



MD BUYLINE LEADING EDGE REPORT

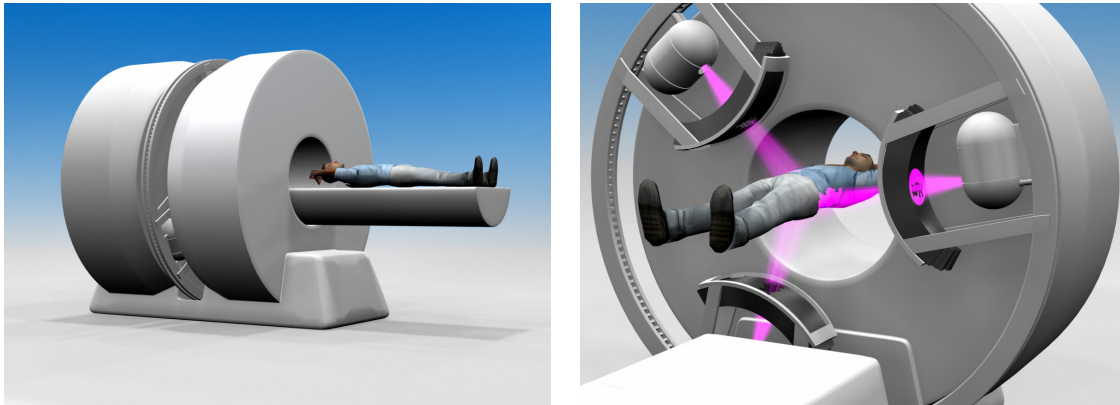
New Renaissance™ in Radiation Therapy?

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Executive Summary

Linear accelerators (LINAC) were first developed in the 1950s and allow physicians to deliver high-dose radiation accurately to a prescribed location. The therapy is so effective that external beam radiation is now used to treat approximately 450,000 cancer patients each year. Now, ViewRay, a private company located in Gainesville, FL, is developing the Renaissance™ System, which is a combination of an MRI system and three gamma sources. This marries enhanced images of soft tissue tumors with the real-time, volumetric tracking ability while the radiation beam is on.



The goal of the Renaissance System is to provide more accurate delivery of radiation therapy by accounting for tumor target motion while the radiotherapy beam is on. The results should be faster treatment times, greater tumor target lethality, and less adverse effects from radiation exposure outside the tumor margins.

Advancements to linear accelerators such as IMRT (Intensity Modulated Radiation Therapy) have allowed physicians to further customize the shape of the radiation field to better conform to the tumor. This has proven successful in sparing more healthy tissue and improving patient outcomes. The next critical frontier is treating tumors located in areas of the body subject to constant movement.

New IGRT technology that combines CT imaging with LINAC technology has proven effective in registering the location of a tumor before and after a treatment session. Respiration gating has also allowed the technology to compensate for breathing motion; however, other natural body movements can cause the tumor to move out of the radiation field. This can lessen the dose to the tumor while damaging adjacent health tissue.

The Renaissance System offers the promise of a safer and quicker process of delivering external beam radiation. Not only will physicians be able to see the position of the tumor but they will be able to make adjustments during the procedure. This will allow physicians to compensate for the movement or even stop the treatment if the tumor is getting out of the border. The end result will be a more effective therapy with less side effects from the radiation.

The Renaissance design enables it to fit in the 'vault' (common term for the room) of existing linear accelerators and thus into existing treatment rooms. Minor modifications would have to include active shielding for the magnet component of the device (est. \$25-50K). Although not all tumors necessitate the highest level of technology, the biggest benefit will be seen for tumors in the lungs, liver, colon, and pancreas. These are all areas subject to motion.

This technology is a potential replacement for LINAC and IGRT for those facilities with cancer patient populations just described. Keep in mind that the most important differentiation between this technology and existing technologies is the precision of the imaging and its ability to update the tumor position during the treatment, not the radiation generating component. As one physician experienced with Renaissance explained:

"The cobalt source has its advantages and disadvantages. The advantage is it is much more reliable. It requires fewer moving parts and a lot less ramping up and getting warmed up because it does not require a lot of electricity to generate the machine. I think from a clinician's point of view it will be a benefit over a linear accelerator. The drawback is the energy produced by the cobalt source is much less than a LINAC-based system. But this loss is made up by the increased number of beams you can use and the use of intensity modulated radiotherapy, which makes up for the change in energy." Dr. Ken Oliver, University of Florida, Gainesville

The MRI component of Renaissance is the key to its higher reimbursement. The financial comparisons we have included with this report detail the potential increases in profitability with Renaissance when looked at side by side with other oncology treatment technologies. [For those detailed spreadsheets, click here.](#)

The company plans to have the Renaissance System available by Q4 2008. Because ViewRay's system incorporates existing medical technologies with proven clinical histories, the company expects an accelerated market entry; no ground-breaking science is required.

Economics

ViewRay estimates the capital cost of the Renaissance System at approximately \$4 million. In comparison, existing LINAC-based systems range from \$1.4 million to over \$3 million for systems that integrate CT and LINAC technology into one unit. In addition to the initial outlay, service and labor costs on unique, high-end technology can be costly. One advantage of the Renaissance System's design is it has fewer moving parts than existing radiation therapy technology. This should translate to less downtime. Also, because of automation, the labor component (20 to 30 minutes per treatment) should be similar to existing IGRT technology. Based on 5,000 treatment sessions per year, a facility should see costs of approximately \$250 per session (not including treatment planning).

