Enhancing Patient Care and Practice Economics through Office-Based Electron Radiation Therapy

A White Paper for Dermatologists

IntraOp Medical Corporation

I. Introduction

Radiation therapy, traditionally used to successfully treat many internal cancers, can also provide highly effective—and often superior—therapy for skin cancers. Electron radiation therapy, which uses high-energy rays, is the choice for safe, effective skin cancer treatment without the risks of surgery. Recent advances in technology have made electron radiation therapy (RT) more accessible, allowing the logistics of patient focused care to remain at the dermatologist office.

New innovations—including an affordable, self-shielded, electron linear accelerators, are providing dermatology practices with cost-effective and practical options for delivering electron therapy for a wide variety of skin cancers.

As a standalone treatment or a complement to surgery, targeted electron radiation therapy provides an elegant alternative for difficult-to-treat skin cancer cases, from cosmetically challenging tumors to diabetic patients, and any other patient for whom surgery is not the preferred treatment. In fact, any non-melanoma skin cancer can be treated with radiation therapy.

Most electron therapy applications have long enjoyed strong Medicare and private payer reimbursements. When implemented appropriately from a business and administrative standpoint, dermatology office-based electron radiation therapy requires a relatively low patient volume to break even and need not involve significant capital expense to dramatically enhance practice economics and resource efficiency.

With the advances in electron radiation therapy and recent changes in Mohs surgery reimbursement, dermatologists would be well served to investigate the feasibility and benefits of incorporating office-based electrons into their practice and offering a multi-disciplinary skin cancer treatment solution.

This white paper explores the benefits of electron radiation therapy, available electron technologies and logistics of incorporating them into a dermatology practice for enhanced patient care and satisfaction as well as practice revenues.

II. Background

Many dermatologists have familiarity with the various radiotherapy treatment technologies and delivery options available today. Radiation therapy for skin cancer has a significant history that dates back more than 75 years. Radiation Therapy (RT) was even part of the Medical School curriculum for most

Dermatology programs as late as the 1990's. Radiation treatments generally provide a high rate of cure and low recurrence for non-melanoma cancers.

However, the inconsistency in technique and technology of the 1950s and 1960s that continued to be used in dermatology, often resulted in inaccurate dosage, uneven cosmetic results, and occasional radiation-induced malignancies. Since the late 1970's, however, improved electron radiation therapy technology has enabled more predictable and precise radiation therapy for skin cancers. Today, the long-term radiation-induced malignancy risk is less than 0.03%, or less than 3 in 10,000 patients.

These advances have been slow to enter the skin cancer market for a number of reasons. One reason was that cancer centers built during the past several decades catered to mainstream radiation therapy with little attention to the unique needs of skin cancer patients. As a result, surgical techniques, not radiation therapy, provided a more effective and practical answer for skin cancer treatment and became the standard of care.

As a result, RT inevitably became the "exception" treatment for skin cancer and primarily used only on difficult and high risk cases. Most patients are referred for radiation at either a hospital or a radiation oncology center where the patients can be treated by electron RT with a traditional linear accelerator in a shielded bunker.

Electron radiation therapy is most effective for superficial tumors like skin cancers, which are generally less than 4 centimeters deep. High-energy electrons have maximum impact near the surface and can be fine tuned to penetrate depths between 1 and 3cm to optimize the dose for the patient's specific tumor or lesion. Because external skin lesions are often small and visible, they will benefit from extremely precise targeting of the power of high-energy electron RT. Also, electron RT has superior dose distribution and symmetry, delivering a consistent, predictable dose with every treatment, eliminating "hot spots" and guesswork commonly associated with older technology.

It has started to become clear that the long held cautions and prejudice of using RT for dermatology was due to the variety and inconsistency of different techniques being used. This shift to a nearly exclusive use of electrons for dermatological RT has produced the consistency of treatment to deliver excellent cure rates and cosmesis.

