



Trends-in-Medicine

September 2004

By Lynne Peterson and D. Woods

SUMMARY

Hospitals have money in their budgets for linear accelerators, and they generally are purchasing new IMRT-capable machines rather than upgrading older machines.

◆ IMRT is becoming more mainstream, but the market is not yet mature. Reimbursement is expected to decrease, but that is not likely to affect usage. ◆ Sites that have IMRT are using it; very few IMRT-capable linacs are not being used for IMRT.

◆ IGRT is still relatively new, and few hospitals and clinics other than leading-edge institutions plan to purchase it in the next year, but an average of 33% of sources said they plan to adopt it within four years – as new equipment, not upgrades.

◆ TomoTherapy is attracting a great deal of interest, and sources view it as a serious threat to Varian, in particular, but few institutions plan to buy it in the next year.

Trends-in-Medicine has no financial connections with any pharmaceutical or medical device company. The information and opinions expressed have been compiled or arrived at from sources believed to be reliable and in good faith, but no liability is assumed for information contained in this newsletter. Copyright © 2004. This document may not be reproduced without written permission of the publisher.

Trends-in-Medicine

Stephen Snyder, Publisher

1879 Avenida Dracaena

Jensen Beach, FL 34957

772-334-7409 Fax 772-334-0856

www.trends-in-medicine.com

INTENSITY MODULATED RADIATION THERAPY (IMRT)

To check on trends in radiation therapy equipment, 49 (46 U.S. and three non-U.S.) physicists, radiation oncologists, and other experts were interviewed, most at the American Association of Physicists in Medicine (AAPM) meeting in Philadelphia PA from July 25-29, 2004.

Intensity modulated radiation therapy (IMRT) allows extremely precise external beam radiotherapy treatments for prostate cancer, metastatic brain tumors, primary brain tumors, head and neck cancers, as well as other cancers. Because IMRT is so precise, higher than normal daily dosages can be used, resulting in shorter treatment times. IMRT software links treatment planning with delivery, resulting in a more optimal radiation dose for the patient.

IMRT has become must-have equipment at most hospitals and cancer clinics. A New England radiation oncologist said, “My medical center has three Varian linear accelerators (linacs), and two are IMRT-capable. IMRT is a natural evolution, but not inexpensive.”

Among the sources questioned, IMRT is now available at all but three U.S. sites, and all of those plan to add IMRT or IGRT over the next year. A physicist at an Ohio hospital which is planning to add IMRT said, “We hope to have IMRT in the next year. We are putting together an RFP (request for proposal) now.” A Washington state facility also plans to add a new IMRT-capable linac within the next six to nine months, and a physicist there said, “It will probably be a Varian with IMRT, not IGRT.” A West Virginia hospital plans to replace its old non-IMRT linac with a Siemens linac machine with IGRT.

Linear Accelerator and IMRT Usage at U.S. Hospitals/Clinics

Linear Accelerator	Current Linear Accelerators (n=176)	IMRT-capable	% of in-place linacs that are not IMRT-capable (n=52)
Varian	58%	66%	56% (29 linacs)
Elekta	17%	57%	19% (10 linacs)
Siemens	15%	54%	25% (13 linacs)
Not specified	10%	---	0

Sources at three non-U.S. hospitals were interviewed, and two of these currently have IMRT. The exception was a hospital in New Zealand, and a physicist from there said, “We have 20 linacs, mostly Varian, but no IMRT – because there is no IMRT in New Zealand yet.” Sites that have IMRT are using it. Only two sources said their facilities have linacs with IMRT-capability that are not being used. A Pennsylvania physicist said, “That’s a management problem.” Another source

said, “We have two new Siemens linacs and one Varian linac, all with IMRT, but the Varian isn’t used because it is five years old.”

A couple sources bemoaned the fact that so many hospitals are adopting IMRT. One said, “The concern I have is that IMRT and IGRT are not an advantage for everyone to jump into, but, because of reimbursement, everyone thinks they need one, and that results in inadequate physicians and inadequate staffing. Is the imaging totally used? I’m not sure it is.”

IMRT – A CONTINUING TREND

Twenty-six of the 46 U.S. sites have at least one linac that is not IMRT-capable, but only six of these plan to upgrade existing machines.

U.S. IMRT Upgrade Plans

Site	Linacs without IMRT to be upgraded
Washington	1 Varian or Elekta
Colorado	1 Varian
New York	1 Varian
Indiana	2 Varians
Virginia	1 Siemens
Georgia	2 Varians

Instead of upgrading, most sites plan to purchase new linacs with IMRT capability, and nearly half (18) of these U.S. hospitals and clinics plan to buy one or more new IMRT-capable linear accelerators during the next 12 months.

- *Florida #1:* “We will replace two old linacs this year because they are near the end of their lifecycle. We are spending a lot of time here (at AAPM) looking at the different equipment. The issues that will tip the scale are features, what the technology can do, and implementation.”
- *Florida #2:* “We are building a new cancer center, and we will get Varian linacs, all with IMRT.”
- *Georgia:* “We plan to buy a Varian within a year, with IMRT. We will go with Varian because we feel it is best to match treatment planning and verification system; it’s important to mesh with the same vendor.”
- *Ohio:* “We are hoping to put together an RFP now for a linac with IMRT.”
- *Texas:* “We have 12 linacs, and by the end of the year we will have 20 linacs. Of the 12 that we have, nine are IMRT-capable and all of the new ones will be IMRT-capable. All of the IMRT machines are Varian.”
- *Washington:* “We plan to get a new IMRT-capable linac within six to nine months. It will probably be a Varian with Pinnacle TPS – but IMRT, not IGRT.”
- “I’m here (at AAPM) to come up with a plan to buy new linear accelerators.”

