UNDERSTANDING PROSTATE CANCER OPTIONS

RADIATION ONCOLOGY

ARIZONA ONCOLOGY

Each year approximately 180,000 men are diagnosed with prostate cancer, the most common cancer diagnosis in men, second only to skin cancer.

Treating the Disease

Radiation therapy is an effective tool for treating prostate cancer. Prostate Brachytherapy, and Intensity Modulated Radiation Therapy (IMRT) are advanced technologies that deliver targeted radiation.

Improvements over time have increased the chance for cure, while reducing the complications from radiation delivery. Treatments are well tolerated in appropriate patients.

Treatments for disease still contained within the prostate include surgery and radiation, both offering prolonged, disease free survival. Surgery is generally offered to younger patients and is very effective for early stage disease. However, surgery is associated with higher rates of impotence and incontinence.

Radiotherapy, effective for early stage disease, is also an important tool in the fight against more advanced cancers.

Radiation Treatments

Radiation can be delivered from the outside with Intensity Modulated Radiation Therapy (IMRT) or Stereotactic Body Radiation Therapy (SBRT), or from within the prostate, with permanent or temporary radioactive sources (seeds).

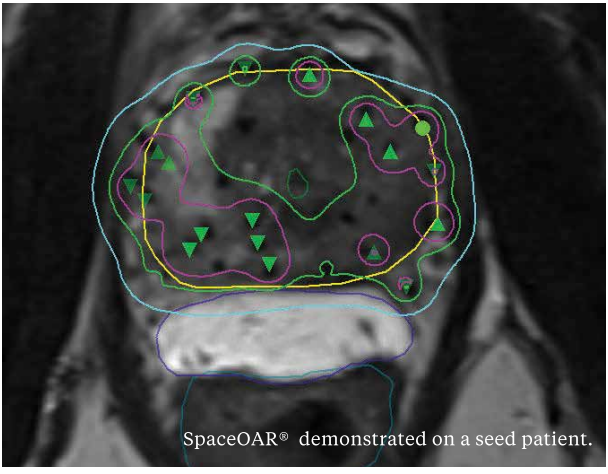
IMRT was historically given in small doses on a daily basis for 7-9 weeks, but now the treatment time is often under 6 weeks. Permanent implant (seeds) is done once, while temporary implants (High Dose Rate Brachytherapy or (HDR)) are typically done 2-3 times.

Recently available data recommends that patients with higher-risk disease have two types of radiation treatment in combination.

Complementary Technologies

SpaceOAR®

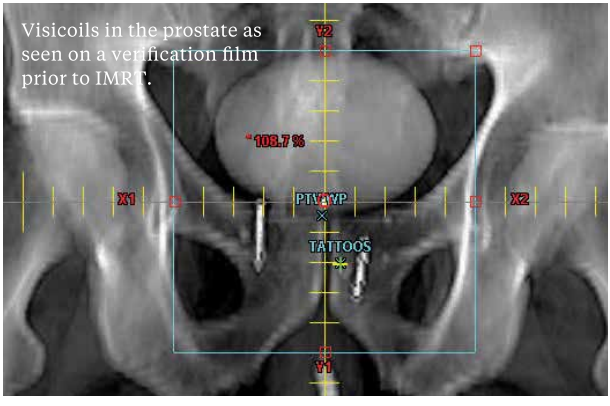
An important advancement in the treatment of prostate cancer was the introduction of SpaceOAR® (Spacing Organs At Risk) in 2015. This minimally invasive procedure injects a hydrogel behind the prostate to help reduce potential damage to surrounding normal organs in close proximity to the prostate.



SpaceOAR® demonstrated on a seed patient.

VISICOIL™

This is a flexible linear fiducial marker for use with today's most accurate image guided radiotherapy treatment plans. These markers are used to determine the exact location of the prostate. They aid Radiation Oncologists in developing treatment plans and enable Radiation Therapists in executing the specified treatment plan.



Visicoils in the prostate as seen on a verification film prior to IMRT.

TYPES OF RADIATION USED TO TREAT PROSTATE CANCER:

Prostate Brachytherapy

Prostate Brachytherapy, also referred to as seed implantation or interstitial implant, is a popular form of treatment for prostate cancer. It dates to the early 1970's when it was performed utilizing an open abdominal procedure. This technique was not successful because implant quality could not be well controlled.