III. Benefit to Patients

Studies have shown that electron radiation therapy is as effective as surgical treatment for any non-melanoma skin cancer, including all basal and squamous cell carcinomas, with five-year cure rates at more than 95%. For certain of these cancers, such as peri-neural involvement and PD lesions, electron radiation therapy, combined with surgery, increases cure rates from 38% to over 90%. See Appendix I for the reported experience and findings of a couple well known institutions.

In particular, electron therapy provides significantly enhanced cosmesis with little scarring or other visible tissue damage, compared to surgical treatments, and virtually no risk of infection, since no incision is required. This makes it of particular value for patients with cancers in highly visible and cosmetically sensitive areas, such as the nose, ears and eyelids. Given that many skin cancers occur on the face, this population often represents a high percentage of a practice's patient load.

Improved cosmesis also benefits patients with large regions of tissue tumor involvement and recurrent skin cancers who would sustain significant tissue damage with the multiple surgeries required for treatment. For these and other patients, electron therapy eliminates the need for painful and costly skin grafts.

Also, because treatment involves no loss of blood, electrons also deliver benefits over surgical intervention for patients with large tumors on extremities or in other areas with compromised blood supply. Typically, electron radiation therapy is preferable for diabetics and others with blood-clotting impairments. Finally, it is the choice for patients who are poor candidates for surgery due to a variety of factors, such as age and fragility.

Benefiting every patient, electron radiation therapy treatment does not require anesthesia and is significantly less painful than surgery, with less trauma and faster recovery.

Also important, in certain cases, including Mohs surgery, electron radiation therapy is a complement to surgery and will help safeguard against cancer recurrence.

IV. Benefits to Dermatology Practices

For dermatologists delivering electron radiation therapy in-house, patient benefits come hand-in-hand with a range of benefits for the dermatology practice itself.

In today's competitive medical marketplace, a multi-disciplinary offering provides a dermatology practice with a uniquely competitive advantage.

The benefits of RT will clearly attract patients with special needs, such as the elderly, those with cosmetically challenging tumors, or large field treatment areas. This new patient growth coupled with strong existing reimbursement (Appendix Table II) will provide immediate economic benefit to the dermatology practice. Additionally, since RT patients will be treated by a radiation oncologist the dermatologist will have more capacity to see and treat new patients.

To illustrate this, consider the example of an elderly patient with a basal cell carcinoma on her forehead. Typically, this patient would be treated with Mohs surgery and require a complex 1 to 3 hour surgery, due to the age of the patient and the cosmetically sensitive nature of the tumor location. Treating with electron RT will free up roughly 1-3 hours of the dermatologist's time, not including the additional time that might be required for post operative plastic surgery. In this case, it is reasonable to assume that four simple 30-minute Mohs surgeries could be performed in the 1-3 hours saved on this complex case. Meanwhile, the reimbursement for the RT treatments is more than the Mohs surgeries, with no associated costs, meaning that the dermatology practice gains both in economic terms and in resource productivity.

When office-based electron radiation therapy is delivered in-house by a qualified radiation therapy caregiver, physicians can offer these benefits while continuing to capture significant revenues for the cancer treatment process without devoting time to lengthy cancer surgeries. Instead, dermatologists can leverage the practice hours to expand patient volume and boost revenues.

V. DermaBeam and Mobetron Technology

Today few dermatologists routinely consider electrons as an alternative or complement to surgical treatment. In large part, this is because the logistics of electron radiation therapy delivery have been problematic due to linear accelerator equipment size and shielding requirements. Moreover, with radiation treatments historically provided at oncology centers, dermatologists no longer remain part of the continuum of care, compromising both patient relationships and revenues.

DermaBeam electron beam radiotherapy delivered by the Mobetron represents a significant technological breakthrough. Fine-tuned to meet the needs of free-standing dermatology practices, the Mobetron is a compact, affordable, self-shielded electron linear accelerator that delivers electron radiation therapy without the need of a radiation bunker or extensive room modifications.

Now, for the first time, in their offices, dermatologists can provide electron radiation therapy that is as powerful and effective as the radiation therapy provided in specialized cancer centers, in the comfort of their own office.