A few sources planning to get a new IMRT-capable linac want to wait a little longer; their plans are for new IMRT-capable linacs within the next three years, but probably not within the next year. An Indiana physicist said, “We want a new linac, but not in the immediate future. Money is a consideration.” A physicist at a Utah hospital said, “We currently have five linacs. We are done (buying) for now, but we will buy more in three to five years.” A Pennsylvania physicist said, “Maybe in two years, we’ll buy a new linac.” A West Virginia physicist said, “We are getting ready to build a new hospital in three to five years, and we will upgrade then.”

Several other sources commented that they weren’t sure about a purchase, but if they do buy a new linac, they insisted it will be IMRT-capable.

Linear Accelerator and IMRT Plans at U.S. Hospitals/Clinics

Question	Usage Outlook
Purchase Plans	
Buy new linac in the next year	46%
% of new linacs that will be IMRT-capable	100%
% of non-IMRT linacs to be upgraded	47%
% of Linacs with IMRT-Capability	
Currently	56%
In 1 year	70%
In 2 years	79%
In 3 years	83%

Vendors Being Considered for IMRT Purchase

Vendor	Number of sources considering
Varian	6
Elekta	3
Siemens	1
TomoTherapy	2
Varian and TomoTherapy	2
All (Varian, Elekta, Siemens and TomoTherapy)	4
Not specified	5

Sources generally agreed that the IMRT market is not yet mature. A Texas source said, “There is still lots of growth potential for IMRT. Varian has been selling IMRT-capable linacs for years. Many small clinics and smaller hospitals already have IMRT-capable equipment, but they need the treatment planning pieces and ancillary support training.” Elekta’s CEO said there has been a slowdown in the U.S. but the Asian market remains strong, “We are looking at capital purchases here... There are a lot of hospitals that haven’t been around for a long period of time, and a lot of capital dollars are being funneled into building renovation rather than capital equipment. That is part of the slowdown process that occurred earlier in the year. Concerns about the economy, cost structures, and reimbursements are always part of it as

well...I'd say that there is growth market in Asia where the markets aren't as saturated as they are in the West. But I think the market here in the U.S. is far from saturated. This is new technology...I'd say image-guided visualizing surgery is the wave of the future, and non-interventional is the way of the future – it's here now and here to stay. We just have to get better at what we do in technology.”

IMRT is becoming more mainstream, with sources crediting increased competition among hospitals as well as generous reimbursement. A Pennsylvania source said, “More and more hospitals are practicing IMRT and it is becoming more popular and more mainstream...The number of patients benefiting from IMRT is growing because physicians like fancy technology, and state-of-the-art technology is better for the patient.”

Sites that have IMRT are increasing their use of it. On average, sources use IMRT for 24% of radiation therapy procedures. A Texas source said, “I'd say that 30% of our current radiation treatments benefit from IMRT, and the patient load is expected to grow significantly over the next several years. We get 4,600 new patients a year, and, with long-range planning, we expect 5,000 to 10,000 patients a year.” An Indiana physicist said, “We use IMRT mainly for head & neck cancer and prostate cancer.” A Texas physicist said, “The patient load is expected to grow significantly.”

TREATMENT PLANNING SOFTWARE

Radiation treatment planning software uses sophisticated algorithms to manipulate gantry arms, radiation beam length, duration, and intensity. Sources said they use a wide variety of treatment planning software (TPS) vendors and were mixed as to what they consider the best. One source said, “Although Varian is the Cadillac of linacs, it is not a leader in IMRT software. Pinnacle was the highest rated TPS before IMRT. Now, it's spread around – CMS, Nomos, Varian. There is no clear software leader.” A Canadian physicist said, “All the TPS is comparable.” A Washington source said, “We are getting a new Varian with IMRT, but with Pinnacle TPS, because we have Pinnacle for standard treatment planning, and it is the easiest transition.” A Virginia physicist said, “I think CMS is more user-friendly (than Varian).” A West Virginia source said, “Changing your TPS vendor is a big deal and a major effort, so it is not done easily.”

TPS at U.S. Hospitals/Clinics

Company	TPS	Usage
Philips/ADAC	Pinnacle	42%
Varian	Eclipse	26%
Nomos	Corvus	19%
CMS	Focus	9%
Elekta	PrecisePlan	4%
Nucletron	TheraPlan Plus	

However, a Varian official said Varian is gaining ground, “Varian is No. 1 in sales today, ADAC's Pinnacle No. 2, CMS No. 3, and Nomos No. 4, but in terms of installed base, ADAC is No. 1 and CMS No. 2. There are about 18 different companies with TPS.”