Reimbursement is an issue with any new technology. CMS has indicated it will aggressively reimburse leading edge technologies that improve patient outcomes. A direct indication that CMS financially supports updating the position of a tumor is reflected by the 2006 Final Rule in which Medicare will reimburse multiple images taken during a treatment session. ViewRay is currently working with CMS to establish a CPT code to reflect the use of the Renaissance System.

Existing technical reimbursement for IGRT technology falls under several basic components: planning, image guidance and therapy. CMS has not yet established a CPT code that reflects the use of a MRI during a radiotherapy guidance procedure because integration of MRI for IGRT is still unique. As a guide, CT guidance for IGRT has an average CMS reimbursing of \$125 per procedure. In general, MRI technology is reimbursed 35% to 45% higher than CT technology so the MRI guidance portion of the Renaissance System should be approximately \$223. This is similar to MRI guidance for stereotactic localization.

Although the therapy component of the Renaissance System is unique, existing IMRT payment levels can be used as a guide. Under APC 412 (IMRT Therapy) the average reimbursement per treatment is \$334. Not including one-time payments for immobilization devices and therapy planning, a facility would see \$557 per session. The therapy planning component would add at least a one-time payment of \$829 (APC 310). Because the Renaissance System is capable of

storing and recalculating the delivery radiation it is possible that a facility may bill for more than one therapy planning session during the course of the treatment.

Along with improved outcomes, a revenue-producing business plan is important to the success of any new technology. Based on 5,000 treatments per year for the Renaissance System (or 20 cases per day), a facility would see a profit margin of approximately \$6,085,000 over a five-year term. Lower-volume facilities would break even with this technology with as little as 2,100 treatments per year. Based on the same business plan, tomotherapy projections are approximately \$4,886,000 and IMRT \$3,892,000. This reflects a very good revenue-generating business plan for a wide range of treatment facilities. Treatment centers will see positive revenue while providing leading edge therapy; this is a win/win situation for patients and providers. *For financial impact comparisons of the Renaissance side-by-side with competing technologies, [click here](#).*

The Company: ViewRay, Inc.

ViewRay was formed in 2004 and is a private company focused on improving the effectiveness and safety of radiation therapy. It is located in Gainesville, FL. The company is currently developing its Renaissance System; the technology is based on the exclusive licenses and patents developed by Jim Dempsey, Ph.D. of the University of Florida. The company's equity funding has been provided by future users of the technology such as radiation oncologists, medical oncologists and physicists. This reflects the excitement and need for the technology in the field of radiation therapy.

ViewRay is lead by Russell Donda who servers as the company's CEO and Chairman of the Board. Donda has a 25-year successful track record in business and more than 10 years experience in developing medical technologies from inception to market. He was previously one of the founding managers of Regeneration Technologies, a leader in allograft implants. At that company, Donda led in the development and strategic planning of novel medical technologies.

The Renaissance System is based on the integration of a MRI scanner and three gamma ray sources, each with their own multi-leaf collimator. Because ViewRay's system incorporates existing medical technologies with proven clinical histories, the company expects an accelerated market entry; no ground-breaking science is required. The MRI component is being designed by Magnex Scientific Ltd., a Varian, Inc. company. The gamma ray sources will originate from MDS Nordion of Canada. ViewRay projects that it will market the Renaissance System by Q4 2008.

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The Technology: Renaissance™ System

Essentially, the Renaissance System is designed to function as a large robot. Its design enables it to fit in the vault of existing linear accelerators and thus into existing treatment rooms. From the outside, the system looks and functions similarly to an existing MRI system. During the treatment the patient is positioned on a table between two circular magnets. Three gamma ray sources located in the MRI gantry revolve around the patient in a motion similar to a conventional linear accelerator. This design means the system has fewer moving parts than existing radiation therapy technology.

The Renaissance System addresses a primary imaging problem: the human body is dynamic and thus the position of tumor targets can change. In addition, radiation therapy typically is given over a period of seven to eight weeks and the accuracy of radiation therapy is diminished over this period of time. Patient movement during treatment also affects the position of the tumor. Even though a patient may be immobilized, movement due to breathing, bowel gas, and other organ motions can affect tumor position. This presents a difficult challenge when using external beam radiation to treat a tumor. Mechanical restraints and motion detectors developed over the years have helped reduce whole body motion problems. However, these technologies have not evolved to the point where physicians can take full advantage of the IGRT and IMRT delivery technologies with the radiotherapy beam on.

The MRI component of the Renaissance System offers physicians several distinct advantages. It offers zero dose scatter radiation with the ability to provide a much better resolution of sarcomas buried in soft tissues. It also has the ability to acquire very rapid images during the therapy. This means the system can update the real-time image and provide gating of the therapy beam several times a second. The result is that oncologists can change the treatment plan to compensate for unexpected movement of the tumor target outside of the target area.

In order to perform the task the system's computer acquires data at a rate of 40 megabytes per second. This requires high performance 64 bit computing with large storage. The first generation System (the Renaissance™ System 1000) is designed to store all the imaging data, calculate the planar reconstructions, reconstruct actual dose to target, and provide gating of the beam during the treatment. Thus, the system watches the pathology during the treatment and can shut the beam down if the tumor moves outside the planned radiation field. In addition to the gating capabilities, the computer system can take the MRI data from the daily treatment and reconstruct the real-time accumulative dosages to the tissues on a daily basis. This information about where the dose has actually gone in the patient is compiled into a unique daily report for the physicist and the physician and further allows the physician to change the plan during the course of therapy as needed.