DermaBeam takes advantage of the proven performance of IntraOp's advanced Mobetron technology, which successfully delivers powerful electron radiation therapy using a mobilelinear accelerator that is less than one-eighth the weight of a conventional linear accelerator. The patented mobility and built-in shielding of the Mobetron represent a significant technological breakthrough.

For more than 10 years, the Mobetron has been used around the world to deliver electron radiation directly to the tumor bed during surgical resection. This procedure, known as intra-operative radiation therapy (IORT), has been used in a wide range of internal cancer and is typically followed up with a reduced course of EBRT and has produced astounding results.

For skin cancer, the tumor is already accessible and visible, so it was a logical evolution for the Mobetron to treat skin cancer. To properly address the specific requirements of skin cancer, IntraOp modified the Mobetron for the dermatology application. By reducing the delivered dose rate per minute to insure minimal impact to the epidermis, the Mobetron is perfectly suited to be used as an external beam machine to treat skin cancers over a series of multiple treatments that will kill the cancer and preserve the epidermis.

Unlike conventional radiation therapy, the Mobetron's DermaBeam treatment is specifically designed to target small anatomic areas with a high degree of precision to minimize damage to healthy tissue. Typically, patients receive one to two minutes of radiation five days a week during the course of five or six weeks.

Breakthrough DermaBeam technology provides dermatologists and their patients with an important new treatment option. Initial physician and patient reaction to the procedure at existing installations has been enthusiastic.

VI. The DermaBeam Business Solution

Recognizing that multi-disciplinary medical treatments can be complex, IntraOp has partnered with radiation oncology specialists to create a turnkey electron radiation therapy program for dermatology practices that minimizes management time and capital expenses.

With its partners, IntraOp will manage set up of the radiation therapy program, from start to finish. This includes obtaining permits, ensuring compliance with the local regulatory agency and working with the dermatologist to establish radiation therapy coding and billing, along with the technology installation and testing.

Following Mobetron installation IntraOp will provide an onsite dosimetrist, radiation therapist, and radiation oncologist if a practice does not already have these relationships. Dermatologists continue to see patients as before but refer potential radiation therapy cases for a consultation in-house by the radiation oncologist, who functions as part of the practice team. For patients who go on to have radiation therapy, the radiation oncologist prescribes and delivers the course of treatment using the Mobetron in the dermatology office.

IntraOp will lease the Mobetron device to the Dermatology office in a revenue share and per patient charge arrangement. The dermatology practice will bill for the radiation therapy technical fee component, and will split that revenue with IntraOp. The radiation oncologist will bill and receive all professional fees for the radiation therapy delivery. This particular arrangement ensures that all parties in the venture are in compliance with Stark regulations. Through this program, a dermatology practice enjoys significant added revenue, while the radiation oncologist delivers the actual services and dermatologists are free to see other patients.

Using this model, estimates are that dermatology practices will offset their complete radiation therapy set-up and operating costs by treating as few as six patients each month and will recoup their entire initial investment by treating 220 total patients overall. The latter should easily be achieved during the first year of Mobetron use.

VII. Conclusion

As radiation therapy technologies have matured, electrons provide an effective, cost-efficient and relatively easy-to-implement treatment for skin cancer, benefiting both patients and dermatology practices. Electron RT is the choice for skin cancer therapy because these high-energy rays are appropriate to effectively treat 95% of all skin cancers seen in a typical dermatology practice.

IntraOp's self-shielded, mobile Mobetron electron therapy device, with its specialized DermaBean system for dermatology applications, is optimized for use in the dermatology office. When implemented through IntraOp's turnkey program, the device can pay for itself after treatment of as few as five patients per month. Given this, for many dermatology practices, the Mobetron can provide the dermatologist with an opportunity to offer a multi-disciplinary approach to treating skin cancer, while having an immediate economic impact on any size dermatology practice.

