

**Research Center of
Charged Particle
Therapy Hospital,
National Institute of
Radiological Sciences,
Japan**

**The protection of
the small intestine and colon from
carbon ion particle irradiation
by means of Gore-Tex soft tissue
patches for patients with pelvic
tumors**

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Takenori Ochiai**

Phase I/II clinical trial of Carbon-ion therapy for patients with locally recurrent rectal cancer

Purpose

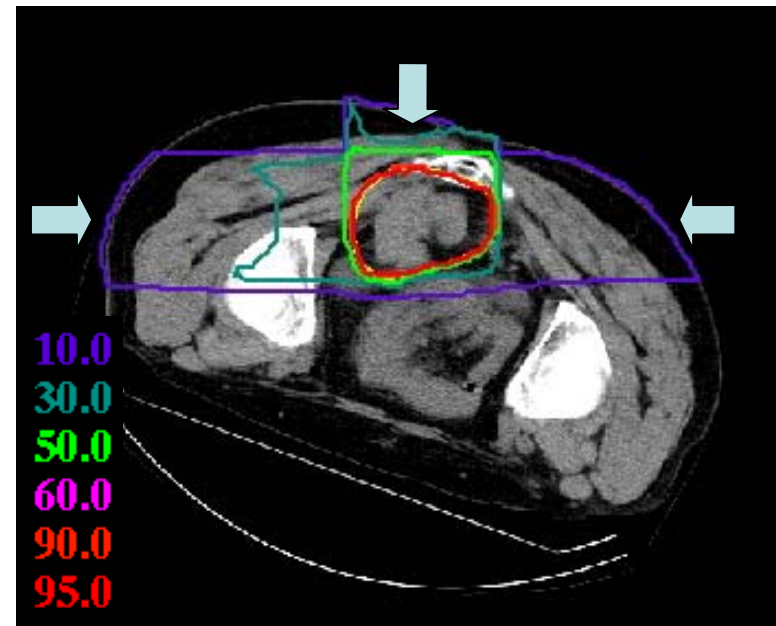
To evaluate the tolerance and the effectiveness of carbon ion radiotherapy in patients with locally recurrent rectal cancer

Treatment Data

April 2001 - February 2006

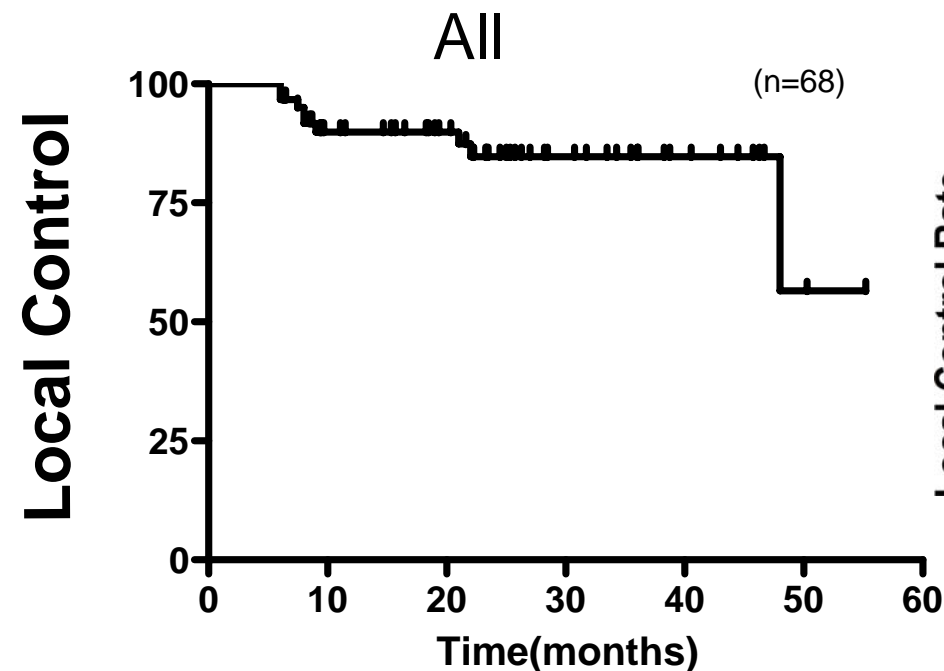
Total Dose(GyE)	Fraction Dose(GyE)	Total Number	# of lesions
67.2	4.2	16/4w	10
70.4	4.4	16/4w	16
73.6	4.6	16/4w	42

GyE = carbon physical dose x
relative biological effectiveness(RBE)



Local Control Rates

(locally recurrent rectal cancer)