Another unique aspect of the Renaissance System is the use of a gamma ray source, instead of a linear accelerator, to produce the radiation. In general, linear accelerators are incompatible with the magnetic field of an MRI. That is not the case with the Renaissance System: gamma ray sources release radiation without the complex parts associated with linear accelerator radiation production and hence, the MRI's magnetic field does not interfere with the source's operation. Moreover, in the absence of complex parts, the gamma ray system is potentially very reliable. Historically, gamma ray sources were not capable of producing the higher levels of radiation produced by a linear accelerator. IMRT technology has now allowed gamma ray treatments to be on par with linear technology. Combined with IMRT technology, this further improves delivery of the beam so less radiation is needed. To compensate for the lower output, the ViewRay technology has incorporated three gamma ray sources into the Renaissance System.

One common problem with current imaging and therapeutic technology is the adverse affects of scattered radiation on patient outcomes. The combination of MRI and gamma ray sources makes the Renaissance System considerably safer than existing technology because it eliminates

surface doses from a CT scanner or other X-ray sources. During a course of tomotherapy, a patient may receive 30 to 35 CT scans. This additional radiation increases a patient's chances getting cancer from the treatment by 1% to 2%.

Patients being treated in the neck and head regions have a higher risk of developing cataracts and the use of gamma ray sources has sometimes resulted in patient skin burns. However, the potential for such burns is alleviated by virtue of the magnetic field generated by the MRI: low energy electrons, the skin burn culprits, are automatically and harmlessly swept back to the device and away from the patient.

Tumors located in areas such as the lung, prostate, breast, colon and uterus are subject to movement. These are also areas surrounded by critical organs that can be affected by exposure to radiation. The ability of the Renaissance System to deliver accurate treatment and account for the real-time movement of the tumor can spare healthy tissue. The result promises to be improved outcomes by delivering more effective treatments with fewer side effects.

Financials

Costs:

- Capital: \$4,000,000.
- Consumables: \$10 (depreciated per treatment).
- Labor: \$55.
- Service contract: \$260,000 (estimated).
- Total cost per use (based on 5,000 patients per year): \$250 (does not include treatment planning).

Reimbursement (Planning):

- CPT 77301 (IMRT Treatment Planning): \$1,513 (professional).
- APC 310 (Radiotherapy dose plan, IMRT): \$829 (technical).

Reimbursement (Guidance):

- CPT 76393 (MRI Guidance): \$513 (professional).
- APC 335 (MRI): \$223 (estimated technical).

Reimbursement (IMRT/Therapy Delivery):

- CPT 77418 (IMRT Treatment Delivery): \$686 (professional).
- APC 412 (IMRT Treatment Delivery): \$334 (technical).

Total technical payment per session: \$557

Total technical payment over the course of treatment: $\$557 \times 35 = \$19,495$ (not including treatment planning).

The Market

The American Cancer Society estimates there are over 1,334,000 new cancer cases in the U.S. each year. It is the number two killer behind heart disease (556,902 deaths per year). Although the rate of cancer has increased over the years, the five-year survival rate has also increased over 20%. This success rate is due to a combination of early diagnosis and more effective treatments.

There are multiple forms of cancer treatments including surgery, chemotherapy, brachytherapy, and external radiation therapy. Approximately 40% of cancer patients may need radiation therapy. This means almost 450,000 patients are candidates for radiation therapy. Depending on the source, the current market for radiation therapy technology ranges from \$1.2 billion to \$1.6 billion per year.

First developed and marketed in the 1950s, the medical linear accelerator represented a technological breakthrough in the way that radiation was delivered to treat cancer. These machines operate by using microwave energy to accelerate electrons to nearly the speed of light over a short distance, usually one meter or less. The electrons then strike a target and produce high energy X-ray photons. Currently, the radiation therapy market is dominated by four major players: Varian, Electa, TomoTherapy, and Siemens. Varian has been the leader in this market for years and is responsible for over \$800 million in revenue each year for the U.S. market alone.

IMRT, the predecessor of IGRT, was first developed in 1992. Since research has demonstrated its ability to improve patient outcomes, the IMRT market has experienced rapid growth. At present, the technology is being used in approximately 25% to 44% of radiation therapy patients depending on the source. Industry analyst estimate this portion of the radiation therapy market is worth approximately \$250 million per year.

Radiation Therapy Options

The field of oncology beam radiation has grown extensively. X-rays were first discovered by German physicist Wilhelm Conrad Roentgen in 1895. Since that time, approximately 50% to 60% of all cancer patients are treated with some form of radiation therapy. Current technology, such as 3D CRT, IMRT and IGRT, provides more accurate delivery of the beam. Radiation therapy works because radiation destroys a cancer cell's ability to reproduce; the body then naturally gets rid of these cells. Presently, there are two methods of delivering radiation therapy to the patient: brachytherapy (internal) and external beam radiation therapy.

External beam radiation therapy uses high-energy photons to kill cancer cells and shrink tumors. The electrons collide with a metal target, producing radiation in the form of photons or X-rays. When the radiation strikes the human body, highly energized ions are produced, which are lethal to both normal and malignant cells. These highly energized ions are created from naturally occurring water in the body. Both good and bad cells suffer from radiation but the good cells have the ability to adapt over successive regenerative cycles while the malignant cells are not able to adapt and do not survive. External beam therapy is primarily used for the treatment of breast, colorectal, lung, prostate, head, and neck cancer.

