MANAGEMENT OF NMSC

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DISCLOSURE

- Consultant for Sensus
- I ran an ACGME Micrographic Surgery and Cutaneous Oncology Fellowship
- I am member of SRT Consensus Group

MULTIPLE APPROACHES

- Mohs Micrographic Surgery (Mohs) and other surgical approaches
- Other Destructive Methods
- PD-1 /Hedgehog Inhibitors
- Superficial Radiation Therapy (SRT)

100+ Years of Innovations in NMSC Care

1920s

100+ YEARS AGO

SRT Innovation

Dermatologists initiate the research and development of fractionated superficial radiation therapy (SRT), setting the stage for a promising new NMSC treatment modality[1]

SRT cure rates:[1]
80% to 90%
for NMSCs

100+ Years of Innovations in NMSC Care

1930s
1970s

FOR DECADES

SRT Is a Commonly-Used First-line, Standard of Care in Dermatology

SRT and surgical resections are the primary treatment modalities, giving patients both non-surgical and surgical first-line treatment options[1,2]

56%
of US-based dermatologists offered SRT in the 70s[1]

100+ Years of Innovations in NMSC Care

1970s

50+ YEARS AGO

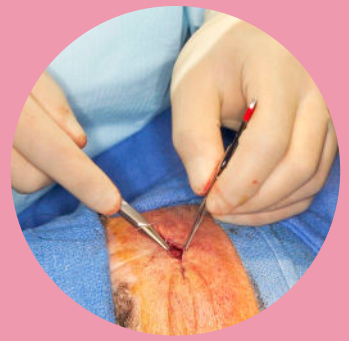
Surgical Innovation

The Mohs micrographic surgery (MMS) technique is optimized. Dermatology residency programs begin training on MMS, while government regulations start limiting use of SRT[1]

MMS cure rates:[2]
Up to **99%** for BCC
95% for SCC

100+ Years of Innovations in NMSC Care

1980s **2014**



FOR 35+ YEARS

MMS Takes Over As the Primary Standard of Care for NMSC

With better cure rates than SRT, MMS becomes the new first-line treatment, and SRT moves to a second-line option for patients who do not want, or are not candidates for, surgery[3]

SRT moves to a **second line NMSC** treatment[3,4]

100+ Years of Innovations in NMSC Care

2015

~10 YEARS AGO

SRT Innovation

High-resolution dermal ultrasound (HRDUS) imaging optimizes SRT delivery, and the first highly targeted noninvasive image-guided SRT (IGSRT) device–the SRT-100™ Vision–receives 510(k) clearance for the treatment of NMSC and keloids[5]