In the late 1980's it was revived with the addition of ultrasound guidance and a change to direct insertion of needles (containing the seeds) from outside the body between the scrotum and rectum. Ultrasound guidance enables the permanent placement of seeds within the prostate under direct visualization with the probe.

Advantages

This revised method is vastly superior, with greatly improved tumor control and a lower complication rate. Seed implantation is an outpatient procedure and takes about an hour. Most patients can return to their normal activities within 3 days.

Results are equivalent or superior to external beam radiation or radical prostatectomy (with data beyond 15 years) for qualified patients.

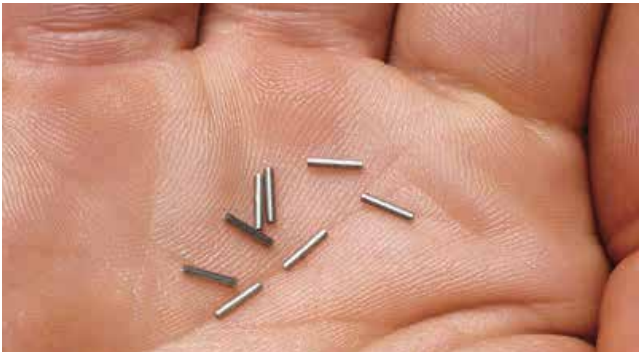
The radioactive seeds have a "rapid dose falloff", which means they deliver most of their dose in close proximity to the seed. The seeds are made of iodine I-125, encased in titanium, making them inert and able to stay in the body permanently. The iodine seeds deliver most of their radiation over 6 months.

Since seeds are implanted directly into the prostate gland, it will receive a very high dose of radiation, while most of the surrounding tissues are spared.

The only portion of the bladder that receives a significant dose is that which is directly touching the prostate. SpaceOAR® hydrogel helps to reduce radiation to the anterior rectal wall.

Some patients may desire an implant but have significant urinary obstructive symptoms. These patients may benefit from having a prostatectomy instead, as it tends to improve urine flow for this group of men.

Continued improvements in external beam radiation have allowed higher local doses and better sparing of normal tissues and a shortening of delivery time to a routine 5-6 weeks YET we are still not able to achieve the same radiation dose used with an implant.



In some cases of early disease, it remains unknown whether these higher doses are necessary for long term control of the disease.

A larger volume of the bladder and rectum are radiated with external radiation, even with the newest techniques, but side effects are typically less troublesome than with an implant because they are slow to develop and often resolve faster. Specifically, there is very little risk of urinary retention (i.e. needing a catheter) for non-implant patients.

Eligible patients for seed implant

Implant can be used alone for early-stage disease and for favorable, intermediate risk patients. It is now often recommended in combination with external radiation for more advanced disease.

Implant historically has been limited to low-risk or favorable-risk patients, which includes men with a small amount of cancer and a PSA less than 10, and Gleason score of 6 or less.

Fortunately, we have national trial data confirming that Brachytherapy alone is also excellent for favorable, intermediate-risk patients (men with a Gleason score 3+4, or PSA 10-20 with Gleason 3+3, or >50% of the cores involved with Gleason 3+3).

Patients with more advanced disease (men with a PSA greater than 20 or a Gleason of 4+3 or higher) benefit with the use of implantation as a portion of the treatment after a 5-week course of external beam radiation.

Patients who have had a prior TURP need to be evaluated with ultrasound (volume study) to determine if they are a candidate for implant.

Patients with a very large defect or symptoms of significant obstruction are at an increased risk of complications and are better served by one of the other treatment options.

Selection criteria includes a patient's general health, anatomy and size of the prostate gland. Issues with any of these can make implantation difficult, impossible, or increase the potential side effects.

If the volume study determines the prostate is too large, hormonal therapy may be used to reduce it to an acceptable size. A second ultrasound study is done after 3-4 months of treatment to re-check the size.

Some patients may be offered hormonal therapy in addition to radiation based on risk factors, regardless of the size of their prostate gland.