Delivery of external beam radiation consists of three parts: simulation, treatment planning and treatment delivery. Simulation involves locating the tumor and determining the best layout of the patient and the radiation therapy device. During the procedure, the radiation therapist places the patient on the table in the treatment position. Masks, pads or other devices may be used to help the patient to hold still during the simulation and treatment processes. Several images are taken with a special X-ray machine or CT scanner. The radiation oncologist then locates the tumor volume and the region to be treated on these images.

The next phase is treatment planning. Here the dosimetrist, physicist and radiation oncologist use a special computer to align the radiation dose distribution that will be delivered to the tumor. Then the dosimetrist and the radiation oncologist determine the best arrangement of radiation beams needed to treat the patient and the radiation oncologist places small marks on the patients to help guide the daily treatments.

During the treatment delivery, the radiation therapist places the patient on the treatment table of the linear accelerator in exactly the same position that was used for simulation using the same immobilization devices. The therapist positions the patient using the alignment lasers and the marks that had been placed on the patient during simulation. He or she may put special shields between the machine and critical body parts to help protect normal tissues and organs. The therapist goes outside the room and turns on the linear accelerator from outside. Beams from one or more directions may be used and the beam may be on for as long as several minutes for each field.

The total treatment process can take 10 to 30 minutes each day. The majority of this time is often spent positioning the patient. Patients usually receive radiation treatments once a day, five days a week for a total of six to nine weeks. The patient's diagnosis determines the total duration of treatment. Occasionally, treatments are given twice a day and, depending on the stage of the cancer and the condition of the patient, radiation therapy may be an outpatient procedure. As patients enter the final weeks of treatment, they are likely to experience fatigue. Some patients experience gastrointestinal side effects such as nausea or diarrhea.

External Beam 3D Conformal Radiation Therapy (3D CRT)

3D CRT uses digital diagnostic imaging, computers and special software to conform the radiation beam to the shape of the tumor. It is a newer method of delivering external beam radiation therapy first used in the late 1980s. It differs from standard therapy in that it uses multiple CT scans to feed digitized images into a radiation planning computer. This provides a more precise image. The computer then designs multiple custom shaped, high energy X-ray beams delivered from different angles.

The set-up and treatment of 3D CRT is similar to conventional beam therapy. Each treatment session lasts approximately 10 to 20 minutes five days a week over a course of six to eight weeks. Counting set-up, the total time of each session is 15 to 30 minutes. The advantage of the technology is it can deliver a higher dose of radiation directly to the target providing more effective treatment with fewer side effects.

It should be noted that without IMRT technology, 3D CRT cannot conform well to three-dimensional objects, largely because of the uniformity of beam strength. Researchers in the field of radiation oncology estimate that approximately 30% of tumors exhibit concave features, thereby posing difficulty for treatment with conventional conformal radiotherapy.

Financials

One financial advantage of a linear accelerator is its flexibility: it can be used for multiple treatment areas of the body. As a base, APC Code 301 was used for the therapy component because this is one of the most common codes billed under CMS. APC 260 (Level 1 Plan Film) reflects the simulation or X-ray component. Combined, this represents a payment rate of \$173 per session not including treatment planning costs and reimbursement. Based on 5,000 treatments per year a facility would see cost of approximately \$116 per session. Profit margins over the five-year term are approximately \$1,044,000 over the five-year life of the equipment.

Costs:

- Capital: \$1,400,000 (Linear Accelerator).
- Consumable Costs: \$10 (depreciated per treatment).
- Service contract: \$65,000.
- Labor: \$45.
- Capital cost per procedure: \$116 (based on 5,000 overall procedures per year).

Reimbursement:

Reimbursement (planning not included in calculator)

- CPT 77285 (Set Radiation Therapy Field): \$265 (professional).
- APC 305 (Level II Radiotherapy dose plan): \$234 (technical).

Reimbursement (X-Ray Guidance)

- CPT 77417 (Radiology Port Films): \$22 (professional).
- APC 260 (Level 1 Plan Film): \$43 (technical).

Reimbursement (Therapy)

- CPT 77414 (Radiation Treatment Delivery): \$89 (professional).
- APC 301 (Level II Radiation Therapy): \$130 (per session).

Total Technical payment per session: \$173.

Total Technical payment over the course of treatment: $\$173 \times 35 = \$6,055$.

Intensity Modulated Radiation Therapy (IMRT)

Currently, IMRT is used in approximately 40% of radiotherapy patients. IMRT evolved from the inability of 3D CRT to irradiate tumors that are concave, surrounded by normal tissue or in very close proximity to sensitive normal tissue, without causing excessive radiation exposure of adjacent normal tissue. It further allows radiation oncologists to tailor each dose of treatment so as to minimize the affects on the surrounding tissues.

IMRT is similar to conventional LINAC-based radiotherapy because the radiation is delivered from multiple directions. By incorporating a multi-leaf collimator, IMRT offers the added advantage of using varying intensities of hundreds of small radiation beams to produce dosage distributions that are more precise than possible with conventional 3D CRT. The multiple beams produced allow the oncologist the shape the beam to conform to the contour of the tumor. The intensity of the beam is modulated by a multi-leaf collimator.

