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G. 知的財産権の出願・登録状況
(予定を含む)

1. 特許取得
なし。

2. 実用新案登録
なし。

3. その他

文献1　表A.　QALY算出に用いた有害事象のコストと効用値のモデル、および陽子線治療とX線治療の相対リスクを示す。過去の文献から割り出された値では、乳癌、前立腺癌、頭頸部癌、髄芽腫すべてにおいて、陽子線治療で相対リスクが低下している。

項目	従来のX線治療でのリスク	年間コスト(€)	効用値低下率	相対リスク**** (X線治療を1とした場合の陽子線でのリスク)
乳癌				
虚血性心疾患増加	43%[1]	初年度6466, 次年度以降616　*	10%	0.24
他の心血管系疾患増加	27%[1]	初年度4265, 次年度以降796*	20%	0.24
放射線肺臓炎	14%*	1706*	-	0.04
前立腺癌				
前立腺癌関連死	2.5%（15年間）	-	-	0.8
軽度放射線腸管障害	14%*	105.2*	7%*	0.6
重度放射線腸管障害	4%*	1774.9*	7%*	0.6
軽度放射線泌尿器障害	9%*	242.2*	7%*	0.6

重度放射線泌尿器障害	0.5%*	571.3*	7%*	0.6
頭頸部癌				
総死亡率	16%(8 年間) *****	-	-	0.76
歯科処置	-	初年度 1608.7、次年度以降 271.7	-	-
髄芽腫				
放射線二次癌による死亡	0.11%**	-	-	0.48
心臓病や他因死	0.056%**	-	-	0.77
聴力低下	13%	5054*	18%	0.12
IQ 低下	4.25 点	2448***		0.12
甲状腺機能低下	33%	114*	10%	0.12
成長ホルモン不足	18.7%	19 歳まで 13478、その後 1348***	20%	0.12
骨粗鬆症	2.4%	50 歳以降 363 ***	2%	0.12
致死的でない癌	0.32%	19565*	-	0.12

1. 一般人との比較。心疾患のリスクは放射線治療後１０年以降の生涯リスク。
* 1 事象毎あるいは 1 年のみ
** 1 事象毎、診断後 10～20 年間
*** 1 年毎、生涯に渡り
****陽子線治療対従来 X 線治療
*****平均値。診断後数年間が高い。

文献 1　表 B. 陽子線と従来 X 線治療との比較

	乳癌[1]	前立腺癌	頭頸部癌	髄芽腫	計
年間患者数	300	300	300	25	925
Δ 費用*	5920.0	7952.6	3887.2	-23646.5	
Δ QALY*	0.1726	0.297	1.02	0.683	
費用/QALY	34290	26776	3811	費用削減	
総費用差(€) **	1.8M	2.4M	1.2M	-0.6M	4.7M
総 QAL 差**	51.8	89.1	306.0	17.1	464.0

1. 心疾患のリスクが高いグループを治療したと仮定。

*患者一人あたり、陽子線治療 ― 従来 X 線治療。

** 1 年間治療された総患者に対して。

文献 2　表 A. 患者 100 人あたりの放射線誘発有害事象

変数	聴力低下	甲状腺機能低下	骨粗鬆症	成長ホルモン不足	非致死的二次がん	致死的事象
従来の X 線治療	11.9	16.3	0.4	17.1	1.2	1.91
陽子線治療	1.4	2.7	0.1	2.0	0.7	0.38
差	10.5	13.6	0.3	15.1	0.5	1.53

＊過去の報告から、患児の QOL が陽子線治療で改善が期待できる 100 人当たりの人数。

文献２　表 B. ５歳の髄芽腫を基本例として計算した費用と結果

変数	陽子線治療	従来の放射線治療	差
放射線治療費用（€ ）	10217.9	4239.1	5978.8
副作用費用(€)	4231.8	33857.1	−29625.3
総費用（€ ）	14449.7	38096.2	−23646.5
LYG	13.866	13.600	0.266
QALY	12.778	12.095	0.683
LYG: 生存年数の延長　；　QALY: 生活の質（QOL）質調整生存年			

＊それぞれの有害反応に対する薬剤費や、有害反応による患者の能力低下による生産性の低下を考慮すると、陽子線治療のほうが対費用効果も優れていることがわかった。

＊一つの陽子線治療施設が、髄芽腫だけで施設を維持するためには、年間１１０例の髄芽腫を治療する必要がある。

＊しかし、仮に髄芽腫だけの治療で施設維持が不可能であって、費用節約(cost-saving)にならなくても、陽子線治療は明らかに対費用効果が優れている(cost-effective)。

