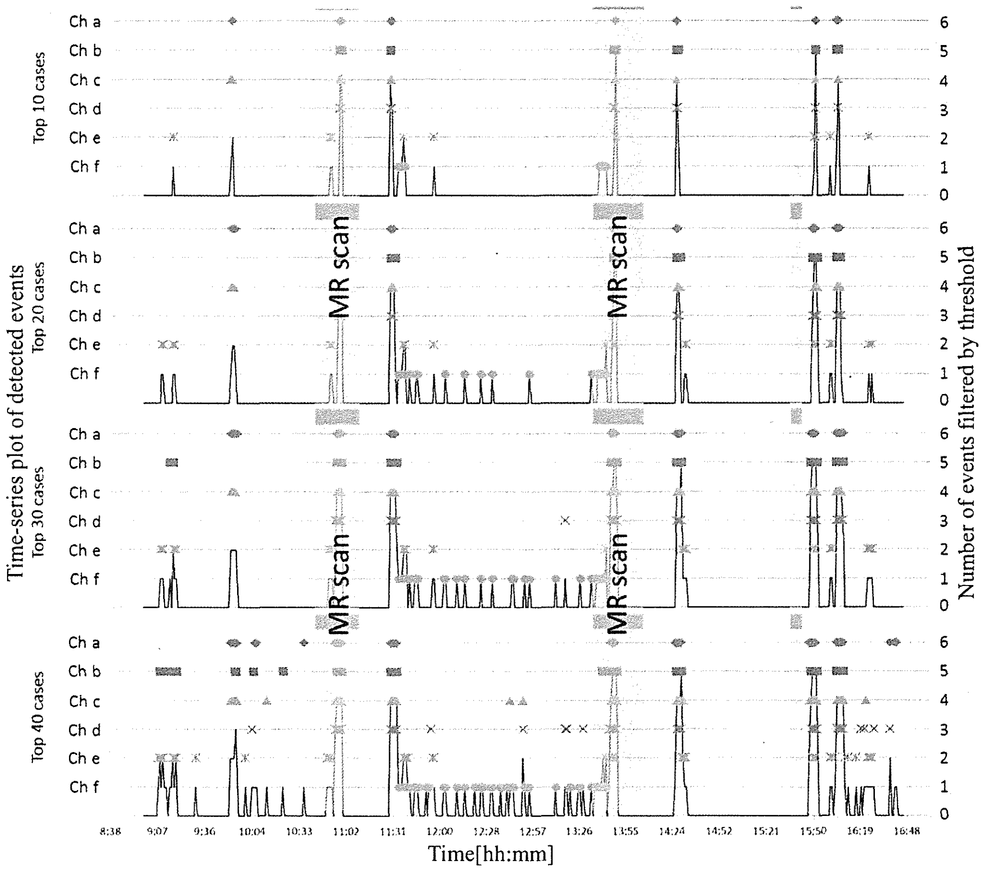


Figure 8. Time-series plot of detected events. Filtering threshold was dynamically changed to pick up the top 10 to 40 events in each channel using the file size variation shown in Fig. 6. Total number of detected events for channels (a)-(f) at a time period is plotted with a line.

medical doctors. During MR scanning, a blue screen is recorded, with a corresponding small file size. Thus, before and after MR scanning, the file size changes remarkably. The phase change before and after MR scanning (10:56, 11:30, 13:46, 14:27, 15:49, and 16:05) was easily distinguished with the proposed system. The phase change from anesthesia to surgery (9:52) was also detected with the top-10 file size variation. The layout of the operating room changes from anesthesia induction mode to surgical operation mode. The location of the surgical table and surgical staff changes at this time point.

A recording error of the microscope view was detected from a file size change at 9:11. Blue screen is recorded temporarily from the system error. The change of sight from the microscope view to the blue screen enlarged the file size variation ratio.

At 9:17, channel (b) shot the motion of the anesthesiologist, and channel (e) shot the change in brightness in the microscope view. Although this event does not reflect intraoperative trouble situation, the switching on or off of the light source of the microscope could be detected because the brightness of microscope view drastically changed, leading to large file size variation.

At 9:55, all surgical staff began to work busily around the patient to start the surgical procedure because the induction of anesthesia had completed. This situation was detected from channels (a), (b), and (c).

At 11:38, channel (f) was extracted because the splash window (Microsoft booting logo) of surgical navigation system had more motion compared to the window during its use. Channel (e) did not record any special events at 11:38 while it was extracted with high variation ratio in file size. In this case, the file size variation increased because the size of the neighboring files was so small, and thus the file size at the time period (11:38) was relatively large.

Suturing hand motion at 13:43 and the shut-down process of the surgical navigation system indicated that the operation would finish shortly. Other situations detected from the top-40 events were not significant, representing false positive cases.

At around 10:20, the suction pump did not work correctly, so the supporting nurse checked the suction pump beneath the surgical table. Although this was obviously visible in channel (c) (Fig. 9), the file size did not change enough to mark the event as a candidate. To detect such an event, the file length in time must be optimized. This is because, when the file length is one minute, file size reflects whole motion recorded in one minute movie. In this case, the supporting nurse moves so quickly, and motion size was not large enough to increase one minute file size. But, if the file length is for example just 10 second, file size would increase drastically. However, shorter file length can be too sensitive to change of motion size, and it might lead to false positive detection. The filtering algorithm is also a key factor and must be modified.