Evaluation for Brachytherapy

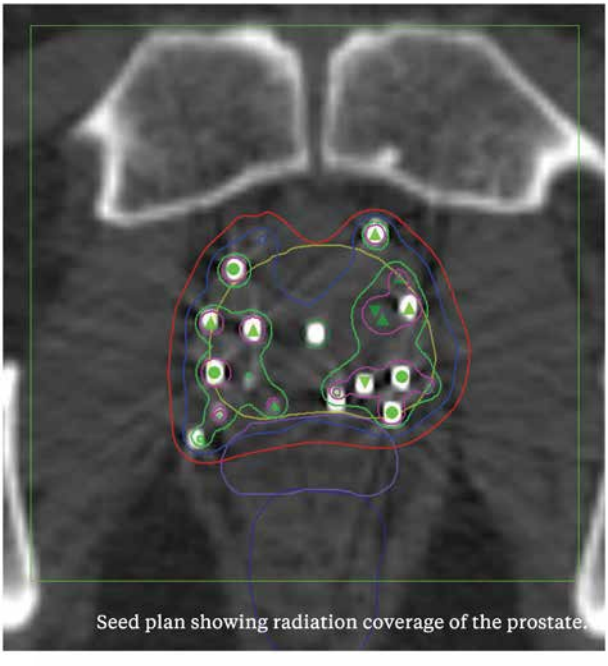
Initial consultation includes evaluation of the disease and discussion of the risks and benefits of treatment. Patients interested in Brachytherapy will have an ultrasound volume study scheduled for their next appointment. Some men will be sent for additional imaging to rule out gross evidence of cancer spread outside the prostate before proceeding.

The volume study allows us to determine the size of the prostate gland, judge the anatomy, and preplan the number of seeds that will be required. Planning is done by making a three-dimensional, computer generated model of the patient's prostate gland.

Seeds are then ordered, with the implant scheduled about 4-6 weeks later or 2-4 weeks after external beam radiation is completed. The actual implant will require anesthesia and a bowel prep to cleanse the GI tract.

SpaceOAR® hydrogel is injected after the seed placement has finished. A urologist may be present to assist.

Patients who are to receive external radiation before the implant will go for preparation, which includes insertion of 2 VISICOIL™ (small gold markers) into the prostate. These flexible linear fiducial markers are used to determine the exact location of the prostate before each daily treatment.



Seed plan showing radiation coverage of the prostate.

Despite the tolerance most patients have for the implant, no procedure is risk-free and all patients will experience some side effects.

Normally, side effects from radiation are easily tolerated, with patients resuming normal activities within 3 days (including work and/or recreation). Patients will initially experience symptoms upon waking from anesthesia. Symptoms may include a small amount of urinary bleeding, hesitancy, urgency, irritation and frequency. Less than 10% of patients will leave the hospital with a catheter because they were unable to urinate after waking from anesthesia.

Urinary symptoms tend to peak from 2-4 weeks after the implant procedure, then resolve slowly, with most patients urinating at pretreatment levels by 6 months.

Chronic urinary irritation can occur in up to 10-15% of patients. Urinary incontinence is uncommon. Up to 5% of patients can require placement of a catheter after the initial procedure, with less than 2% requiring it for longer periods (6-12 months).

Previously, rectal damage was rare and has been further reduced using SpaceOAR® hydrogel.

Of those patients with no erectile dysfunction pretreatment, impotence will occur in approximately 30%. Typically, 75% of the effected patients respond to oral medications such as Viagra®, Levitra® or Cialis®.

IMRT

Advantages

IMRT allows higher external beam radiation doses to be delivered safely; higher than what was previously possible with daily treatment.

Randomized trials have shown that higher doses to the prostate are beneficial, demonstrating improved outcomes. Studies have also confirmed that patients treated with IMRT experience fewer side effects than with older techniques, despite the higher doses. IMRT for the prostate is always done with image guidance.