文献２　表 C. 費用と活動性の差：陽子線治療と従来 X 線治療

費用発生源	費用の差（€ ）	効用値の差
全体の差	-23646.5	0.683
放射線治療	5978.8	-
知能指数低下	-12206.9	-
聴力低下	-2735.5	0.057
成長ホルモン不足	-14263.2	0.367
甲状腺機能低下	-202.0	0.009
骨粗しょう症	-18.3	0.001
致死的＋非致死的二次がん	95.6	0.021
他の致死的有害事象	-	0.230

文献３. 表. 局所直腸癌再発への従来化学放射線治療と重粒子線治療の増分費用効用比

治療方法	著者	年	症例数	５年生存率（%）	５年局所制御率（%）	再再発による費用(¥)	無病生存率の ICER(¥)	1%生存率増加あたりの ICER(¥)
従来治療法	Willet et al	1991	30	27	38	1752218	10424	12205
	Bussierses et al	1996	73	31	29	1337219	20300	16343
	Valentini et al.	1999	47	22	31	1429441	16769	9271
	Wing et al	2000	107	30	50	2305550	6323	15066

平均			64	27.5	37	1706107	13454	13221
炭素線	Tsujii et al	2008	90	42.8	19.5	936770		

ICER, Incremental cost-effective ratio （増分費用効果比）

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髄芽腫への放射線治療による内分泌機能障害発生率に関する陽子線治療の従来 X 線治療への優位性

（米国臨床腫瘍学会 ASCO 2010 より）

線種	施設・出典	解析対象数	内分泌障害発生頻度（%）
X 線	Ribi, eta al. Zurich University Neuropediarics, 2005, 36(6), 357-65	51	31 (61%)
X 線	Yasuda, et al. 北海道大学 Jpn J Clin Oncol, 38(7), 486-492	16	8 (50%)
陽子線	Yock et al. Massachusetts General Hospital ASCO Proceedings, 2010	59	17 (29%)

研究成果の刊行に関する一覧表

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ARTICLE

The PTSim and TOPAS Projects, Bringing Geant4 to the Particle Therapy Clinic

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Though the Geant4 Simulation Toolkit has been widely accepted in the particle therapy community, with research and clinical use at most of the major centers currently involved in this innovative approach to cancer treatment, the high level of Geant4 expertise required for these applications has proven a serious barrier for users. The PTSim collaboration in Japan and the TOPAS collaboration in the United States wrap and extend the Geant4 toolkit to meet the needs of this critical community. PTSim has provided a common platform to model three Japanese proton and ion therapy facilities plus three more in other countries, allowing users who are not Geant4 experts to accurately and efficiently run Geant4 simulations for any of these pre-built configurations. Building on a rich history of proton therapy applications at MGH (site of the world's first proton therapy system), NCC Korea, and elsewhere, the TOPAS project aims to take flexibility further, allowing any particle therapy clinician or researcher to Geant4-simulate their own real or envisioned facility still without requiring a Geant4 expert. We describe these projects, how their designs bridge the gap between flexibility and ease of use, what key missing software components they have contributed and how the two projects may evolve together.

KEYWORDS: particle therapy, ion therapy, carbon therapy, proton therapy, Monte Carlo, simulation, Geant4

I. Introduction

Geant4[1, 2] is a software toolkit to simulate the interaction of particles in matter. It has been widely used in various fields from high energy physics (HEP) to nuclear physics to space and medicine. A key area for Geant4 in medical physics has been particle therapy, radiation therapy performed with protons or heavy ions.

Particle therapy promises improved treatment and reduced side effects for many cancers compared with other therapeutic options such as x-ray or surgery. Thirty-five particle therapy centers are currently in operation world wide, with at least twenty-five more currently in planning or construction.[3] Monte Carlo simulation can be helpful in design of such treatment facilities and in the comparison of treatment plans. Such Geant4 simulations have been carried out at many institutions with good agreement to measurement.[4, 5]

While Geant4 has been heavily used in medical physics research, applications on the clinical side are limited by issues of computation speed and, more importantly, the level of Geant4 expertise required to perform these simulations. Key differences between the needs of clinical medical physics and those of Geant4's original user base, high energy physics, result in needs not met by the already rich toolkit of Geant4.

In parallel with improvements to accuracy and speed within Geant4 itself, groups of Geant4 developers and medical physicists have formed focused projects to address the specific needs of this community for reliability, repeatability, geometry, accuracy, speed, functionality and ease of use.

This paper describes two such efforts, one in Japan, PTSim (Particle Therapy Simulation),[6] and another in the United States, TOPAS (TOol for PArticle Simulation). Both projects are designed along principles of Object-Oriented technology, are implemented like Geant4 in the language C++ and have committed to make their software freely available. The goal is that all users of particle therapy facilities, researchers and clinicians, should be able to exploit Monte Carlo simulation with improved reliability, repeatability and ease of use.

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