One distinct advantage of IMRT technology is improved outcomes. One study performed at Memorial Sloan Kettering found that IMRT increased the success rate of reducing tumors from 43% to 96% while reducing complications from 10% to 2%. Another found that breast cancer patients being treated with IMRT were 30% less likely to suffer side effects or physical damage from radiation.

Complication rates with IMRT have also been low. Studies reflect less than a 1% rate of grade 2 to 3 mild complication rate and a 0% grade 4 to 5 serious complication rate. Overall success rates of IMRT now compare favorably with the results obtained from radical surgery because the greater number of beam directions produced allows for more of the high dose radiation to be confined to the tumor (this is why it is referred to as a conformal beam). This not only decreases radiation to normal surrounding tissue but increases the chance of destroying cancer cells.

The drawback is conventional IMRT requires a lengthy and complex treatment plan and set-up process for treatment planning. More complicated procedures requires more time for each treatment fraction. The total treatment time ranges from 20 to 30 minutes. Other potential concerns with IMRT include a higher risk of error due to the complexity of planning and delivery, and difficulties in quality assurance, radiation safety, and portal verification.

Financials

IMRT outpatient reimbursement is based on a per-treatment scenario. Typically, 30 to 40 treatments are required. The payment level is considerably higher than standard 3D CRT. For the technical reimbursement the combination of APC Code 412 (IMRT Therapy) and APC 260 (Level I Plain Film) are two of the most common codes used. This represents a payment rate of \$377 per session. This does not include treatment planning costs and reimbursement. Based on 5,000 treatments per year a facility would see cost of approximately \$181 per session. Profit margins over the five-year terms are approximately \$3,892,000 over the five-year life of the equipment.

Costs:

- Capital: \$2,500,000 (Linear Accelerator w/IMRT).
- Consumables: \$10.
- Labor: \$55.
- Service Contract: \$165,000.
- Total cost per use (based on 5,000 patients per year): \$182 (does not include treatment planning).

Reimbursement:

Reimbursement (Planning not included in calculator)

- CPT 77301 (IMRT Treatment Planning): \$1,513 (professional).
- APC 310 (Radiotherapy does plan, IMRT): \$829 (technical).

Reimbursement (X-Ray Guidance)

- CPT 77417 (Radiology Port Films): \$22 (professional).
- APC 260 (Level 1 Plan Film): \$43 (technical).

Reimbursement (IMRT/Therapy)

- CPT 77418 (IMRT Treatment Delivery): \$686 (professional).
- APC 412 (IMRT Treatment Delivery): \$334 (technical).

Total Technical payment per session: \$377.

Total Technical payment over the course of treatment: $\$334 \times 35 = \$13,195$.

Image Guided Radiation Therapy (IGRT)

IGRT is a combination of advanced imaging and automated positioning technology that is used to complement IMRT. Base KV or MV imaging systems utilize orthogonal X-ray devices, ultrasound or cone beam CT for the imaging component. These are then incorporated with a LINAC therapy system. IGRT has simplified the process of registering the tumor's position and realigning the patient before each treatment. Physicians are better able to compensate for the positioning accuracy of the tumor between treatments.

During the procedure the patient is first positioned on the table and an image is taken. The image is compared to an initial reference image. This allows for the therapist to register the image with the reference image. The total treatment time is 20 to 30 minutes.

First receiving FDA 510(k) approval in 2002, the TomoTherapy Hi-Art® system is the most recent advancement in IGRT technology. It is designed to integrate a CT image, IGRT, IMRT, treatment planning, and automated positioning technology into a LINAC-based therapy system. The system offers two distinct advantages for patient treatment. One is the real-time CT image allows the system to calibrate the tumor's position in 3D update. The other is the CT gantry provides a unique platform for both treatment and imaging. This allows the TomoTherapy system to deliver the radiation in a helical pattern. The primary difference with a helical pattern is the device rotates the beam source around the patient. This allows the treatment to be generated from different positions. Along with improved accuracy, healthy tissue surrounding the tumor is subjected to much lower dosages of radiation. The result is a more accurate delivery of radiation directly to the tumor.

Current technology has the ability to triangulate the position of a tumor down to 1 mm or less but uncertainty is created if the target moves during the course of treatment, which lasts two to 10 minutes. New gating technology has allowed IGRT systems to provide tracking such as respiration as many as 30 times per second. Still, movement from a hiccup, cough or natural organ fluctuations are not accounted for. The treatment plan therefore adds some residual accounting to the tumor's margins and this has the potential to damage health tissue.

Financials

Like 3D CRT external beam radiation, reimbursement is on a per-treatment basis. Using the TomoTherapy Hi-Art System as a guide, facilities typically will see three payments. There is at least a one-time payment for the treatment plan. It is possible in the future that CMS will allow for additional payments for treatment planning as improved IGRT results are documented. In addition, CT guidance (APC 282, \$125) and IMRT Treatment Delivery (APC 412, \$334) is billed for each session. Not including planning, this can account for an average payment of \$459 per patient under Medicare. Based on 5,000 treatments per year a facility would see cost of approximately \$214 per session. Profit margins over the five-year term are approximately \$4,886,000 over the life of the equipment.

Costs:

- Capital: \$3,000,000 (Hi-Art System).
- Consumable costs: \$10.
- Service contract: \$260,000.
- Labor: \$55.
- Capital cost per procedure: \$214 (based on 5,000 overall procedures per year).