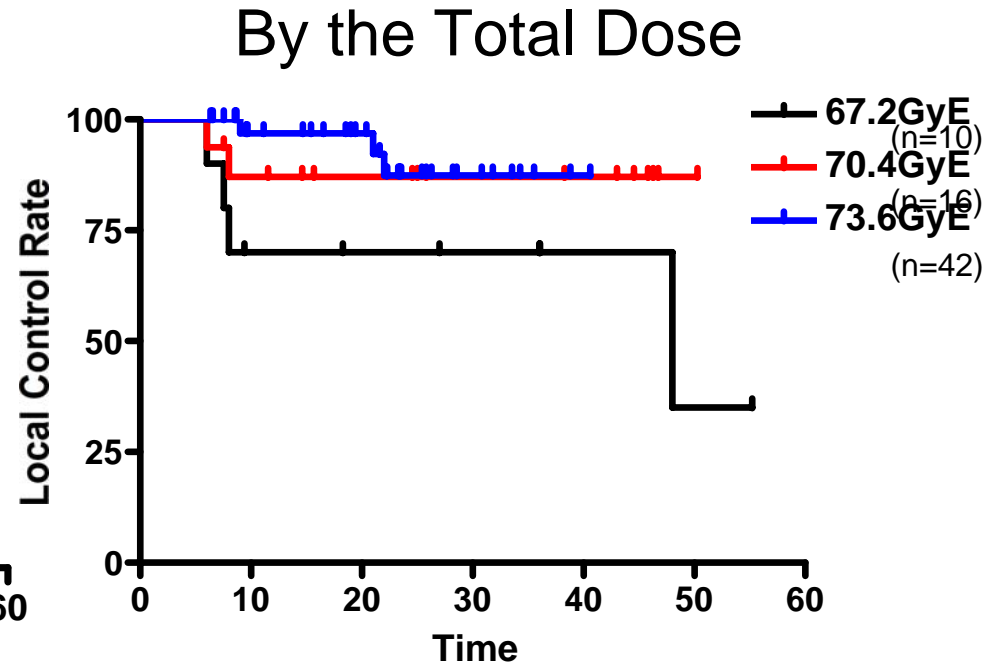


Local Control Rates

1y 93%

2y 83%

3y 79%



3yLocal Control Rates

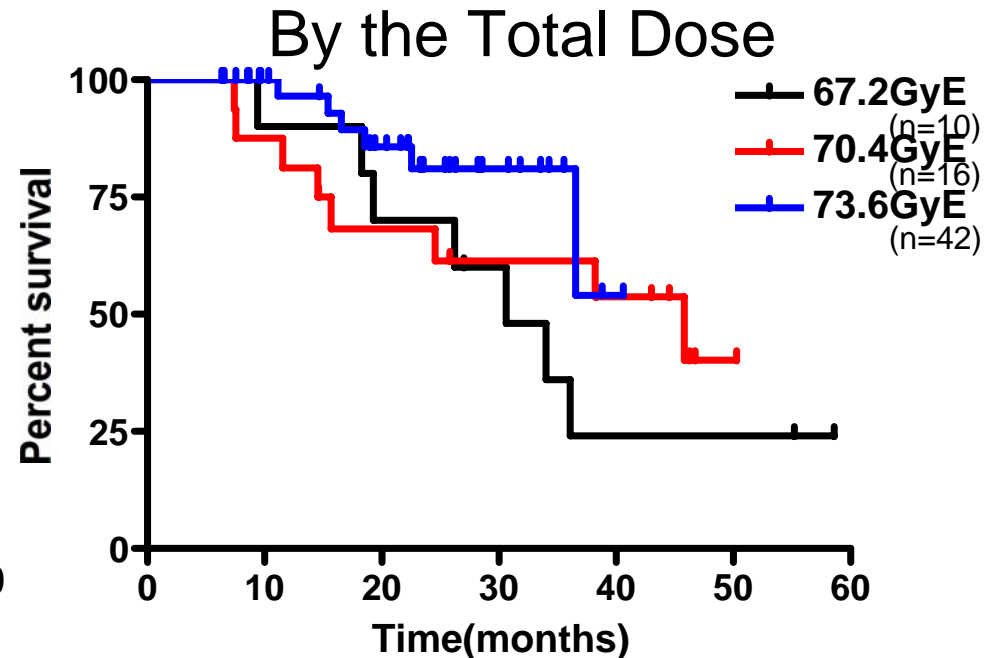
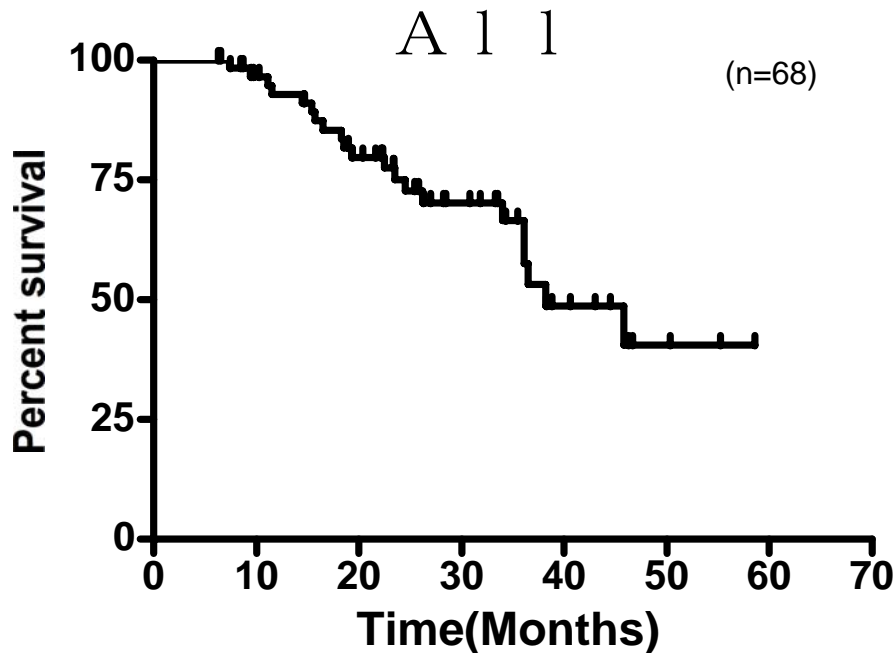
67. 2GyE:70%

70. 4GyE:87%

73. 6GyE:87%

Overall Survival

(locally recurrent rectal cancer)