Several sources agreed that Varian's software is improving. A Pennsylvania source said, “Varian's software is getting better and more popular.” Another physicist said, “ADAC is better (than Varian) in terms of logarithms and other things. However, Varian is catching up, and (Varian's) Eclipse now costs much less than ADAC. I'm going to train next week on Varian's new software version, and we're planning to buy it. It's really very good and will do a number on ADAC and the others. Varian's 6.2 version of Eclipse was terrible, and we decided to use Impact. But I saw the latest version in Las Vegas and the 7.x versions will be killers. Down the road, Varian will kill the competition; it's like Microsoft – so big that it has more than half the market.” A Maryland physicist said, “We use Pinnacle software. Varian software isn't as widespread as ADAC, which is used by 60% - 65% of people. Varian is expensive, and we're happy with Pinnacle.” A Florida source said, “Varian doesn't work as seamlessly as ADAC software. We've always had ADAC.” A Minnesota physicist said, “We have Nucletron's TheraPlan now, but we are getting Varian's Eclipse.” A Texas physicist said, “We have Eclipse, but we aren't using it yet. We are in the evaluation phase. We are studying how to use it. We have a long history with Nomos, and we bought Pinnacle in 1995, so there is a lot of experience and history with those systems. We are actively evaluating the Varian software, though we didn't buy Eclipse bundled. There are some efficiencies with it, more integration.” A Colorado source said, “We like ADAC Pinnacle. It's the best software. We use it because it's a better product. I don't think Varian does software very well, but I heard that the new Varian contouring tools are very impressive. I'd say that Varian software is cutting into ADAC sales because Varian is giving it away...People do like (Varian's) Eclipse; I'd say it is a good system.”

IMAGE GUIDED RADIATION THERAPY (IGRT)

IGRT is an enhanced version of IMRT, with the ability to integrate diagnostic imaging data with the beam control device to compensate for movement of internal organs and tissues within the body during a radiation procedure. IGRT provides more precise targeting than IMRT, with even less damage to surrounding tissue. It uses a CT scanner and computer modeling to determine field size, taking into account breathing, because patients are unable to hold their breath for the treatment. IGRT is aimed at specific cancers, where a patient's breathing is a factor in determining where the tumor is. As in IMRT, multiple layered collimators are used to modulate the dose to different areas. A New England physicist said, “IGRT is going to open up a whole new world. IGRT is just beginning...With IGRT, the medical physicist

will be responsible for the technology. It is the beginning of a true evolution, a new phase of radiation oncology.”

IGRT is viewed as the next technological step, but it is still considered too new for widespread adoption. A Pennsylvania physicist said, “There are still many unclear problems with IGRT – and many unsolved problems. My understanding is that you have to predict tumor motion based on the image. In research, that isn’t a problem, but, practically, there are many problems and complicated issues. And if something fails, it’s a disaster for the patient, so we’re not ready for that.”

Only two sources have any plans to purchase IGRT in the near future. A West Virginia physicist is getting a Siemens to replace an old linac with no IMRT, and a New York hospital is getting a new IGRT-capable Varian linac.

IGRT is viewed as more complex and time-consuming to use than IMRT. An Indiana physicist said, “If a target is within the body, it’s usually moving due to breathing, and other things. The lung, abdomen, and other tissue are exposed, and so IGRT is more time-consuming.” A Texas physicist said, “IGRT definitely takes longer to do. Right now, it’s in its infancy, but it will become more efficient with time.” Another source said, “IGRT is more time-consuming, but it’s worth it.” A fourth source said, “Trying to image in between and during treatments will have the same aspects as IMRT, but it will take longer. Delivery is no different; however, the imaging part may take longer.” A fifth physicist said, “Initially it is more time-consuming, but we expect it to become more efficient as it becomes more common, and the time will gradually go down. But the time won’t affect our usage.”

Several sources said that IGRT is not yet ready for prime time. One commented, “IGRT is not as mature as IMRT by any stretch of the imagination. All the issues – for example, quality assurance and clinical technique – are not fully worked out.” Another source said, “There are still a lot of questions about IGRT. It is still largely untested.” An Indiana physicist said, “IGRT is still relatively new and many issues are not solved...Using markers on the outside of the body doesn’t necessarily correlate with what’s happening inside the body, so IGRT is still in the early stages of development. However, we’re always looking for the newest and best technology. The question is, can you improve survival rate 5% or more? If yes, then it’s worth it. If it’s only 1%-2%, then I’m not sure.” A Georgia radiologist said, “IGRT is so new that we are mainly gathering information right now. It will be at least a year before we get it.” A Siemens official said, “IGRT will take time to catch on. People have just started thinking about how to use it to affect treatment decisions. Right now, there is reimbursement only for the U.S. and for IMRT – not for IGRT.”

Some sources mentioned that IGRT is not reimbursed the same way as IMRT, even though it costs more. That could be an issue if hospitals were ready for IGRT now. A Texas physicist said, “IGRT is not reimbursed, and that’s going to be

a factor when it comes to purchasing decisions. Not all clinics are driven by money, but they have to be reimbursed. Money is always considered, even at our clinic!” Another source said, “We hope to get IGRT, but the key question is, ‘Is someone going to pay for it?’ It’s not reimbursable, so if someone isn’t going to pay, the answer may be ‘no.’” A third physicist said, “There is a real shortage of capital across the country...It is not an inexpensive acquisition, and hospitals are having to weigh whether to buy an IMRT- or IGRT-capable machine or a new cath lab. Hospitals are faced with tradeoffs, equipment is getting more and more expensive, and access to capital is getting more and more restricted.” Elekta’s CEO said, “I don’t know if IGRT will be a reimbursable procedure; it’s specifically designed, so I think it would be reimbursable. The key consideration is that if image-guided and beam therapy can keep patients out of the hospital, then all the technology we’re providing makes a lot of sense.”

Yet, most sources believe IGRT will soon become mainstream. A BrainLab official said, “In two years IGRT will be a different world at this (AAPM) meeting.”

