

## **The Need for Superficial Radiation Therapy (SRT) Treating Skin Cancer**

### **Skin Cancer - Overview**

Skin cancer accounts for more than 40% of all malignancies in the United States. It is estimated that up to 1.3M new skin cancer cases are diagnosed annually in the United States and over 2.5M worldwide. This is projected to increase at a rate of 4% each year. Over 95% of these skin cancers are basal or squamous cell carcinomas. Other skin cancer categories include melanoma, mycosis fungoides, Kaposi's sarcoma, Paget's disease and apocrine carcinoma. The annual death rate from skin cancer in the United States is approximately 10,000. The primary treatment options providing both high cure rate and low recurrence include surgery and less invasive superficial radiation therapy. United States annual medical expenditures for treating skin cancer exceed \$1.0B with Global expenditures exceed \$3.0B.

The incidence of skin cancer has steadily increased over the past 75 years. During the 1930's, 1 in 1500 developed skin cancer. In 1960, the rate had risen to 1 in 600 and in 2000, the rate increased to 1 in 66. The National Cancer Institute estimates that 1 out of 7 is now at risk for developing some form of skin cancer during their lifetime. Increased exposure to the sun without skin protection and a decreasing natural ozone layer are cited as the chief causes of this increase.

### **Occurrence/Recurrence**

Over 80% of skin cancers occur in the head and neck regions that include scalp, forehead, eyelids, ears (both inner and outer), nose, lips, cheek, chin, jaw and supraclavicular. These are high-risk recurrence locations by as much as 25% depending on lesion diameter, and if not properly treated.

### **Demographics**

Skin cancer, like all cancers, takes a long time to develop from a single mutated cell to a visible change seen on the skin. Older adults are more susceptible. 50% of skin cancer cases occur in adults aged over 60, with males more at risk than females by a factor of two. The US Census Bureau projects that by the year 2025 the over 60-age group will double in size from 2000. This is further evidenced by the rising number of nursing convalescent homes for the aged, which has steadily increased to over 17,000.

### **Need for Superficial Radiation Therapy (SRT)**

The traditional methods for treating skin cancer with proven high cure rates above 90%-95% and low recurrence of less than 10% involve special surgical procedures and less invasive SRT. Although other treatment methods are emerging, many are still in development stages requiring further clinical studies for cure rate/recurrence outcomes and evaluation of after-effects such as edema, permanent pigment loss, atrophy, hypertrophic scarring, motor and sensory neuropathy.

SRT has been a proven skin cancer treatment method treating basal and squamous cell carcinomas since the 1950's providing a high cure rate and low recurrence. Medicare part B and most insurance carriers readily accept SRT treatment for reimbursement. SRT becomes a logical choice for primary lesions requiring difficult or extensive surgery with sensitive structures in the head and neck regions – the fold in the nose, eyelids, lips, corner of the mouth, and the lining of the ear that would otherwise lead to a poor cosmetic outcome – and treatment procedures do not require the use of anesthetics. SRT also eliminates the need for skin grafting when surgery would result in an extensive defect. Cosmetic results are rated excellent in comparison to other treatments with a small amount of hypopigmentation or telangiectasia at the treatment site.

### **Business Opportunity for SRT**

The benefits of SRT need resurgence and awareness among the Primary Care Physician, Dermatology and Patient Communities. Over the past few years, new surgery techniques and government funding of treatment options such as laser technology and hormonal creams diminished the use of SRT. Many SRT systems now in use are approaching their useful life and will require replacement. Many Oncology centers have older SRT devices that perform thousands procedures per year. As the patient population ages, the need for skin treatment increases as does the need to bring skin cancer therapy to the patient, especially at the more than 17,000 nursing convalescent facilities. The known high cure rate and low recurrence of SRT combined with the benefit of cosmetic outcome and a friendly reimbursement environment creates a niche opportunity. Focused consumer and practitioner educational awareness of the benefits of SRT are keys for success. Awareness through such organizations as ASTRO, AAPM, AAD and AARP provides access to the over 2300 Oncology centers, 14,000 Dermatologists, 4000 Medical Physicists and the over 50 age group population in the United States.

### **Summary**

There are many compelling facts supporting development of a new SRT system for a niche market business opportunity. These include the following; **a)** skin cancer now accounts for 40% of all malignancies in the United States **b)** the incidence of skin cancer is rising 4% annually **c)** medical expenditures now exceed \$1.0B annually to treat skin cancer **d)** 50% of those over the age of 60 will develop some form of skin cancer **d)** the over 60 population is expected to double over the next 20 years with males twice as much at risk than females **e)** over 80% of skin cancers occur in the head and neck regions containing sensitive structures susceptible to poor cosmetic outcomes **e)** less invasive SRT provides excellent cosmetic results with a high cure rate and low recurrence **f)** treatment procedures do not require the use of anesthetics **g)** the current installed base of SRT devices are reaching their life expectancy **h)** over the years large x-ray manufacturers shifted focus to high priced LINAC technology systems and no longer offer affordable special purpose SRT systems for treating skin cancer **i)** a need for educational awareness to increase use of SRT and **j)** Medicare part B and most insurance carriers readily accept SRT for reimbursement.

## **Why Treat Skin Cancer with Superficial X-Ray Therapy?**

In addition to treating basal and squamous cell carcinoma, superficial x-ray therapy can also be used for the treatment of cutaneous lymphoma, especially thin nodules and thick plaques, Kaposi's sarcoma, lymphocytoma cutis and keloids.

Patient satisfaction is high with outpatient dermatologic radiotherapy. In a study performed at the Skin and Cancer Foundation Victoria, Melbourne on patients undergoing superficial x-ray therapy for non-melanoma skin cancer, the patients were asked to rate the general outcome of their treatment as well as the cosmetic outcome of their treatment. Of 245 respondents, general outcomes were rated 76% excellent, 21% good, 3% average and one patient reported a poor result. Cosmetic outcomes were 61% excellent, 32% good, 6% average and 1% less than average or poor.

Superficial X-ray Therapy is most advantageous for the treatment of non-melanoma skin cancers in the head and neck region and/or combined with the following patient situations;

- 1 – Patients who refuse surgery (fear of surgery or needle phobia).
- 2 – Patients who are not medically fit for surgery, who have contraindications for reconstructive surgery such as patients receiving anti-coagulants and patients unfit for general anesthesia.
- 3 – Patients in who x-ray therapy may give a better cosmetic outcome, especially in the linings of the ear, the folds in nose, the lip and corners of the mouth.
- 4 – Patients in who x-ray therapy may provide a simpler option than extensive reconstructive surgery involving skin grafting.
- 5 – Patients in who surgery may cause nerve damage or functional impairment such as tumors overlying the spinal accessory nerve or marginal mandibular nerve.
- 6 – Patients with deep or lateral marginal involvement following excision of tumors where surgery is not feasible or not likely to be tolerated or refused.
- 7 – Patients who have a high risk of residual microscopic size disease such as a patient with a completely excised tumor with perineural invasion and no clinical signs or following surgery of poorly differentiated squamous cell carcinomas.
- 8 – Patients with small volume or marginal recurrent disease following surgery which may require x-ray treatment of the full length of the scar and a safe margin clearance.

### Sources:

Skin and Cancer Foundation Victoria, 2000, Webster and Smales, Melbourne  
Radiation Treatment & Radiation Reactions in Dermatology, Johnson and Webster, 2004  
World Health Organization  
National Cancer Institute  
US Census Bureau