Survival Rates

1y 91%

3ySurvival Rates

67. 2GyE:36%

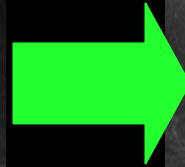
2y 75% 70. 4GyE:61%

3y 67% 73. 6GyE:81%

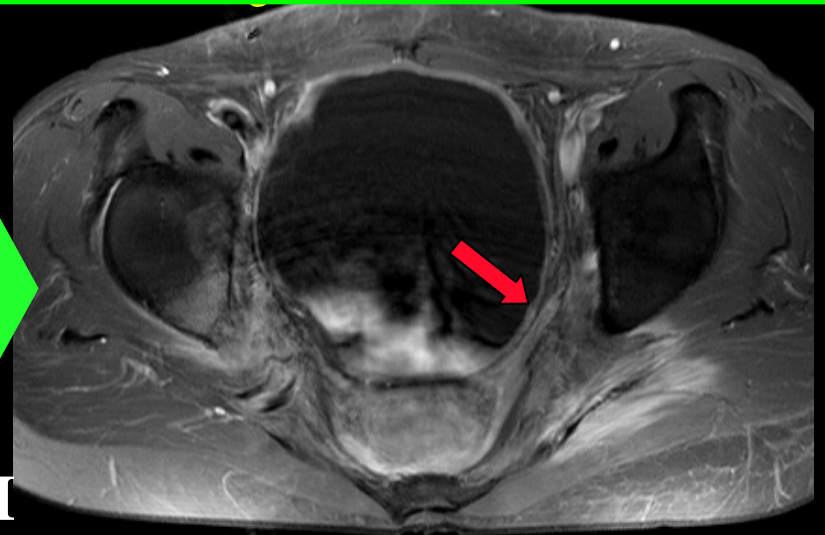
Case 1: 59y F 73.6GyE/16fr



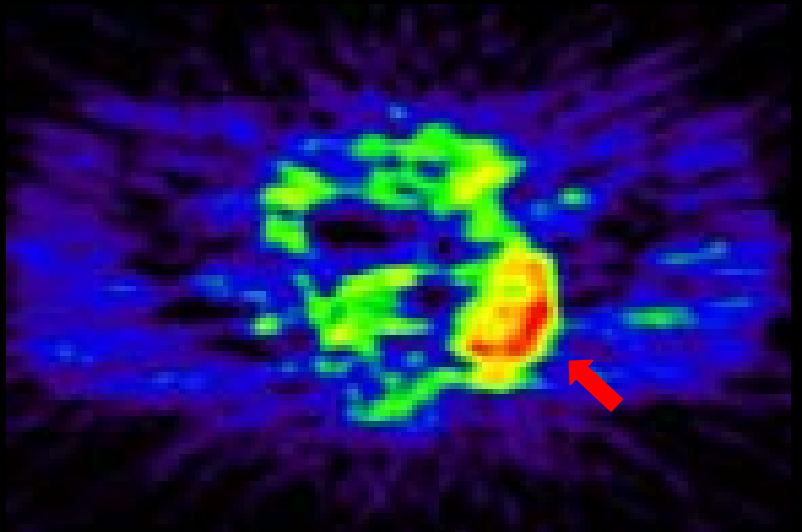
Before Treatment



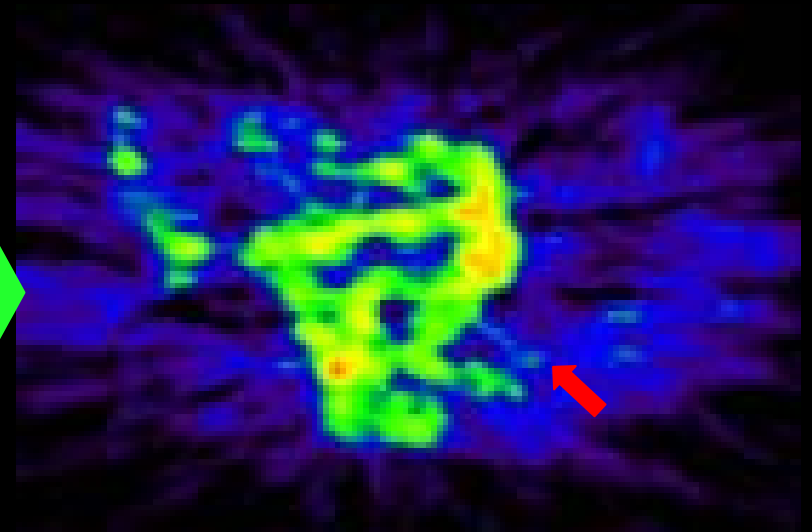
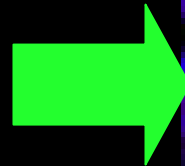
MRI



10 months after Treatment

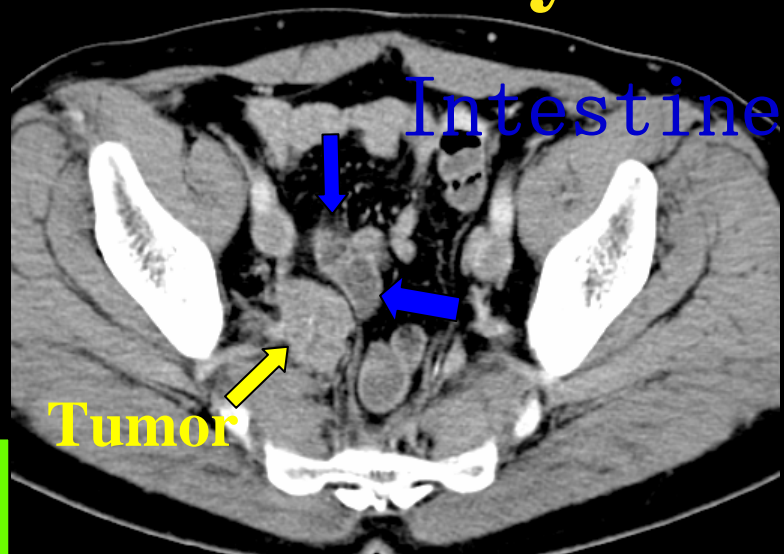


Before Treatment

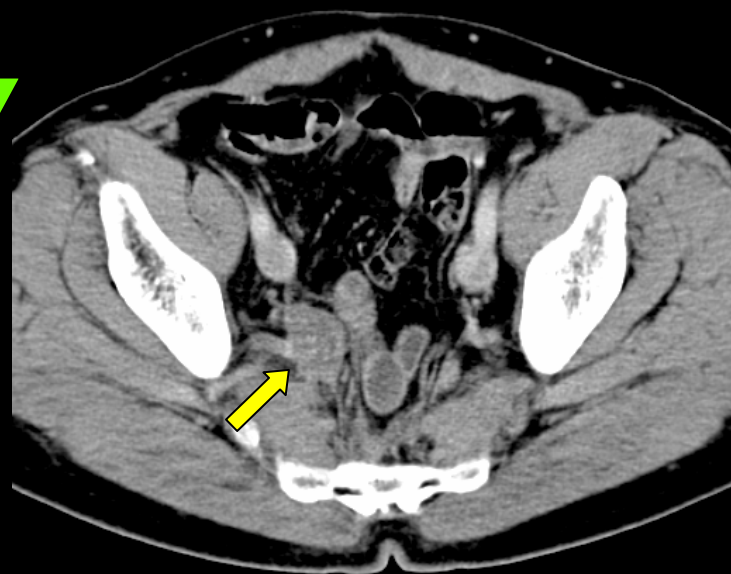
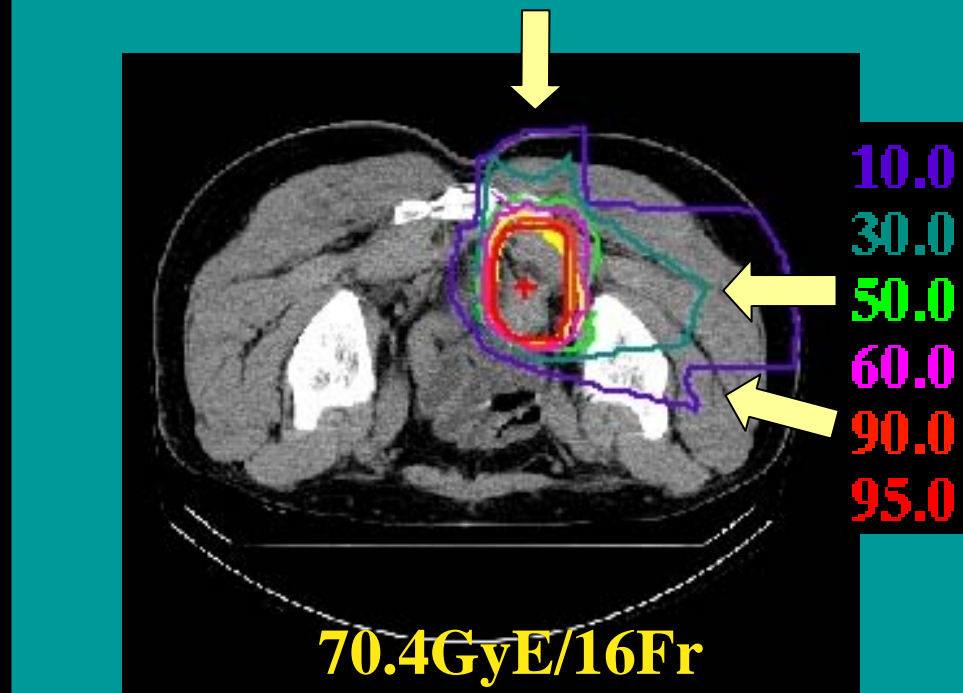


One month after Treatment

Case 2 :59yM



Before Treatment



1 month after Treatment



8 months after Treatment

BACKGROUND

Carbon ion radiotherapy is effective and safe in the management of patients with pelvic tumors. Intestines are critical organs for this treatment. To exclude the small intestine and colon from the clinical target volume (CTV) and reduce the exposure of them, we use expanded polytetrafluoroethylene (Gore-Tex soft-tissue patch, W. L. Gore & Assoc Inc, Flagstaff, Ariz) which is a strong and easy-to-use material and does not need to be removed after the conclusion of radiotherapy.