Over the next four years, an average of 33% of sources plan to adopt IGRT. A physicist said, “We are going to eventually get it, but, in general, IGRT is probably three to five years away.” A Maryland physicist at a private clinic said, “IGRT brings everything to a new plane.” A Texas source said, “We are actively working on developing IGRT within our institution. IGRT is a moving target, and technically we are doing some of it, and we plan to expand that dramatically.” A New England physicist said, “IGRT won’t take long to catch on; it’s another critical step.” A West Virginia physicist said, “We may get IGRT in four years. We just got IMRT off the ground, and I convinced our administration to buy it. IGRT is something I will have to convince our president to get.” A Missouri physicist said, “There is no reason not to buy IGRT. You have to move with the technology. In 10 years we will wonder how we treated all these patients without it.” Another physicist said, “More centers are feeling the need to start offering it.” Another source said, “IGRT is just beginning...and with it we are seeing the beginning of a true evolution – a new phase of radiation oncology.”

On average, sources estimated that 38% of patients treated with IMRT would benefit from IGRT. A New Jersey source said, “Most IMRT patients would benefit, especially lung cancer patients.” A Georgia source said, “A lot of the IMRT patients would benefit because we do a lot of prostate cancer.”

Varian’s cone beam CT software delay is not affecting the decision by these sources to buy IGRT – most sources just aren’t ready for IGRT yet. A radiation oncologist said, “I’ve not seen the cone therapy that everyone is playing with, but in concept it could be a powerful addition. So, once they get the cone working, in a rapid fashion, user-friendly environment, it will be a powerful tool. What Varian is doing is putting the cone-data acquisition on these things to breathe new life into them, so they can acquire a volume. They can use them as CT

scanner applications, sort of breathing new life into the conventional simulator market.” A Florida source said, “It’s not a big problem, but it is a concern. If we were shopping for IGRT, it would delay the purchase, but we aren’t shopping yet...But the hospital wouldn’t let us do a purchase that big if we can’t use it.” Another Florida source said, “It is not necessarily a negative, but the quality is not there yet.”

Each of the three major vendors has an IGRT product. A Massachusetts physicist said, “It won’t hurt Varian being second, and it won’t hurt Elekta being first. For Varian, one year won’t make or break that company; it’s how they do over several years that matters. How they do in the long run, that is what will make the difference. It’s a five year window. By that time – and the community is small – everyone knows what’s going on. So, in five years, people will know what’s up.”

THE MARKETPLACE

Sources agreed that there is no geographic pattern to U.S. linac or IMRT adoption, except that it has been adopted faster in metropolitan areas. The CEO of Varian commented that distribution is fairly even geographically and between major medical centers and community hospitals.

Several sources suggested that both TomoTherapy and Varian are candidates for a buy-out, but officials of those companies denied they had any interest in that. Among the speculations:

1. **That GE would buy Varian.** A source said, “GE (which is a strategic partner with Varian) would be a tough cultural fit.”
2. **That GE would buy TomoTherapy.** TomoTherapy officials insisted they are not interested in any buy out, and GE is an unlikely candidate in any event since it was an early financial backer of TomoTherapy but pulled out.

Competition

Elekta and Siemens are considered Varian’s biggest competitors when it comes to linacs and service, though TomoTherapy presents a growing threat. Sources were equally divided as to which of these companies is challenging Varian the most in linacs. There was little differentiation in service. In TPS, ADAC’s Pinnacle was the clear leader, but Varian is gaining ground with its Eclipse software. Sources offered these comments on how Elekta, Siemens, and Varian compare.

- *West Virginia:* “We are very happy with Varian. I’ve worked with the other two, and I would be happy with Elekta as well. Elekta and Varian are comparable.”
- *Hospital physicist:* “Elekta is working hard, but, in our community, Varian is still getting accelerator sales. Varian throws the big packages together and gives you the treatment planning software.”

- *Virginia:* “Varian does a better job than the others in service and in reliability.”

- *Canadian physicist:* “I would stay with Varian if we bought a new linac. The MLC is better with Varian than with the others. The software is comparable, but the advantage is the accelerator itself.”

- *Elekta consultant:* “Of course, we think Elekta is the most competitive against Varian. Varian is popular and well established in the US. Elekta is number one worldwide and Siemens also has a good reputation. For services, which is an important factor, today’s machines are so sophisticated that the big centers have their own service engineering group.”

- *Washington radiation oncologist:* “It’s a very competitive market right now. Varian does have the number one share and its sales force is very attentive. Elekta is trying very hard and maybe has knocked Siemens down to number 2.”

- “Siemens, Elekta and Varian are variations of the same thing.”

Pricing

The IMRT market is becoming increasingly competitive, in terms of price as well as players in the market, though sources were not aware of any significant discounting of software. The level of competition in linacs is viewed as more competitive now than when IMRT was launched in the 1990s in terms of linacs and treatment planning software, but sources did not have an opinion about the competitiveness of services. No single vendor stood out as more competitive than the others among these sources.

Of the sources commenting, only one source plans to change vendors, and two are considering a switch. One of these said, “We have Siemens, but we probably will go with Elekta for our new IMRT.”

Nineteen sources said that they are unlikely to switch vendors in the next several years, even for a better price. A New England physicist said, “People often select vendors and stick with them for many years. Service and support are intangibles.”