Reimbursement:

Reimbursement (Planning Not Included in calculator)

- CPT 77301 (IMRT Treatment Planning): \$1,513 (professional).
- APC 310 (Radiotherapy does plan, IMRT): \$829 (technical).

Reimbursement (Guidance)

- CPT 76370 (CT Guidance): \$162 (professional).
- APC 282 (CT): \$125 (technical).

Reimbursement (IMRT/Therapy)

- CPT 77418 (IMRT Treatment Delivery): \$686 (professional).

- APC 412 (IMRT Treatment Delivery): \$334 (technical).

Total Technical payment per session: \$459.

Total Technical payment per patient over the course of treatment: $\$459 \times 35 = \$16,065$.

Stereotactic Radiosurgery (CyberKnife)

Stereotactic radiosurgery is designed to offer very precise delivery of external beam radiation. The CyberKnife (manufactured by Accuray) is one of the most advanced robotic stereotactic systems. It offers the unique combination of a 6 MV linear accelerator transducer mounted on a robotic arm. This, combined with image guidance technology, treatment planning, orthogonal images, and computer controlled robotics allows it to provide sub-millimeter accuracy. It is FDA approved for treatment of tumors located anywhere in the body.

The basic set-up is similar to other IGRT procedures. Before a treatment the system correlates live radiographic images with pre-operative CT or MRI scans. This allows it to correlate the tumor with the bony structures of the body. During the procedure the system automatically updates the position of the tumor. This allows therapist to correct for tumor movement thus minimizing damage to surrounding healthy tissue and critical structures. Respiratory tracking also allows system to compensate for the patient breathing during the treatment.

As with external beam systems, a patient may require multiple treatments. Each treatment lasts 30 to 40 minutes. Because the system is capable of delivering a high level of radiation patients typically require only three to four treatments. In comparison, other systems require 30 to 40 treatments of a course of six to eight weeks.

Financials

From a financial standpoint, the lower utilization and longer treatment times are compensated by very aggressive reimbursement. Under CMS the first CyberKnife treatments are reimbursed at a rate of \$5,250. Treatments two through five have been paid at \$3,750. Based on 350 treatments per year a facility would see costs of \$3,068 per treatment. This translates to a profit margin of \$1,266,531 over a five-year period. Lower use facilities could break even with as few as 280 treatments per year.

Costs:

- Capital: \$3,650,000 (CyberKnife).
- Consumable costs: \$20.
- Service contract: \$460,000.
- Labor: \$120.
- Capital cost per procedure: \$3,068 (based on 100 patients per year, three to four treatments per patient).

Reimbursement:

Reimbursement (planning not included in calculator)

- CPT 77295 (Treatment Planning, Complex): \$1,300 (professional).
- APC 310 (Level III Radiotherapy dose plan): \$883 (technical).

Reimbursement (X-Ray Guidance)

- CPT 77417 (Radiology Port Films): \$22 (professional).

- APC 260 (Level 1 Plan Film): \$43 (technical).

Reimbursement (Therapy)

- CPT G0339 (Robotic Linear accelerator, first treatment): \$686 (professional).
- APC 1528 (New Technology - Level XXVIII): \$5,250 (technical).
- CPT G0340 (Robotic Linear accelerator, Treatments 2 thru 5): \$686 (professional).
- APC 1525 (New Technology - Level XXV): \$3,750 (technical).

Total average technical payment per session: \$4,221.

Total technical payment per patient over the course of treatment: \$4,221 x 3.5 = \$14,773.

Interviews

Carlos E. Vargas, M.D., Assistant Professor, Radiation Oncology, University of Florida, Gainesville, FL

"There are two different forms of IGRT. One form uses conventional IGRT. These systems -- offered by Elekta, Varian or TomoTherapy -- allow you to see the tumor before the treatment. It's like deer hunting except one would have to point the gun, close their eyes for four or five seconds and then shoot, hoping the deer will stay put.

"Now we can see where the tumor is during treatment. The Renaissance System offers real-time images during the procedure. Not only will we be able to see the position of the tumor before the treatment, we can make adjustments during the procedure, and during the course of therapy we can see how the tumor changes or if there is any motion of the tumor. This will allow us to tailor the treatment later on to compensate for the movement or even stop the treatment if the tumor is getting out of the set boundaries. When you exceed the margins of a tumor with the beam the normal tissue can be adversely affected; this can cause serious side effects along with not curing the patient because the tumor has not been hit enough. This can be pretty dramatic in the outcome of the patient. There are also tumors that do not move but there's no way of knowing how they will behave once treated. Most places do a CT, which shows an image, but a CT cannot account for movement so there's no way to tell how much the tumor is moving on a daily basis.

"Existing technology requires us to assume that we have certain dosimetry since we do not have real time dosimetry; we really do not know how much dose is going to the tumor. Real time dosimetry would enable us to know how much dose is actually going to the tumor and whether the target is being hit. Knowing how much radiation the tumor is actually getting is important because when you preplan a treatment there are certain curves that tell whether the tumor was hit, with what dose, and the chances of curing the patient. So let's say you want to give a grade of 70 to this tumor and it happens that during the treatment the tumor is moving a lot. Because of the movement the tumor may not be getting all the radiation prescribed. If there was more information it would be possible to confirm whether the tumor has received the prescribed amount of radiation, which would help determine effectiveness and indicate whether any other structures were damaged.