Gore-Tex Soft Tissue Patch

Gore-Tex Sheet is made of expanded polytetrafluoroethylene(PTFE) and is inert, preventing significant inflammatory responses



Characteristics of the Gore-Tex

Biocompatibility

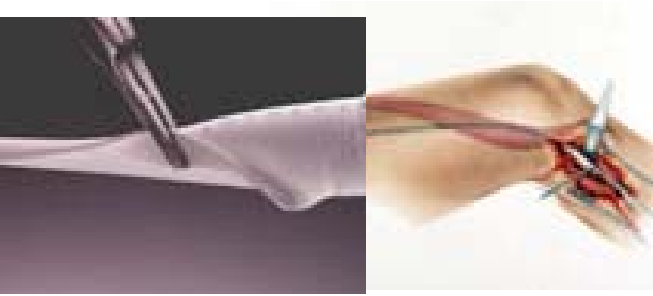
Controlled porosity

Inertness

Strength

Conformability

Applications of Gore-Tex



Vascular Grafts



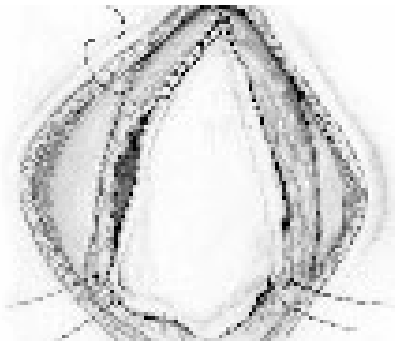
Cardiovascular Patch



Stent-grafts



Suture



Dura Substitute



**Hernia repair
material**

Patient Data

- December 2004 - February 2006
- 7 male, 6 female
- mean age **55.7** (38-79)

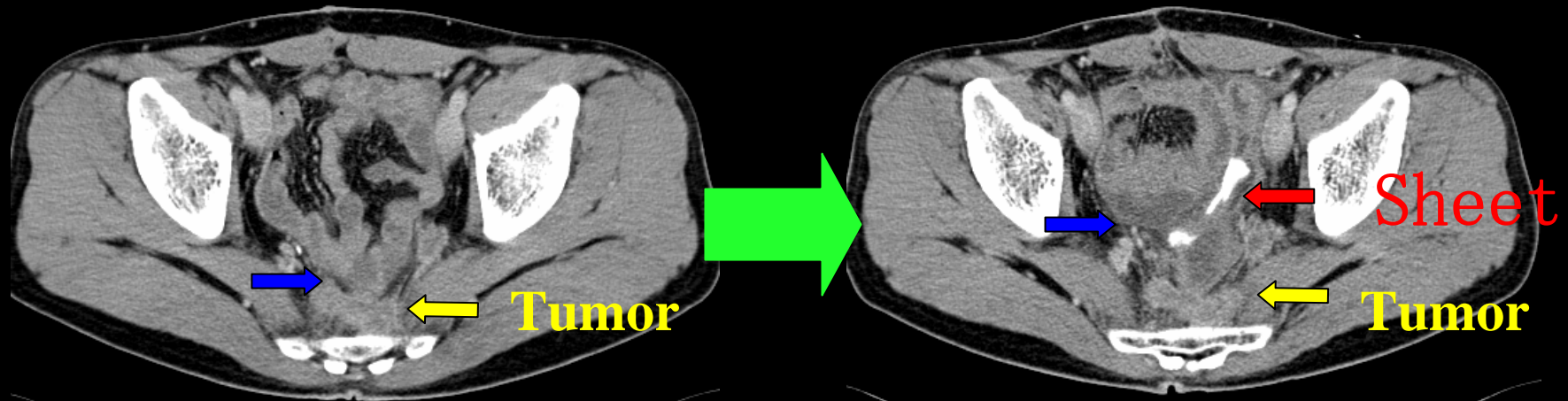
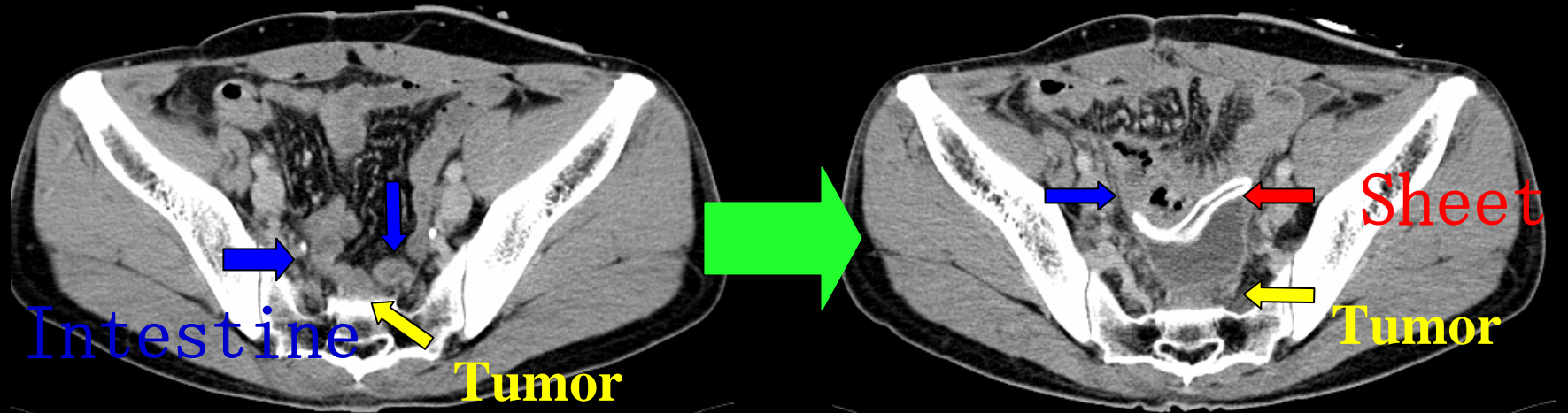
- Diseases