About IntraOp Medical Corporation

IntraOp Medical Corporation provides innovative technology solutions for the treatment and eradication of cancer. Founded in 1993, IntraOp is committed to providing the tools doctors need to administer intraoperative radiation therapy safely and effectively – for all cancer patients. The company's flagship product, the Mobetron, is the first fully portable, self-shielding intraoperative electron radiation therapy device designed for use in any operating room. Key Mobetron benefits include: increased survival rates, better local tumor control, shorter treatment cycles, immediate palliative effect, and fewer side effects. Leading hospitals, from university research centers to specialized cancer clinics world-wide are increasingly using the Mobetron to treat a wide variety of cancers as a vital part of their comprehensive cancer program.

Currently, IntraOp's Mobetron/DermaBeam technology is forging a new paradigm in the effective, efficient treatment of skin cancers in dermatology offices nationwide. For more information about IntraOp Medical and the Mobetron, visit: www.intraopmedical.com

Illustrations

Top row: IntraOp's Mobetron

Bottom row: A patient's hand before and after treatment with DermaBeam electron beam radiotherapy

Appendix I

Cure Rates at 5 Years with Radiation Therapy*

		Basal Cell Carcinoma	Squamous Cell Carcinoma
Hahnemann Univ.		96%	92%
Washington Univ.	< 1 cm	96%	100%
	1 - 2 cm	97%	92%
	2 - 5 cm	90%	86%
	> 5 cm	94%	86%

***** "Radiotherapy for Epithelial Skin Cancer", J. Locke, et. al., Int J. of Rad. Oncol. Biol. Phys., Vol. 51, No. 3, pp. 748–755, 2001 and "Principles and Practice of Radiation Oncology", Perez and Brady, 1987, pp.

Appendix II

Reimbursement Guidelines for Electron RT*

This chart is based on average US global billings for 25 fractions. Actual rates and billings for CMS and private payers will vary by locations.

Electron Radiation Therapy for Skin Cancer								
CPT	**CPT Description**	**Quantity Billed**	**Professional Rate**	**Technical Rate**	**Global Rate**	**Professional Reimbursement**	**Technical Reimbursement**	**Total Reimbursement**
77263	Clinical Treatment Plan	1	$152.35	$0.00	$152.35	$152.35	$0.00	$152.35
77280	Simple Simulation	1	$74.27	$159.63	$233.90	$74.27	$159.63	$233.90
77321	Special Teletherapy Port Plan	1	$45.70	$86.43	$132.13	$45.70	$86.43	$132.13
77331	TC Diodes	1	$0.00	$19.98	$19.98	$0.00	$19.98	$19.98
77332	TC Treat Devices Simple	1	$0.00	$54.88	$54.88	$0.00	$54.88	$54.88
77334TC	Complex Tx Device	1	$0.00	$105.95	$105.95	$0.00	$105.95	$105.95
77300TC	Calculation	1	$29.71	$44.23	$73.94	$29.71	$44.23	$73.94
77336	Weekly Physics	4	$0.00	$70.99	$70.99	$0.00	$283.96	$283.96
77413	Complex Treatment Delivery	25	$0.00	$216.53	$216.53	$0.00	$5,413.25	$5,413.25
77427	Weekly Physician Management	4	$177.10	$0.00	$177.10	$708.40	$0.00	$708.40
99214	Office Visit, established patient (follow-up)	1	$89.89	$0.00	$89.89	$89.89	$0.00	$89.89
99244	Office Visit, consult	1	$179.01	$0.00	$179.01	$179.01	$0.00	$179.01
Total Estimated Reimbursement						**$1,279.33**	**$6,168.31**	**$7,447.64**

** The information provided with this notice is general reimbursement information only as of January 2009; it is not legal advice, nor is it advice about how to code, complete or submit any particular claim for payment. Although we supply this information to the best of our current knowledge, it is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers and bills for the services that were rendered. This information is provided as of the date listed above, and all coding and reimbursement information is subject to change without notice. Payers or their local branches may have their own coding and reimbursement requirements and policies. Before filing any claims, providers should verify current requirements and policies with the payer.*