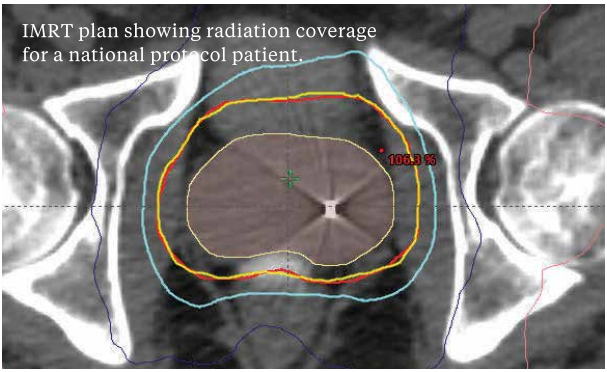
Hypofractionated Radiation is a form of daily treatment delivering higher doses per treatment. These high dose treatments reduce the overall weeks (called Moderate Hypofractionation). Stereotactic Body Radiation Therapy (SBRT) is a specific type of IMRT that uses substantially higher doses of radiation per day to treat prostate cancers. This is done in five or fewer treatments (Ultrahypofractionation).

Moderate hypofractionated treatment results based on a randomized RTOG trial #0415 were published in 2016. Patients treated with 28 treatments or 39 treatments had very similar outcomes for success and toxicity.

Arizona Oncology enrolled men on the National Cancer Institute sponsored trial, and many with the shorter course. We are proud to have participated in the trial and now commonly use the faster treatment schedule on a routine basis.

We also have the capability of treating certain patients with SBRT. Our practice is an active participant in many ongoing clinical trials. For instance, we are currently enrolling qualified men in a trial comparing 5 SBRT treatments against 28 daily treatments.

It is important to note that not all patients will qualify to participate in a clinical trial. Your Radiation Oncologist will discuss any available trials for which you may qualify.



IMRT plan showing radiation coverage for a national protocol patient.

Eligible patients for external radiation (IMRT)

IMRT alone can be used as a treatment for prostate cancer in patients with a limited amount of cancer (PSA less than 10 and Gleason score of 6 or less).

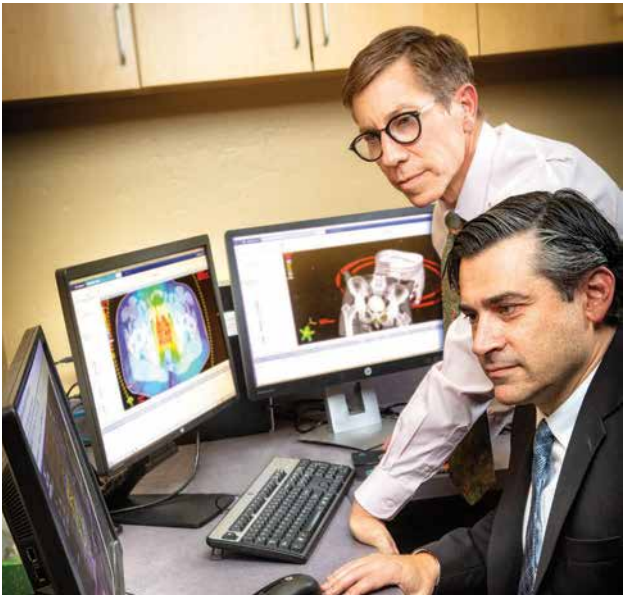
Some patients with intermediate to high risk prostate cancer may also be given IMRT alone or in combination with hormonal therapy. Unlike prostate Brachytherapy, prior TURP is not a contraindication for IMRT.

IMRT, in general, can be done on most patients, regardless of their particular anatomy, prostate size or the patient's size.

The patient's initial consultation includes a physical examination, history and discussion of applicable treatment options.

All patients treated with external radiation will have a CT simulation. CT images are viewed in the planning computer which shows 3-dimensional images of the prostate gland and surrounding normal structures. Additional studies such as an MRI may be ordered, so that they can be combined with our CT scan to increase visibility of the prostate anatomy and look for specific problems such as extraprostatic extension or infiltration into the seminal vesicles. If present, special accommodations will be made.

Your Radiation Oncologist will specify the radiation dose criteria, and treatment plans are then developed using a sophisticated computer planning system that runs through millions of calculations and treatment possibilities. Patients are positioned using external tattoos and in-room lasers. Final adjustments are made using image guidance on the internally placed VISICOIL™ gold markers.