Recurrent Colo-Rectal Cancer	9
Osteosarcoma	2
Ovarial Cancer	2

- Location

Pelvic Side Wall	7
Presacral	4
Anastomotic	2

Case 3 40y M Locally Recurrent Rectal Cancer



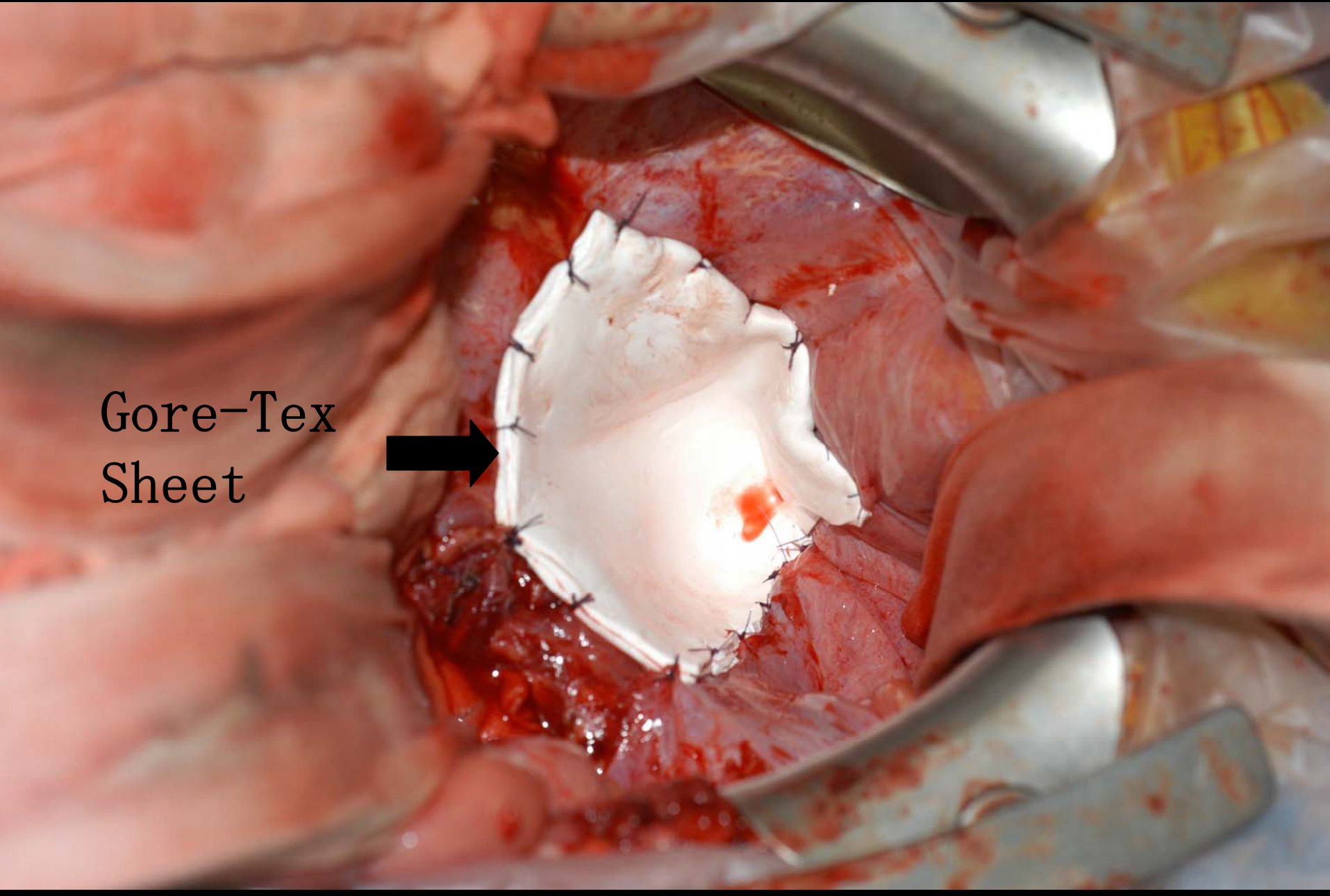
Before Operation

After Operation

Operative Finding

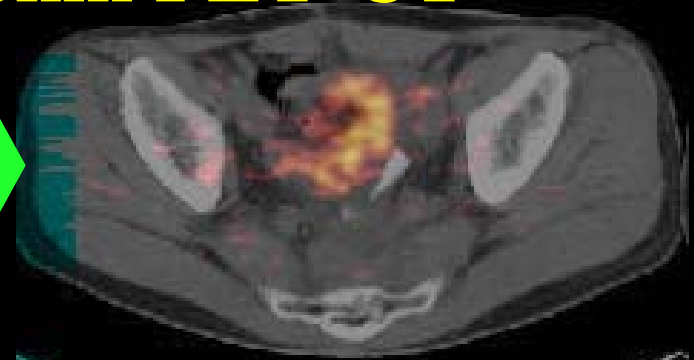
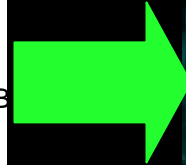
Gore-Tex Sheet

Gore-Tex
Sheet



Case3:Methionin PET-CT

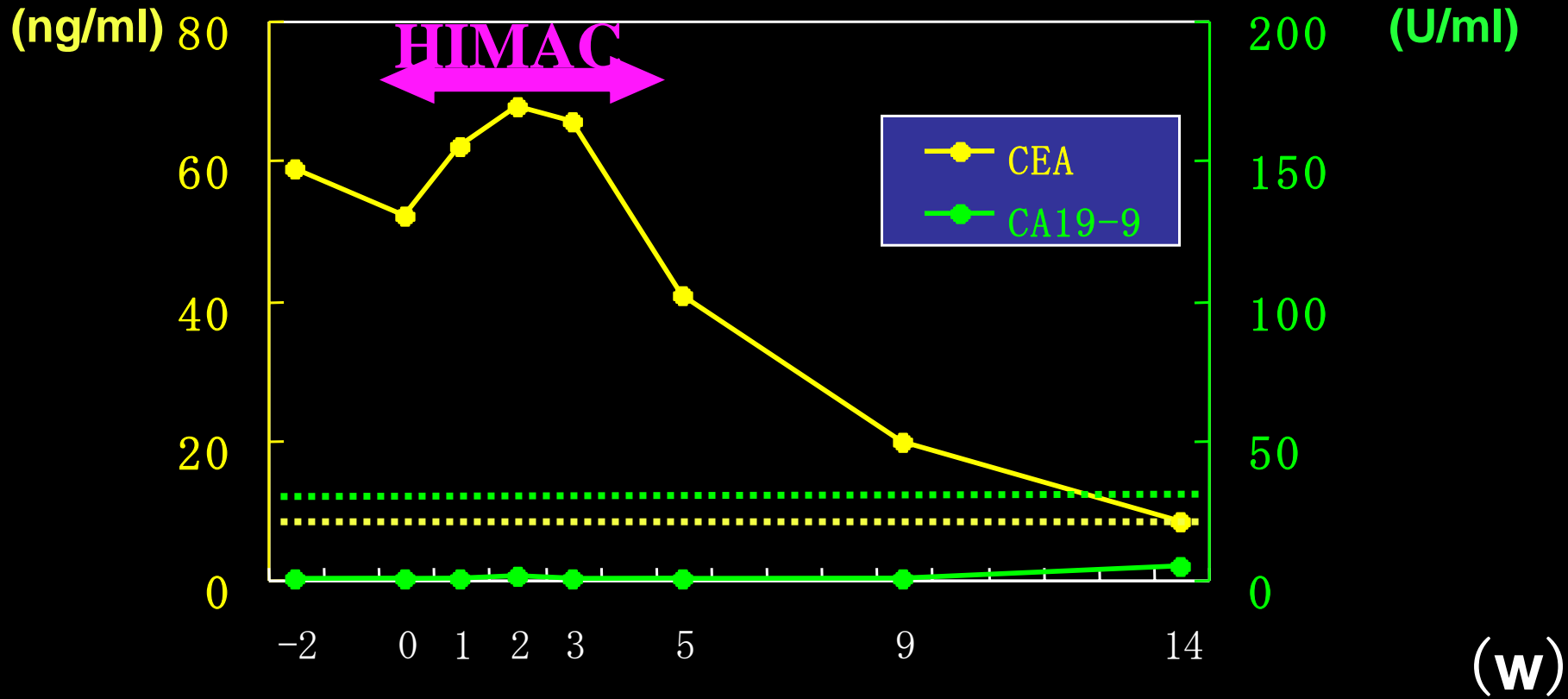
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Before Carbon-Ion