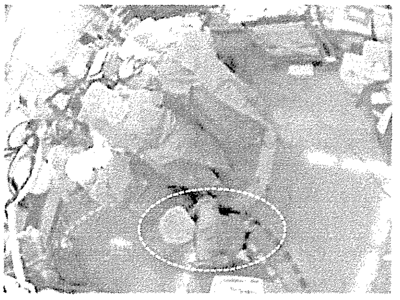


Figure 9. Motion of supporting nurse visible in channel (c). However, the movement was so small that the file size did not change significantly.

4. Discussion

This study implemented an intraoperative video recording and broadcasting system and utilized it to detect candidate incidents to reduce surgical error in the operating room. The video recording and broadcasting system works well for sharing information both in the operating room and in the research institute and doctor's office, and improves the procedure for the pathologist and supervising doctor. A problem for the recording system is the changing standard of video devices. Video signals have several standards and interfaces, such as DVI, HDMI, and HD-SDI. Although a legacy standard is appropriate for medical use due to its stability, legacy devices are difficult to obtain and cutting-edge high-resolution digital images are preferred by surgeons. A problem for the broadcasting system is the speed of the network connection. Intraoperative information is transmitted via the intra-hospital network. The network bandwidth is shared with other devices, so communication speed is unstable. If high-resolution video is adopted for broadcasting, the problem will become more serious. In the future, the operating room will be connected to the research institute and the doctor's office directly using a dedicated optical fiber line.

We analyzed the 6 channels of video source together using majority voting method in this study while those data were analyzed separately in the previous study [16]. Although high file size variation before and after MR scanning can be detected using only one channel, using multiple channels increases the confidence of detected events. For example, at 9:52, 9:55, and 12:52 in Table 1, the same event was recorded from different camera angles, and detected as a candidate event.

Processing time is an important evaluation measure. The operation took 7 hours and 36 minutes (456 minutes) from the patient entering the operating room to the completion of surgery. Thus, human observation in the operating room took 456 minutes. In contrast, when selected events are limited to the top 10, 20, 30, and 40 cases, file checking takes 60, 120, 180, and 240 minutes (one minute per file × 6 channels). If majority voting is applied, only 52 files must be checked, as shown in Table 1, which would take 52 minutes.

The file size and/or file size variation as an index of motion amount is difficult to use as the deciding factor for detecting incidents in the operating room because motion amount is not always related to intraoperative incidents. Movement may increase when no incident occurs, and movement may not increase significantly if an incident does not cause a busy situation. Thus, it is still too early to apply the current system to record daily clinical procedures. The methodology needs to be modified to improve the detection of intraoperative events.

Thus, another method will be necessary to improve incident detection ability. The detection of intraoperative

Table 1. List of times and events when two or more channels were selected as top 10-40 events at a time period.

Time	Channel	Event	Detected level			
			Top 10	Top 20	Top 30	Top 40
9:09	(b)(e)	(b): anesthesiologist is walking around (e): consequence from neighboring files				*
9:11	(b)(e)	(b): anesthesiologist is walking around (e): recording error (blue screen was recorded temporarily)				*
9:17	(b)(e)	(b): anesthesiologist is walking around (e): change in brightness			*	*
9:19	(b)(e)	(b): calculation error (e): consequence from neighboring files				*
9:52	(a)(c)	(a)(c): patient position is changed	*	*	*	*
9:55	(a)(b)(c)	(a)(b)(c): staff is working around patient busily			*	*
10:56	(a)(b)(c)(d)	Preparation for MR scanning	*	*	*	*
11:30	(a)(b)(c)(d)	Post MR scanning process	*	*	*	*
11:38	(e)(f)	(e): consequence from neighboring files (f): booting process of navigation system	*	*	*	*
12:52	(c)(d)	(c)(d): a staff member walks into operating room				*
13:41	(b)(f)	(b): anesthesiologist stands up and walks (f): consequence from neighboring files				*
13:43	(e)(f)	(e): busy hand motion for suturing (f): shut down process of navigation system				*
13:46	(a)(b)(c)(d)(e)	Preparation for MR scanning	*	*	*	*
14:27	(a)(b)(c)(d)(e)	Post MR scanning process	*	*	*	*
15:49	(a)(b)(c)(d)(e)	Preparation for MR scanning	*	*	*	*
16:05	(a)(b)(c)(d)	Post MR scanning process	*	*	*	*
16:38	(a)(d)	(a): consequence from neighbor files (d): preparing to move the patient to ICU				*

Although significant events such as MR scanning and the phase change from anesthesia to the operation procedure were detected as top 10 events, small motion could not be detected without false positive cases.

incidents may be improved using machine learning, such as adaptive boosting (AdaBoost) [17], bootstrap aggregating (bagging) [18], and their combination (ensemble learning) [19]. A machine learning technique will thus be applied to the proposed system. Audio information will also be integrated to capture the atmosphere of the operating room [11]. A Microsoft® XBOX 360 Kinect™ sensor, which provides both visible-light video and a depth map using infrared light, will be installed. The depth map can be utilized as a distance sensor to the target. Using two sets of Kinect™ sensors as a couple of stereo cameras, the position of surgical staff can be measured precisely.

5. Conclusion

This study proposed a multiple-channel video recording and analysis system for detecting intraoperative incidents. The video file size, which indicates the amount of surgical staff motion, is used to detect candidate events. An evaluation experiment showed that multiple channels increase the confidence of an event as current analyzing method using file size showed many false positive results. Although the file size information is useful, it is insufficient for estimating surgical phase change and detecting intraoperative incidents. Other kinds of information, such as audio and locations of surgical staff, should be introduced.

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