Radiation beams enter the body from many different angles or as a continuous arc (Rapid Arc®) rotating all the way around the body. During treatment, the beam shape changes hundreds of times using metal “leaves” that are placed in front of the radiation beam. They shift to form specific patterns modulating the radiation beam according to the prescribed treatment plan and the patient’s individual anatomy.

Actual radiation delivery time is 2 minutes, meaning most patients are in and out of the office in less than 20 minutes.

IMRT Side effects

Side effects of external beam radiation therapy include bowel and bladder urgency, irritation and frequency. Rectal irritation and long-term complications have been significantly reduced with the placement of SpaceOAR® hydrogel between the rectum and the prostate prior to radiation.

The majority of the side effects are temporary, and resolve over 6-8 weeks following the radiation. Most patients will continue their normal lifestyle during this treatment, including work and/or recreation.

Potency is preserved with radiation in the short-term but may diminish with time. Up to 50% of men may have erectile difficulty following radiation. 75% will respond to drugs like Viagra, Levitra or Cialis. Urinary stricture is possible in the long term, affecting approximately 2% of patients.

Image guidance (IMRT)

Image guidance is a necessary component of IMRT allowing treatment fields to be positioned with millimeter accuracy. Image guidance allows us to account for movement of the prostate which occurs naturally due to changes in bowel and bladder filling on a daily basis. It is most often performed utilizing very small VISICOIL™ gold markers, placed within the prostate. These markers can be easily seen with the special imaging tools attached to the treatment machines.

Once the final position is determined, the treatment is delivered. There is no need for these markers to be removed after treatment.

Learn More about SpaceOAR®

One potential toxicity of prostate radiation in any form concerns damage to the rectal tissue due to its proximity to the posterior surface of the prostate gland, typically within 2 mm.

SpaceOAR® consists of two liquids that mix together as they are injected into the narrow space between the rectum and prostate. The patient is under local anesthesia (here in the office), or general anesthesia at the time of Brachytherapy. The liquids, made mostly of water, will solidify into a gel-like substance 8-seconds after injection. This gel increases the distance between the prostate and the rectum and has been shown to significantly decrease long term side effects caused by damage to the rectum.

The gel will remain at full thickness for 3-months during radiation treatment, and is then absorbed slowly. It dissolves completely by 6-months.

The randomized SpaceOAR® hydrogel U.S. Clinical Trial found that patients who received the hydrogel spacer reported significantly less rectal pain during radiotherapy and had significantly less severe long-term rectal complications.

SpaceOAR® was approved in 2015, with widespread insurance coverage starting in January 2016. Arizona Oncology's Radiation Oncologist, Curtis Mack, MD, was the first physician in southern Arizona to be certified to perform this procedure, which he has done for all Arizona Oncology prostate cancer patients who have been treated with seeds and/or daily radiation since February 2016.

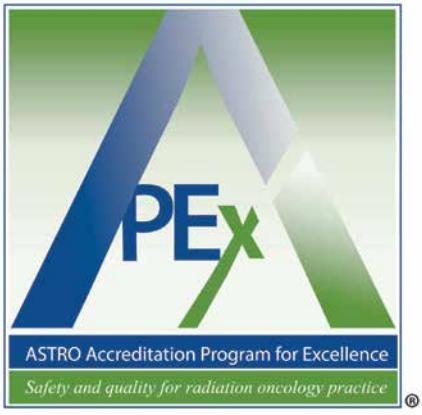
About Our Team

Arizona Oncology's Radiation Oncologists in Southern Arizona are all board-certified by the American Board of Radiology.

Together, we are part of a team of cancer specialists that includes medical oncology, surgical oncology, reconstructive surgeons, pathologists, interventional radiologists and genetic experts.

Arizona Oncology's Radiation Oncologists are supported by a highly-qualified team of physicists, dosimetrists and therapists.

Each of our radiation facilities in Southern Arizona are ASTRO APEx accredited. APEx is the practice accreditation program from the world's premier radiation oncology society, the American Society of Radiation Oncology. ASTRO created this unique program to support quality improvement in radiation therapy practices. Practices that obtain accreditation for their facilities demonstrate the systems, personnel, policies and procedures needed to meet APEx standards for high-quality patient care.



Please let our team know if you have any questions about anything included in this brochure, or about your prostate cancer. We are here to help.

Notes and Questions

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