One Month After Carbon-Ion

Time Course of the level of CEA and CA19-9



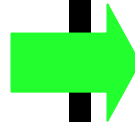
Case4: 64y F Locally Recurrent Rectal Cancer

Intestine

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Tumor



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Tumor

Sheet

Before Carbon-Ion

12M After Carbon-Ion

Dose Distribution

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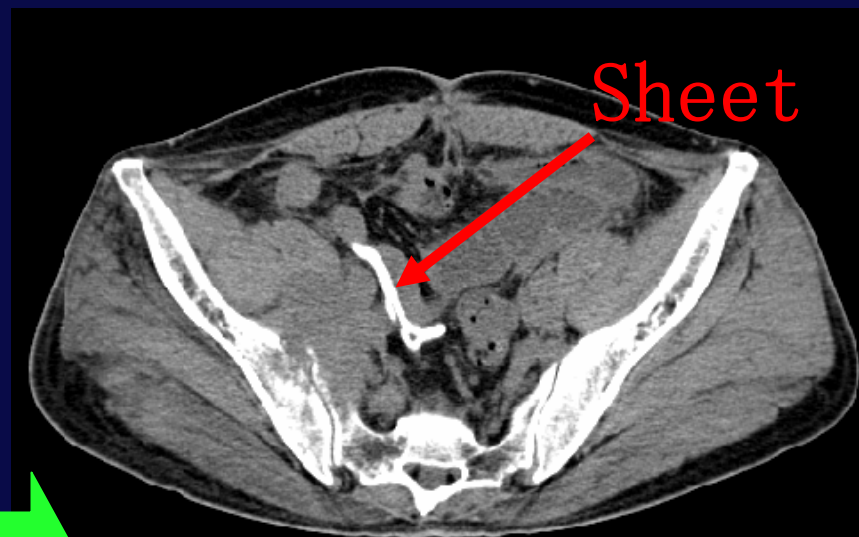
Case 5: 50y M Locally Recurrent Rectal Cancer

CT

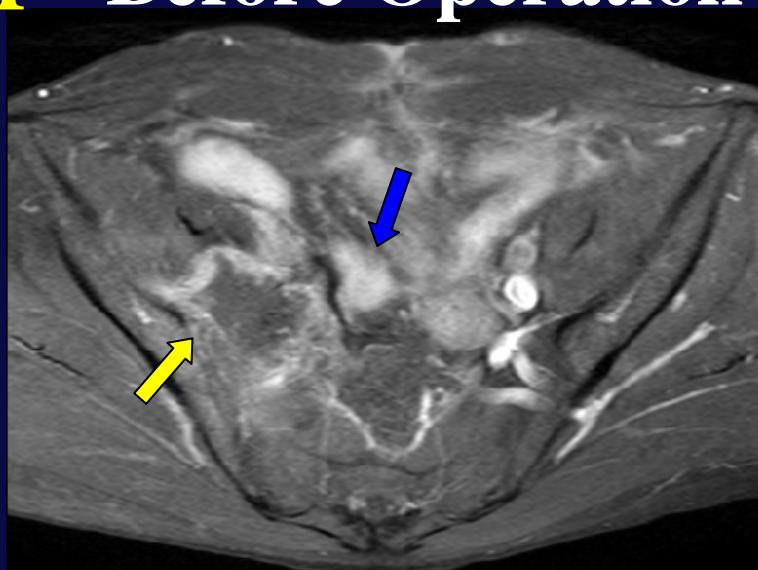
Intestine

QuickTimeý Ç²
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Tumor



MRI Before Operation



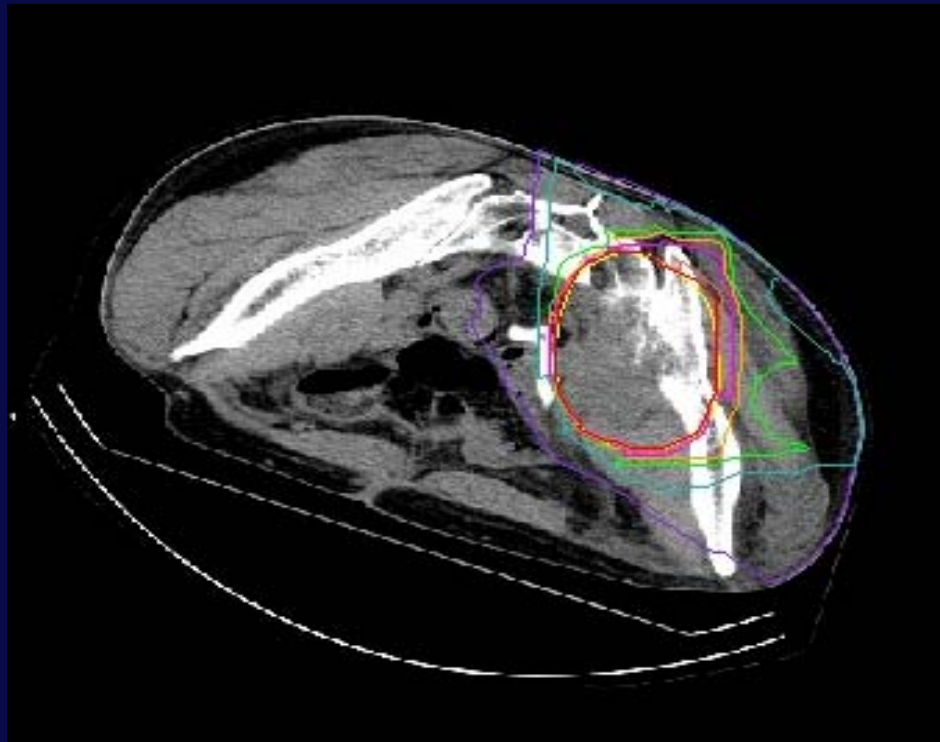
After Operation

PET - C T



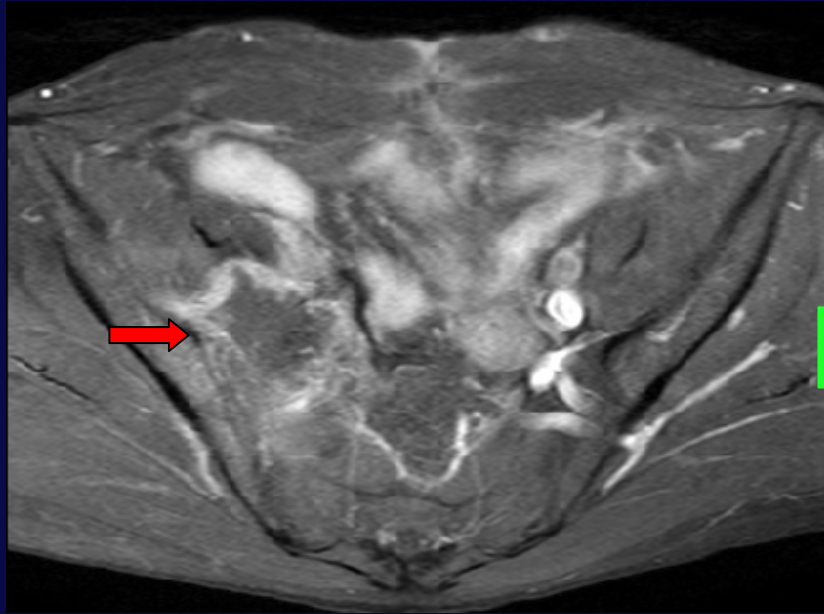
Sheet

Case5: Dose Distribution



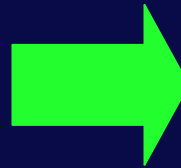
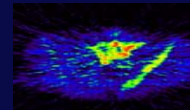
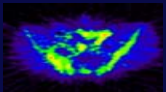
70.4GyE/16Fr