Several sources complained that pricing is not straightforward, making it difficult to compare prices. One explained, “There is so much dealing going on that it is impossible to compare prices. And you can’t call another hospital and ask what they paid for the same product you are considering because the companies make them sign non-disclosure agreements. It is very difficult.” A Washington radiation oncologist said, “The prices among vendors are all becoming very competitive; they’re after each other. Software, too, is all over the place and, again, very competitive.” A Florida source said, “There is a lot of negotiating and special prices, so it is hard to know what people are really paying. But there is a lot of competition going on.” A Georgia source said, “Pricing is comparable.”

Varian is a little more expensive, but it's a little ahead of the game. Pricing doesn't play that large a factor in our process. As long as we feel we are getting the very best price, we rarely even price the others." A Utah physicist said, "I think the level of discounting is increasing." A Michigan physicist said, "There is a lot more competition now. The vendors all talk about it." Elekta's CEO said, "It's a highly competitive market, but Elekta is aggressive in the marketplace and is trying to make a difference. We're bundling, we will finance, and we will do creative things to get equipment into hospitals that need to have them."

Although cost is a factor in purchase decisions for linacs and IMRT, most sources said cost would not prevent them from upgrading or purchasing new equipment. Hospital budgets are tight, but sources agreed that the money is there for radiation equipment if the department requests it. A Cardinal Health official said, "Hospitals are spending on IMRT and IGRT. Reimbursement is down, but it is still very good. Partly, people have a buy now attitude, before it gets to where it is not profitable."

Reimbursement

Generous reimbursement has been a factor in the decision to purchase IMRT-capable linacs. However, sources expected IMRT reimbursement to decrease this fall and to continue to decline, but gradually, and they don't expect this to affect their use of IMRT or the demand for the technology. A New Jersey physicist said, "I expect reimbursement will go down some, but that won't slow use. The early users paid off their linac in the first year. The per-patient revenue will go down. But the number of patients will go up, so the total department income will go up." A Midwestern physicist said, "We expect reimbursement to go down, but that really won't affect our purchasing plans." A Utah physicist said, "CMS reimbursement does pretty well...Down the road, sometime this year, we do expect reimbursement to go down, but we still plan to buy more linacs in the next three to five years." A Maryland source said, "Reimbursement is good. We know that CMS will decrease it in the fall, and that means we'll have to do more work for the same amount of money." A radiation therapist said, "We expect reimbursement to decrease, but that won't affect us." Another source said, "IMRT is being reimbursed at a significant rate, and that is driving a lot of IMRT utilization. A lot of people are getting into it because it is an advantageous business to get into. Reimbursement will come down and will certainly make IMRT less attractive, but it won't affect us. For those patients who use it, we find it's in their best interest – for head and neck, prostate, mesothelioma, etc." A Florida source said, "Reimbursement will go down. I expect a 30% reduction. Our job is to streamline things and find more efficient ways to use IMRT."

THE VENDORS

BRAINLAB

An official said this company has about 35 dedicated Novalis systems installed in the U.S. and 150 component add-on systems (M3) worldwide. This year, BrainLab expects to sell about 15 systems in the U.S. A source said, "We had a strategic partnership with Varian in stereotactic business, but that is now becoming competitive...Varian tried to buy BrainLab, but it hasn't been successful – yet." BrainLab is the market leader in stereotactic surgery with its Gamma Knife.

ELEKTA

Several sources said they prefer Elekta products.

- *Maryland*: "Elekta is very easy to use and is very straightforward, though the cost of its products, especially Synergy, is very high...Elekta is a very practical unit."
- *Netherlands*: "I'm biased toward Elekta, which has great technology. And Elekta software is very good, even though most people use ADAC's Pinnacle."
- *Massachusetts*: "I have a good opinion of Elekta. They have lots of experience."
- *West Coast*: "Elekta is more on target when it comes to keeping the image on the machine, no pun intended. You don't want to be moving the patient around. I think that the Varians have become dinosaurs."

The one complaint about Elekta was service. An Elekta consultant and university hospital physicist said, "Something that irritates me is that some Elekta components come from England, so there can be a 24-hour delay. Still, that hasn't been that big a problem for us, but for some they can be down for three to five days. I established our own service and engineering group in house; 60%-70% of problems are minor and should be taken care of in-house." Another source said, "I sometimes get aggravated with Elekta because of the service; we often have to wait for parts from England. But most of the time they're extra careful, and we have their Gamma Knife, too, so they pay attention to us. So we are satisfied with Elekta. However, I still feel Varian does a better job in service and reliability." An Elekta official said, "We have had no reliability issues since 1996."

Synergy. This was the first linear accelerator capable of performing IGRT. Elekta is taking orders for Synergy, but only one site is known to be operating.

- **Pro.** A Pennsylvania source said, "We are getting four Synergy machines." A Michigan physicist said, "Being first is definitely an advantage (for Elekta)."
- **Con.** An Indiana source said, "Elekta isn't really gaining momentum at all. Instead, I think Elekta had to try to catch up to Varian's lead. Varian isn't much beyond Elekta; Varian is just installing IGRT at (a few locations)." A Utah source said, "Elekta is still behind

Varian in technology.” A Maryland source said, “First to market won’t really make a difference.”

Asked what technology will follow IGRT, Elekta’s CEO said, “I think next is faster plates, faster imagery construction – so you can deliver the external beam therapy more accurately, so your margins stay better, and so that patients have a higher recovery rate without engrossing good tissue.”