"Current IGRT increases the overall time of the procedure because it takes about a minute to take a scan. Afterwards, the image is reconstructed, which is very fast, around 30 seconds. Next any changes to the patient's position must be made. Another cone beam can be taken to make sure the adjustments have been properly done, which ensures precision. This all adds up to an additional five minutes for each treatment on a daily basis. If you are doing IGRT to place seed with X-ray that looks for points it would take an extra five minutes before the treatment. If you

want to be more precise and do it before each beam placement if may take three to four minutes per beam.

"This technology is applicable to anything but the brain and extremities. This is because the brain really doesn't move and the extremities can be fixed pretty well but the abdominal area and the chest moves all the time. This is where it will be the most effective.

"Another advantage is MRI is much better to work with than a CT. This is because it gives you soft tissue resolutions. CT is great but when it is necessary to compare soft tissue resolution to a prostate, liver or bowel it is much easier to see it on a MRI because the edges can be better defined. People have also been envisioning nano-based dyes that work specifically with MRI. This would enable the identification of a tumor and direct the treatment but this could be several years away."

Kenneth R. Oliver, M.D., Assistant Professor, Radiation Oncology, University of Florida, Gainesville, FL

"One primary advantage of the Renaissance System is it would give physicians the ability to observe therapy as it is being delivered. This is something that we have never had the opportunity to do. It would hypothetically give a physician the chance to correct anything going on during the treatment by indicating if a tumor went out of position and in what stage of therapy. This would give us a realistic method of accommodating any changes in dose.

"The areas that have the most motion will benefit most from this technology. This includes lung, prostate and liver cancers. Even tumors that we do not think move much could also benefit. There is a discrepancy with the amount of motion with some tumors that do not appear to move at all. One example would be a lymph nodule verses a central mass on the chest wall. Things like that would greatly benefit from the Renaissance because you could individualize your margins and accommodate motion.

"The ideal is even if it is used to update the position a day later it would be an improvement over current systems. The goal is for the system to accommodate for any error in the same treatment. Right now even knowing movement has happened is really novel in the field and to be able to accommodate it the next day would be exceptional.

"In some tumor types a MRI system provides a much better image, for example, prostate sarcomas that are in tissues and muscles and bones. It is also quite good in open lungs when it is surrounded by normal lung tissue; the tumor in the lung presents a nice image. MRI is the imaging modality of the future as compared to CT scans. MRI also has a lot of different options that you can't achieve with a CT so it is a little more robust and diverse than a CT scan.

"There is a potential of shortening the treatment times but it will take time to figure out if that's the case. My guess is the overall treatment times will be much different. In certain cases the success rate will be greater with the Renaissance because you will be able to accurately treat the tumor every day instead of missing it as little as 10% or 5% of the time. This will translate into improved outcomes for the patient.

"As the Renaissance becomes more precise we should be able to reduce the margins and still hit the tumor. This should translate to into fewer side effects. Right now when you treat a tumor you have to treat normal tissue because you do not know if there is microscopic disease that is extending into the area. Second, you have to allow a little margin to compensate for set-up and patient motion. This amount that deals with set-up and patient motion could be drastically diminished if we had accurate real-time imaging of the patient.

"The cobalt source has its advantages and disadvantages. The advantage is it is much more reliable. It requires fewer moving parts and a lot less ramping up and getting warmed up because it does not require a lot of electricity to generate the machine. I think from a clinician's point of view it will be a benefit over a linear accelerator. The drawback is the energy produced by the cobalt source is much less than a LINAC-based system. But this loss is made up by the increased number of beams you can use and the use of intensity modulated radiotherapy, which makes up for the change in energy.

"Even two to three years ago, we would set up a patient for treatment based on a CT that we did before therapy and never look again to see where the tumor really was. We go through therapy based on a two-dimensional approach that the bone is in the right place as compared to the bone that we looked at when we made the plan. But we did not know anything about where the tumor was or what was happening to it. So we did not know if it moved sideways for instance. Now we can look with this cone beam technology; we can look with a CT to see if the therapy is at least lined up properly at the time of treatment. But then again we do not know what is happening during the treatment itself. We do not know if the patient coughed and the tumor moved or they passed gas and the prostate moved. Any of these things could change the course of the treatment. Something like the Renaissance gives us the final answer to these questions of tumor motion and treatment reliability because you know what is happening during the therapy. This is like the end game in terms of providing accurate therapy."

Chester Ramsey, Ph.D., Director of Medical Physics, Thompson Cancer Survival Center, Radiation Oncology Department, Knoxville, TN

"There are several advantages of IGRT technology. The first that is quoted the most often and is highly supported by the published literature is the ability to reduce patient positioning and uncertainty prior to treatment. With non IGRT treatment you have an inherent uncertainty as to where the cancer is every day. In order to compensate, you treat a larger volume of tissue with the prescribed dose. With IGRT you can see where the tumor is located and thus, you do not have to treat as much of the normal tissue that surrounds the cancer.

"How often you update the treatment plan depends on the system being used. At our institution we take images immediately before the patient is treated. So the treatment itself last in our case two to 10 minutes. We acquire our images and position the patient immediately before the two to 10 minute long treatments start.