IGSRT cure rates:[6]
99%+ for BCC
99%+ for SCC

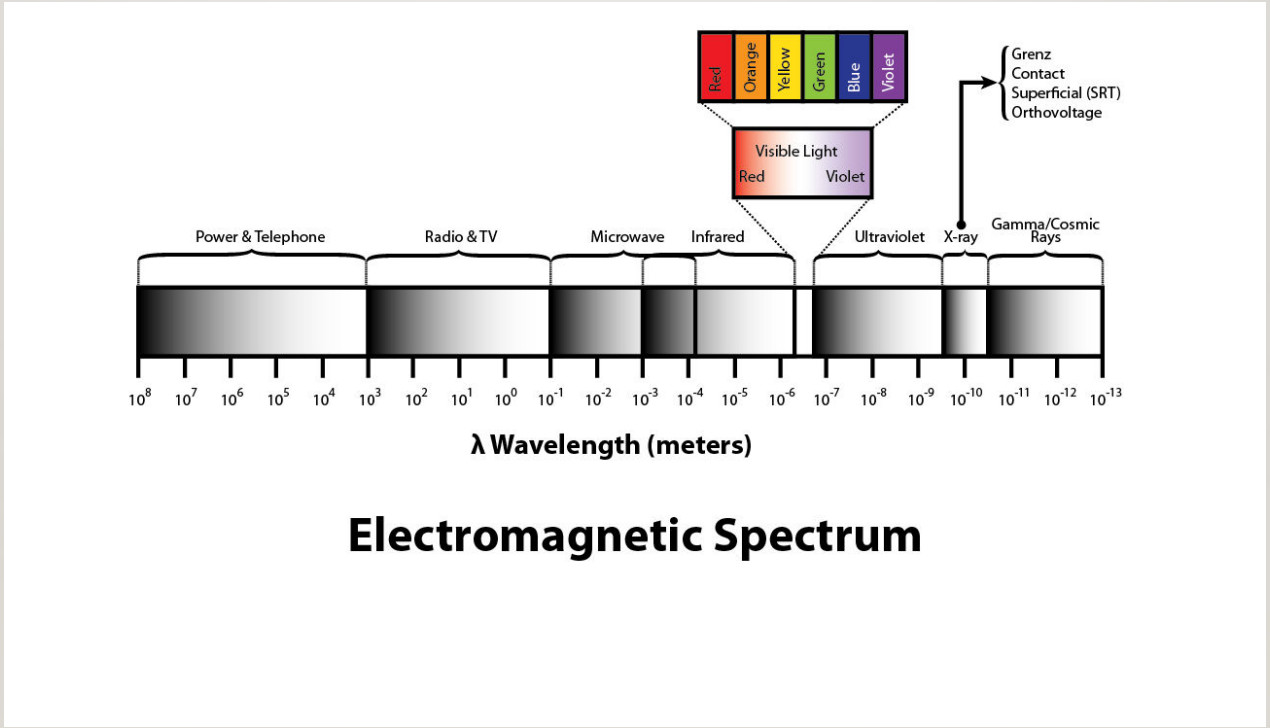
100+ Years of Innovations in NMSC Care

2016
Present

IN RECENT YEARS

IGSRT Ushers In a New First-Line Noninvasive Standard of Care

SUPERFICIAL RADIATION THERAPY (SRT)



Electromagnetic Spectrum

MODERN SRT EQUIPMENT

- Utilizes low energy photon X-rays operating at variable peak voltages of 50, 70, and 100 kVp.

MODERN SRT EQUIPMENT

- Planned calibrated dose delivery is accurate with internal filtration technology.

MODERN SRT EQUIPMENT

- Unit automatically stops when cumulative amount of radiation is delivered.

MODERN SRT EQUIPMENT

- Easy to administer
- Effectively targets and treats lesions
- Delivers gentle indirect radiation which does not penetrate and impact the underlying healthy tissue.

SRT

- FDA approved for total body treatment of non melanoma skin cancer (NMSC)

- Keloid

EVIDENCE BASED THERAPY

- The cure rate for 1715 primary nonaggressive NMSC treated with the SRT-100™ was 98% (Cognetta et al, JAAD 2012).

TUMOR AND PATIENT SELECTION: TREATMENT OBJECTIVES

- To eradicate the tumor while maintaining or improving the patient's quality of life.

NMSC

Most commonly treated with SRT

- Basal Cell Carcinoma
- Squamous Cell Carcinoma

TUMOR SITE

- SRT may be used to treat tumors on all skin surface areas

SRT may give a better cosmetic outcome:

- Scalp
- Eyelid
- External ear canal and helix
- Nasal ala
- Oral commissure
- Lower extremities

CONFUSION

- The differences between superficial radiation therapy, electron beam, brachytherapy and electronic brachytherapy

CONSENSUS

- SRT more energy and deeper penetrating than Grenz ray
- Brachytherapy uses radioactive sources within or directly adjacent to tumor
- Electron beam therapy uses a medical linear accelerator

CONSENSUS

- EBT also requires higher energy to encompass many superficial skin cancers than does SRT
- SRT has higher cure rates and better cosmesis than both brachiotherapy and electron beam therapy
- SRT more cost-effective in terms of both equipment and patient cost

LARGE TUMORS

- SRT may present a simpler option than extensive surgery and reconstruction(skin grafting)
- Minimally higher risk of recurrence than surgery
- What about other benefits?

CONSENSUS

- SRT clearly more beneficial for many NMSC on lower extremities
- SRT has particularly favorable cosmetic benefit on alar rim of nose and periorbital area.

IMPORTANT FACTORS TO CONSIDER

- Treatment margin
- 8-10mm margins are common for BCC
- 10mm is used for SCC.
- Recommendations based on estimates of surgical margins

CONSENSUS

- Beam and delivered dose of SRT has only 1 mm lateral edge drop-off (penumbra) of the treatment site
- Radiation field should be small (umbra)
- So initial measurement of tumor size should be size of lesion plus 2-5 mm margin around the lesion
- Almost all lesions will have size of >2cm.