SIEMENS

Siemens is viewed as an increasingly strong competitor to Varian, and Siemens is considered to be the most aggressive of these three vendors.

- *California:* “We can’t do Siemens CT-on-Rails because our vaults are not big enough even though we just built four new ones. KV-CT gives better soft-tissue definition. The MV-CT is not as good. But if MV-CT pans out, it won’t be hard to implement. We could upgrade that quickly. The KV might take longer.”
- *Florida:* “Siemens is very aggressive, especially on price.” A Maryland physicist said, “I was interested in Siemens last year, but the cost is pretty high. Siemens has high-resolution imaging, but it isn’t good for speed.”
- *New Jersey:* “Siemens machines are less expensive than Varian. The top end Siemens machine is comparable to a mid-line Varian.”
- *Pennsylvania:* “Siemens is less expensive than Varian, but it is also less reliable than Varian.”
- *Virginia:* “We have a Siemens, and I like that. We are looking at (Accuray’s) Cyberknife for next year.”
- *Colorado:* “I like Siemens very much. Siemens is as reliable as Varian. It makes good machines.”
- *Belgium:* “Siemens, Elekta, and Varian are variations on the same thing. Siemens is more original. Varian and Elekta are looking for immediate solutions that are harder to improve on. Siemens is taking a longer look.”

There were some criticisms of Siemens reliability. A Texas physicist said, “Siemens has a reputation that its machines are not reliable in heavy-load clinics.” A New Jersey physicist said, “Varian is doing better than Siemens in New Jersey because of the downtime with Siemens. Siemens has also had a lot of problems with machines acting up, and they often can’t be fixed on site. I’ve heard of ball bearings on the floor. Siemens offers cheaper machines and great deals, but there is a lot of downtime. Elekta is better than Siemens. They don’t break down like Siemens.” Another source said, “Siemens is getting there, but Varian is much better and more reliable.”

However, other sources defended Siemens’ reliability. A California source said, “We are an all-Siemens shop... We have no excessive problems with Siemens on machine breakdown. Our downtime is not very high. We have two of our own engineers plus Siemens’ support.” A Siemens

official said, “Service is very, very local. Perceptions vary even within counties.”

A Siemens official claimed his company is the only vendor with three options for image guidance. He said linac sales have been growing more than 25% year-to-year, “Radiation therapy delivery device sales have been up 5% annually for several years. The use of imaging has been growing tremendously... Varian sales are mostly in the U.S., and they have been flat for Varian and everyone else – except perhaps us—in unit numbers. It is a mature market. The number of new centers being built in the U.S. is increasing about 2%-5% a year. Outside the U.S., sales are increasing faster. China is our second biggest market, and they are buying. We can compete with Varian because of our international business. We’ve always had trouble in the U.S., but we are getting better on pricing and on products. Varian has always bundled, and that has been a successful strategy.”

1. **MV Cone Beam.** This is expected to be released in 1Q05, and it is the least expensive option. With a linac, the cost is about \$1.2 million. A Siemens official predicted this will be the most popular option, “The MV Cone price is more palatable right now.” Upgrades require about two days of downtime for the linac. A source commented, “People think there is something magic about cone beam, but CT is better. I have no idea why the cone beam name is impressing people.”
2. **KV Cone Beam.** This is already FDA-approved, but approval of the flat panel image intensifier is pending. The cost is about \$350,000 - \$450,000 with the flat panel. Upgrades do not require any downtime. KV Cone Beam will work with other linacs (non-Siemens linacs), but another planning system would be required.
3. **CT-on-Rails.** This is Siemens’ IGRT option, which they call VGRT, to compete with Elekta’s Synergy and Varian’s Trilogy. Typically, the table on which the patient lies moves through the CT, but here the scanner moves over the patient. An official claimed to have more than 12 U.S. users. This option has the highest quality image, but it is fairly expensive at a cost of \$2 million - \$2.5 million. Installation requires a “few weeks” downtime.

TOMOTHERAPY’S TomoTherapy Hi-Art System

Interest in TomoTherapy, which combines IMRT with a spiral delivery pattern, is growing, according to sources, and there was a buzz about the new technology at the AAPM conference. In fact, TomoTherapy has made the choice of linac a four-way race, instead of a three-way race. Several sources described TomoTherapy as a viable threat – to Varian mostly, and they believe TomoTherapy is costing Varian sales and making Varian nervous. An Ohio doctor said, “TomoTherapy is terrific, and may be the best way to go.” A Florida physicist said, “TomoTherapy can do both IMRT and

CT, and Varian can't. TomoTherapy has Varian threatened and nervous." Another source agreed, saying, "Although TomoTherapy has its limitations, such as field size, and it is cumbersome, it has a marketing gimmick, and it has Varian worried. TomoTherapy is taking business from Varian. Several sales went to TomoTherapy that Varian thought it should have gotten."

Unlike traditional radiation therapy systems, TomoTherapy delivers radiation with a rotating, intensity-modulated fan beam. Proponents say that TomoTherapy can deliver high doses of radiation without affecting nearby healthy areas. TomoTherapy also uses computerized tomography (CT), integrating imaging with radiation treatment. Doctors can take a CT scan before each treatment in order to determine the exact location of a tumor and adjust the patient's position.