Case5: MRI and PET

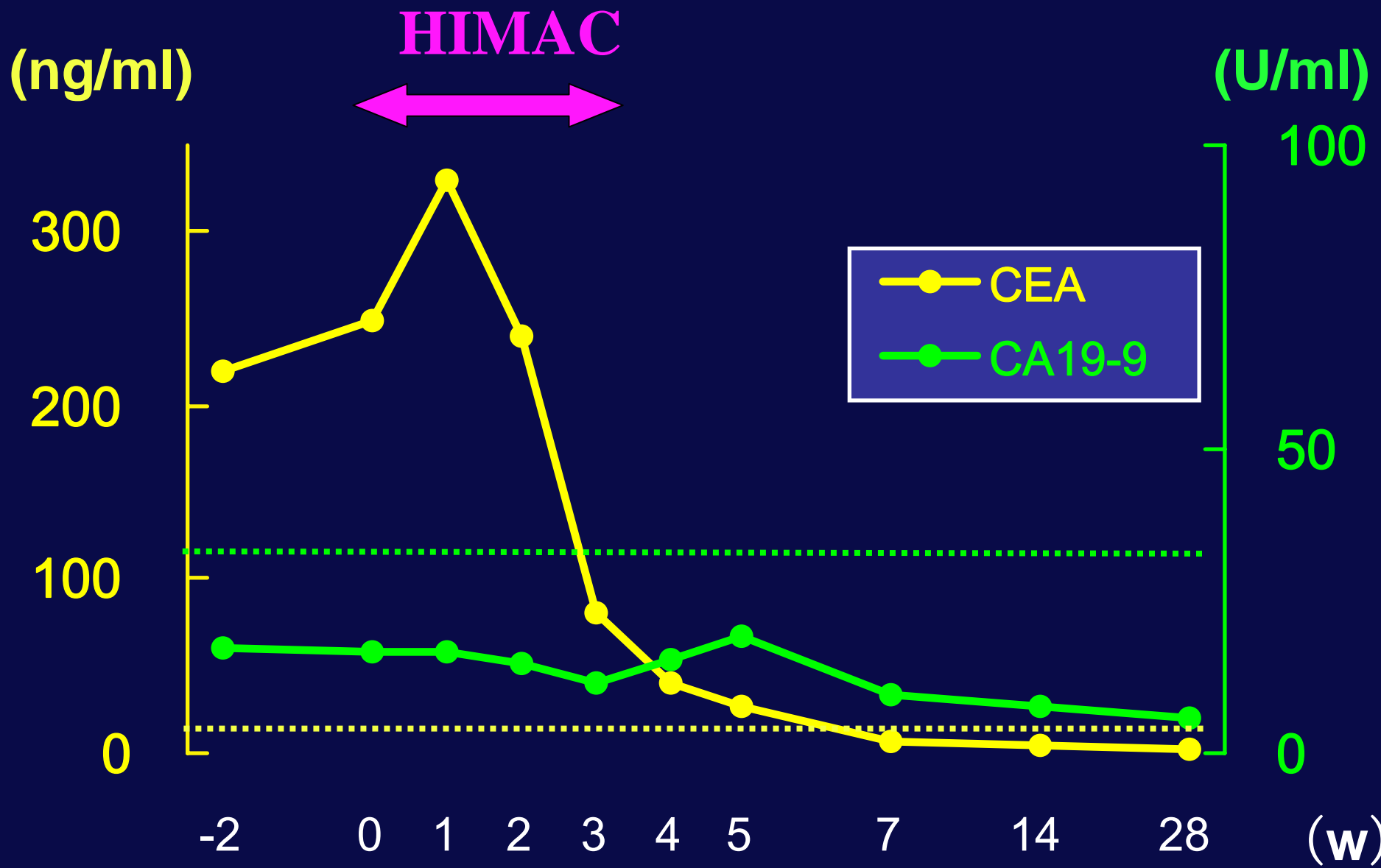


Before Carbon-Ion

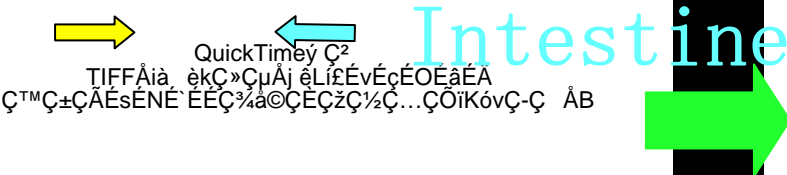
One Month After Carbon-Ion



Case5: Time Course of the level of CEA and CA19-9

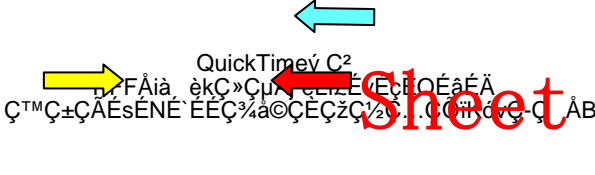


Case 6: 57y M Locally Recurrent Colon Cancer



Before Operation

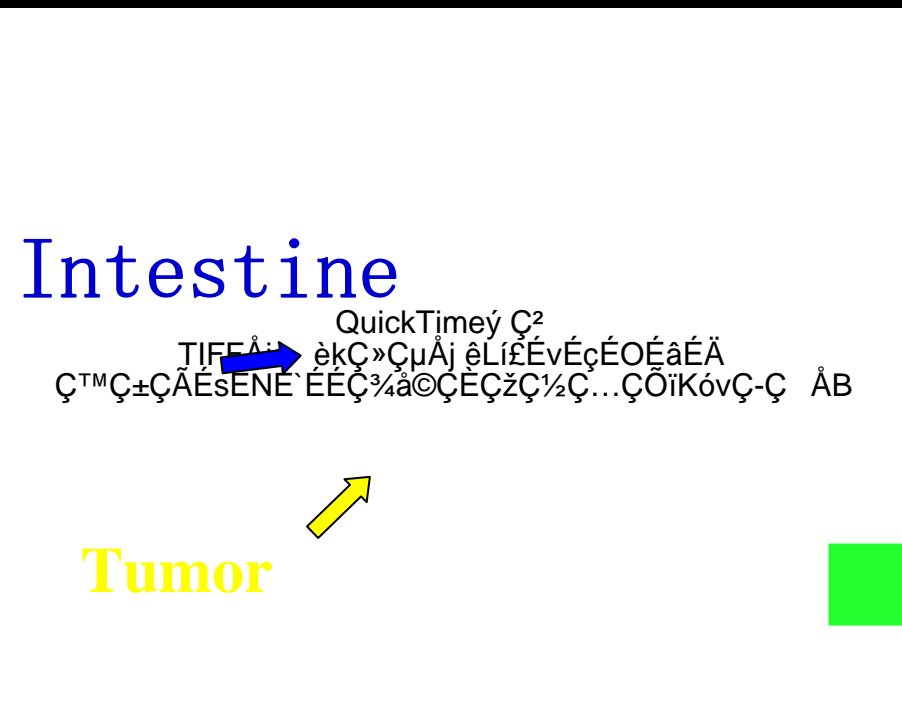
Dose Distribution



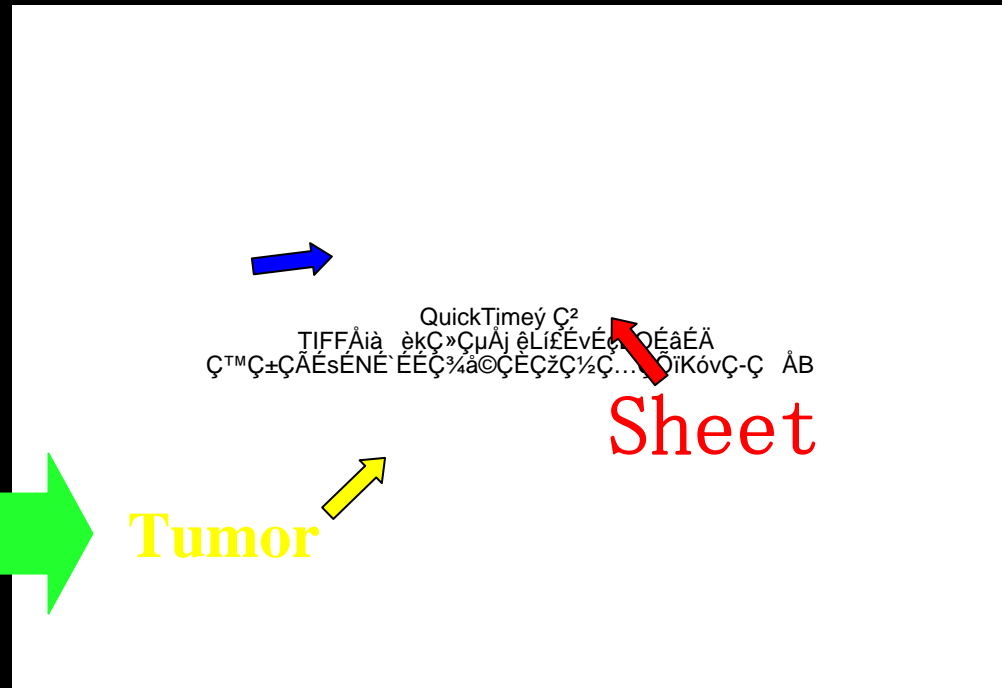
After Operation

4M After Carbon-Ion

Case 7: 79y F Ovarian Cancer

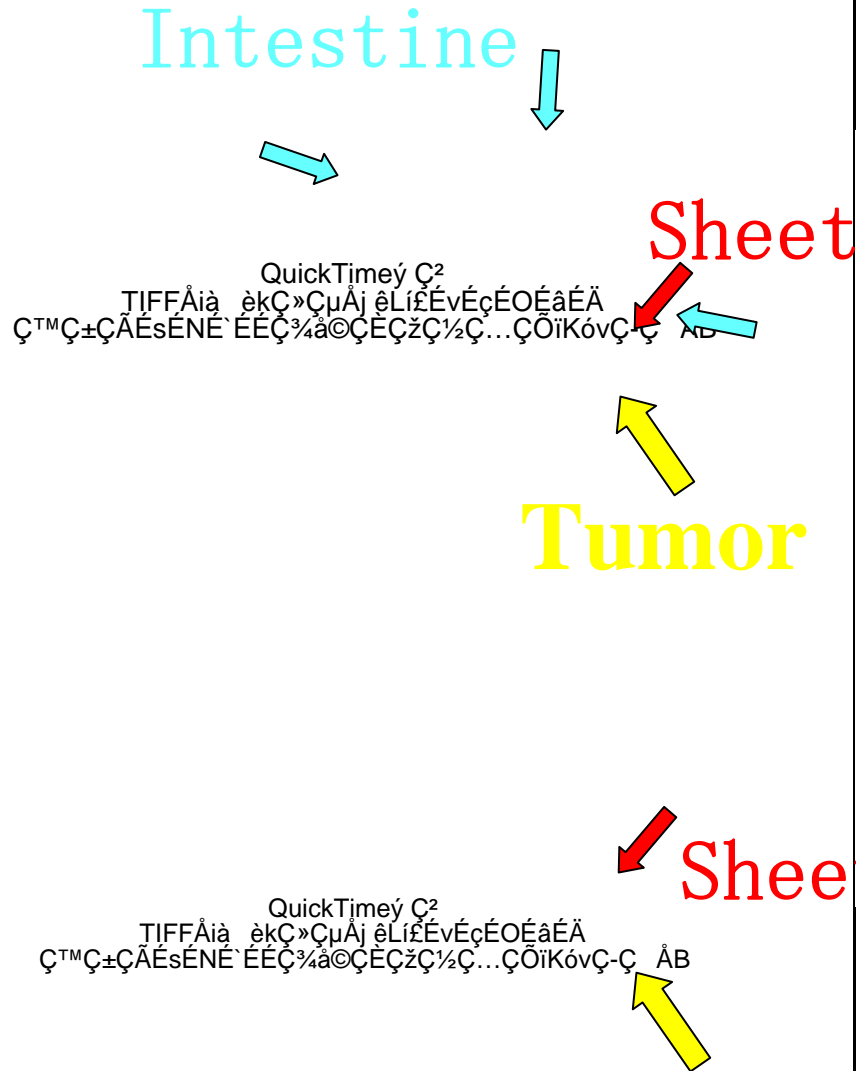


Before Operation



After Operation

Case 8: 42y F Osteosarcoma



Operative Findings

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Gore-Tex
Sheet

After Operation

Summary of patients used with Gore-Tex Sheet

No	Age	Sex	Site	Ope→ HIMAC	Complication	Follow
1	40y	M	preSac	16days	SubIleus	22M
2	44y	M	preSac	14d	none	15M
3	50y	M	Side Wall	39d	SubIleus	15M
4	38y	M	Anast	13d	none	10M
5	64y	F	preSac	10d	none	10M
6	53y	M	Anast	13d	none	9M
7	57y	M	Side Wall	10d	none	8M
8	59y	F	preSac	14d	none	8M
9	66y	F	Side Wall	14d	none	5M
10	69y	M	Side Wall	10d	none	5M
11	79y	F	Side Wall	12d	none	4M
12	42y	F	Side Wall	14d	none	4M
13	63y	F	Side Wall	10d	none	4M

CONCLUSIONS

Gore-Tex is a safe and effective implant material to prevent intestinal damages from carbon ion radiation in successful treatment of pelvic tumors.