"The drawback is a tumor does move. How much depends on where it is located. If it is a brain tumor it does not move because it is locked inside the skull. However, an abdominal tumor located inside the stomach moves just like when you stand up and your internal organs shift around by several millimeters. Obviously, if you breathe things are moving. Also, in conventional non IGRT radiotherapy when patients are positioned on the treatment machine for the daily treatment, they are positioned based on markers that are drawn or tattooed on their skin. The skin is obviously very movable so the marks on the skin may not relate to the daily positions of the internal tumor that you are trying to treat. Thus, the uncertainty of the tumor's position comes from two sources. One is internal anatomical motion; the second is the uncertainty of the external marks drawn on the patient that are used to line up the treatment every day.

"There are all different types of imaging modalities used for IGRT. There is CT-based IGRT but the most common, based on the number of systems installed, is ultrasound. The problem with ultrasound is it has primarily only been used for prostate cancer. There are also systems that use orthogonal X-ray tubes. These systems have X-ray tubes that are permanently mounted on the accelerator itself. This type of image gives you two X-ray films and you try to triangulate from either the bony anatomy or from implanted metal markers that are placed in the tumor.

"Each of these systems has the ability (CT and orthogonal) to triangulate position down to 1 mm or less. However, does that mean that the uncertainty is down to 1 mm or less because the targets can move during the course of treatment? During the two to 10 minute treatment, if a patient hiccups, for example, the machine is not going to know that has occurred. Because of this you have to add some residual accounting for this movement. There are some IGRT systems that provide tracking such as respiration such as 30 times per seconds. This is with X-rays and ultrasound.

"One company in Florida has been looking to incorporate MRI for real-time tracking but it is not commercially available yet. Once it is available I will end up purchasing it. With MRI you can provide volumetric imaging during the actual course of the treatment to compensate for the internal motions. The hypothesis of this technology is to improve outcomes due to the less damage to normal tissue. What this means is that we can give more dose to the tumor, which could potentially improve disease-free survival. It will be years until we know for certain how much of an advantage IGRT clinically really gives.

"IMRT is a different process than IGRT. This is because IMRT shapes the beam and IGRT places the beam. IGRT can also do more than just position the patient. CT-based systems can also monitor the disease during the course of the treatment. During the three to eight weeks of treatment you can see how the tumor is responding. This will allow you to better predict the patient's chances of survival. If you have a patient with a tumor that is shrinking at a slower rate it will tell you that patient needs more aggressive treatment.

"When it comes to time, IGRT with conventional radiation therapy CT-based systems generally add five to 10 minutes to the treatment time. This includes taking the image, interpreting it and repositioning the patient. Ultrasound-based systems take two to five minutes. Orthogonal systems take somewhere in between.

"My understanding is orthogonal X-ray guidance just received a new CPT. There are already new CPT codes for CT and ultrasound guidance. I believe the CT CPT is 76370. All of these three codes pay \$75 to \$100 but this payment is for each treatment plus the IMRT portion or the conventional therapy.

Christopher J. Schultz, M.D., Professor of Radiation Oncology, Associate Director, Radiation Oncology at Froedtert Clinic, Department of Radiation Oncology, Milwaukee, WI

"IGRT represents the evolution of using treatment to try to conform doses of radiation to a target while trying to avoid adjacent critical structures. We started with 3D treatment planning where you could render a patient in 3D images. This has allowed us to pick opposing fields, which has involved into the IMRT concept. When you sum them all together you get the ability to make convex and concave dose distribution. This has allowed us to provide the coverage of the tumor and avoid normal tissue.

"IGRT takes it to the next step. During treatment delivery, on a daily or weekly basis, we are able to verify the positions of the structures we are trying to hit or miss. In the past, we would image the tumor in the beginning of the treatment. Then we would take all of our assumptions about patient position and tumor location, tumor movement and patient movement and build in a margin that we thought represented reasonable movement parameters. Then we did not look again until the treatment was over except for verifying in a two dimensional way that the patient was set up properly and immobilized with rigid immobilization systems.

"Now we have the ability to take onboard imaging with either mega voltage or CT scans with cone beam or fan beam approaches. By marrying a KV axial image right before an MV image we can essentially take a snapshot in 3D and volumetrically say where is the tumor is and where the normal tissues are.

"Different vendors have different approaches and there are pros and cons of each. This is an evolving process. Patient motion during the procedure is where the technology is going in the future. Not will we only position the patient in a static view but there are lots of efforts to monitor movements during treatments such that the beam is gated to be on when the target is in the desired position and turned off when it is not in the desired position.

"MRI is one approach to do this along with using KV or MV in which you can watch a patient's breathing motions. This will enable much tighter margins and allow us to hit what we want to hit and miss what we want to miss.

"IGRT technology that incorporates gating will be a little more difficult to plan on the front end. The actual treatment delivery could be about the same as an IMRT treatment. In the past it used to take 10 to 20 minutes but it now takes 20 to 30 minutes of total time. With some of the older imaging technology it was time consuming to capture an image and process it; new technology does it automatically but you have to reposition the patient so there is a bit of a trade-off in time with the new technology. However, it does involve a substantial infrastructure that in the long term may mean fewer side effects and better control. This will allow us to raise the dosage to beyond what we are using now.

"This may potentially result in fewer courses of treatments. Traditionally, we have been limited by what the normal tissues can tolerate relative to the total dose constraints. If we can deliver higher doses per day to the tumor it is conceivable we could lower the treatment course for some situations. This opens up new dose fractionation schemes, which in the past did not make sense. This is because we were not sure if adjacent tissues were getting the same level of radiation. Overall, IGRT is a continual evolution of different imaging modalities and better delivery methods."

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