Other comments on TomoTherapy included:

- *Washington*: "TomoTherapy will be a competitor for large multi-accelerator clinics or clinics that need a marketing advantage or a sexy device."
- *Massachusetts*: "I know the people, and the technology is excellent, the quality is top notch, and the thought processes behind it are excellent. It is doing a lot to bring attention to the value of (Varian's) On-Board Imaging (OBI)."
- *Texas*: "We're not planning to get TomoTherapy because we don't have enough space for one. However, the advantage of TomoTherapy is that it's a totally integrated system, and that's a big advantage. It uses one system to deliver imaging and the delivery process. The disadvantage is that, over time, we may find that it may not be as effective on some tumor sites and may not show clinical advantage in some areas."
- *West Coast*: "TomoTherapy is fantastic. It's possibly imaging technology at its most developed so far."

Five sources either have plans to buy TomoTherapy or are considering it. A California physicist said, "Our new TomoTherapy unit is just being installed for the rotational therapy unit." An Arkansas physicist said, "Our third vault will host a TomoTherapy unit." A Florida physicist said, "We are considering either TomoTherapy, Varian, Elekta, or Siemens to replace our two old linacs." A New Jersey source said, "We will either choose TomoTherapy or Varian for our new linac. TomoTherapy is interesting, and it is as top-of-the-line as Varian. With IMRT, you have limited field size. With TomoTherapy, you have more angles to spare tissues. TomoTherapy can do cranial and spinal radiation all in one treatment. With a linac, you have to move the patient. TomoTherapy saves time on very complicated patients, but the time is the same on more mainstream patients. Also, TomoTherapy requires less lead shielding." A Texas source said, "If I were starting my own clinic now, I would buy TomoTherapy. It has all the answers available now."

The criticisms of TomoTherapy included:

1. **Speed.** A few sources said they had heard that TomoTherapy is slow. A Maryland physicist said, "TomoTherapy is a good idea, but the speed is slow." Another source said, "We're not planning to get it. It's very expensive, and we heard that the downtime is too long for when you have to change the tubes."
2. **Cost.** Several sources also mentioned TomoTherapy's cost as a barrier. A complete TomoTherapy system costs \$3.2 million, which company officials said is comparable to – if not less than – a top-of-the-line Varian. A TomoTherapy official said, "We are priced like Saturn cars. There is not much discounting, and the price is all-inclusive."
3. **Newness.** A Utah physicist said, "There is a lot of interest in it, but it's still pretty new." A competitor said, "TomoTherapy is discontinuous technology."
4. **Space requirements.**

At AAPM TomoTherapy officials said they had 16 systems delivered, of which 13 were up and running, with 34-35 on order. In fact, officials claimed they are back ordered through March 2005. An official said, "The pent-up demand is too strong for us...I think people are stalling on Varian purchases to check out TomoTherapy." Internationally, TomoTherapy uses distributors in the U.K. and Ireland.

VARIAN

Although many sources said they have a mix of linear accelerators, Varian continues to be considered the market leader – the Cadillac of linacs – with the most reliable, sophisticated, and solid machines.

- *Arizona*: "Varians are faster, but there are fewer segments with Siemens. Varian has networking and planning, however, which makes it more compact, and makes life easier for us."
- *Florida*: "Elekta and Siemens are very aggressive on price, but Varian is considered the best. It's the most reliable, so people settle on Varian."
- *Indiana*: "Varian linacs are better made, more reliable, with a total vision system. They are totally integrated and have great compatibility with software. And – they are American-made, which is a plus for us."
- *Massachusetts*: "Varian has the lion's share, in this country particularly."
- *Texas #1*: "Varian has less maintenance trouble (than Elekta)."
- *Texas #2*: "I'd say the Varian MLC is probably more sophisticated in terms of accuracy and dynamic motion capability, and that's been part of our decision to use Varian."

- *Texas #3:* “Siemens and Elekta are very competitive, but they aren’t as technologically advanced as Varian.”
- *Utah:* “We prefer to buy Varian because Elekta is pretty good market-wise but still behind in technology. Varian has been on the market for along time; it’s the market leader, and its technology is better.”
- *Virginia:* “Varian is the most reliable and most stable, and I like the smaller MLC leaves in the Varian. The Elekta is more cumbersome, but it’s OK.”
- *Wisconsin:* “Varian has a stronger basic performance track record than its competitors.”
- *Colorado:* “Varian has many fine features that are better than Siemens, such as the electron beam. Therapists also like Varian more. Maybe that is a function of where they are trained. You can attract therapists more easily if you have Varian.”
- “Varian is expensive, but it’s like buying a Mercedes. Siemens is very good and perhaps the most competitive against Varian.”
- “Varian has been the Cadillac for years.”
- “Siemens challenges the most, but Varian is more solid and more user-friendly.”

Varian’s CEO said the company currently has 600+ sites. He said Varian sells 450-500 linacs annually – and 55% of these are shipped equipped to do IMRT, with ~60%-80% actually used for IMRT. Asked what advantages Trilogy has over TomoTherapy, the CEO said, “Trilogy is more cost effective because it is faster – the number of patients per hour is higher with Trilogy. We can schedule patients every 15 minutes. TomoTherapy also requires more steps. It (TomoTherapy) is the same concept as Trilogy, but we do it faster and we can do respiration gating now. We also have a better reliability... We see TomoTherapy as a niche market in research. For routine clinical treatment, no one competes with us.”

However, Varian is being challenged by TomoTherapy. A source said, “Varian has to deliver on what it is promising. The OBI presentation is incredible, but it is not deliverable...TomoTherapy is a big challenge to Varian. TomoTherapy will be the market leader in three to four years, but they have had imaging problems, and the CT part has problems with downtime.”

KV cone beam. Varian’s 3-D KV cone beam CT software is designed to simplify the accurate delivery of radiation dose to tumors and to enable new treatment strategies for treatment of tumors in the brain and body. FDA approval has been delayed, but sources said that is not delaying their purchase decisions. A source said, “KV cone beam significantly improves the clinical procedures used for precise delivery of dose to targets in intracranial surgery. Our thinking is to use image guidance and a non-invasive immobilization system.

The cone beam enables entirely new treatment strategies, particularly for prostate cancer and soft-tissue oligo-metastases. In prostate, we’ve had CT-guided treatment for several years. The goal is to substantially reduce the effect of systematic error due to organ motion...For about a year, we’ve been treating oligo-mets in the spine, and we just started doing it in the liver. To do this, the challenges are: (1) patient immobilization, (2) control of motion (typically >2 cm sup-inf), (3) visualization of the target, and (4) managing the poor reproducibility of soft tissue target and critical structure alignment. In the liver, the goal is to reduce liver motion to <5 mm.”

On-Board Imager (OBI). This is an automated, robotic device that uses low-dose, high-resolution imaging and sophisticated software tools to track tumor position and allow clinicians to adjust for position changes at the moment of treatment. Existing machines can be upgraded to IGRT with OBI, or hospitals that want IGRT can purchase Trilogy+OBI. Only a few sites have upgraded to OBI so far; these include: Karolinska Institute (Sweden), Emory University, Henry Ford Health System, and Memorial Sloan Kettering Cancer Center.

Upgrading to OBI, which costs <\$1 million, requires a three-to-five week shutdown of the linac. Most sources said that would not be a problem because they already have other IMRT-capable linacs that could take up the slack. A New Jersey source said, “We would send patients to the other site while one site was down. Or, we’d rent a mobile linac.” Another source said, “It wouldn’t be a problem. Installations often take that long. You double up on other machines and extend schedules. It’s like repair time.” A Georgia source said, “We could transfer patients to other machines.”

The exception was this Florida source: “It would definitely be a problem for us to shut down that long. We would wait until the shutdowntime gets shorter...But each installation is faster.”

At a Varian-sponsored session at AAPM, Timothy Fox Ph.D. of Emory University, and Fang-Fang Yin Ph.D. of Henry Ford Health System detailed their early experiences with OBI for IGRT. Their institutions were the first in the U.S. to acquire OBI earlier this year and to begin using it to position patients for treatment. According to Dr. Fox, Emory clinicians found that most patients needed to be shifted up to 3-4 mm prior to treatment in order to bring a targeted tumor into the best possible alignment with the treatment beam. Each treatment took an average of 17 minutes, including three to five minutes for imaging and repositioning, making the process efficient and clinically viable. Dr. Fox said, “As our physicians gain confidence in the precision of patient setups, they will be more confident about developing treatment plans that reduce the margin of healthy tissue treated.”

Dr. Yin said physicians at his hospital, which already has eight Varian linacs, are planning to use their OBI to develop a breast cancer treatment protocol that compensates for

respiratory motion during treatment, “Dealing with the problem of respiratory motion when treating breast cancer has long been an issue for radiation oncologists. We feel that the On-Board Imager will be of tremendous value in helping us improve the quality of breast cancer treatments.” He offered this advice for people considering OBI:

- Plan for the installation.
- Have a good working team.
- Be sure your existing machine can be upgraded.
- Allow for the machine downtime. “It took us, from beginning to end, about a month. Varian is hoping to get this down to two weeks.”
- The Varian Eclipse planning system is not necessary, but the installation goes much smoother with this.
- Be sure there is sufficient power for the kV.
- High speed network connectivity.
- Allow for the cost of an electrician and circuit breaker.
- A gating device (RPM) is optional.

Trilogy. This is Varian’s latest generation IMRT system. It is considered a complete stereotactic solution, including treatment planning, QA tools, imaging for SRS, high precision point position and monitoring, radiation shaping, and stereotactic RT. By adding OBI, it becomes a complete IGRT system.

- **Pro.** A medical physicist said, “We have a Trilogy linac being installed at one of our clinics. It is a very robust platform for us. As to the initial results, we looked at the deviation, and we found nice accuracy. We’ve tried it on four CNS patients, two ENT patients, and one prostate cancer patient. Our conclusions are: The use of OBI for patient positioning is very effective. Our physicians want to use it on every case. Clinical implementation for kv-kV anatomy matching is intuitive and efficient for online use. Automatch performs best with initial manual alignment, and the clinical protocol for automatch VOI is important for reproducible results.” A Washington physicist said, “Varian’s Trilogy is very impressive, and it is probably the best thing out there. Siemens seems to be in only about four sites on the West Coast. I won’t even consider Elekta because I’ve had so much trouble with that company. They’ve made so many people at our facility mad. The company is extremely difficult – even dishonest.”
- **Con.** A Texas physicist said, “Varian and Elekta will be equivalent eventually, but Varian is delayed. It is a race, and Varian is trying to catch up.”

Varian IGRT machines are constructed to rotate around an axis, vs. Elekta machines, which have weight distributed over a drum. However, sources insisted this does not make a difference in terms of the ability of these machines to perform

IGRT. A Florida expert said, “Both are iso-centric, so it doesn’t matter how they do it mechanically.”