IDEAL PATIENTS FOR SRT

- Elderly
- Poor surgical candidates

CONSENSUS

- SRT does not require that patients stop anticoagulants
- SRT can be used safely in patients with poor circulation
- SRT best for those who cannot do wound care
- SRT best for those with significant fear of surgery and scarring

CONTRAINDICATIONS FOR SRT

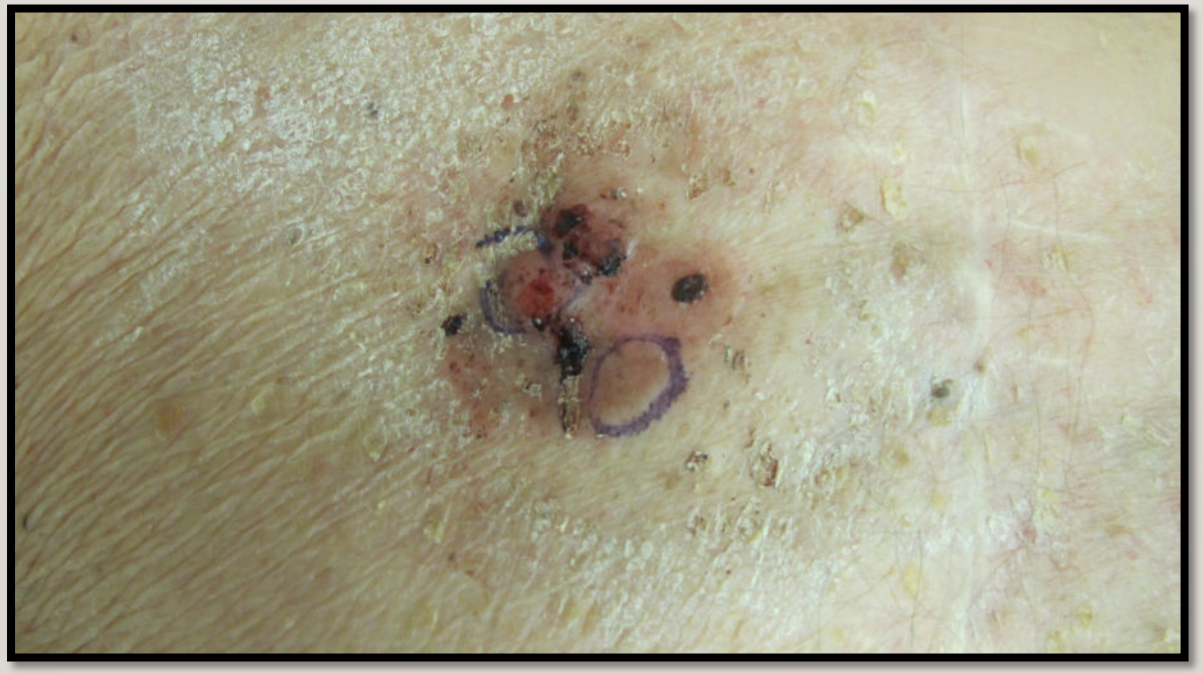
- Pacemaker or defibrillator within the treatment area
- Previous radiation therapy to the area of concern

NMSC: BCC

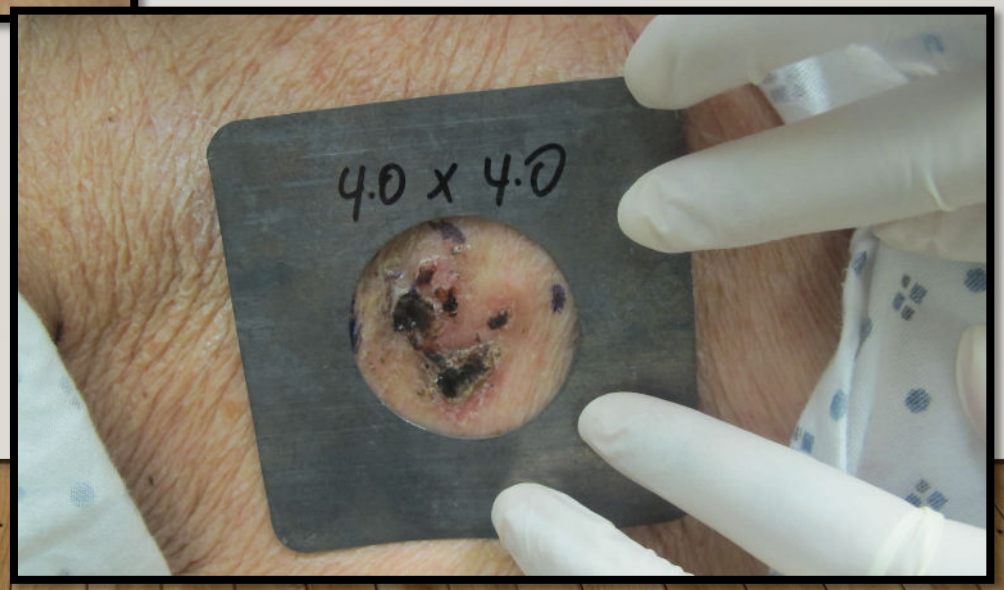
BCC R FOREHEAD

BCC FOREHEAD 4 MONTHS POST SRT

BCC R CHEST

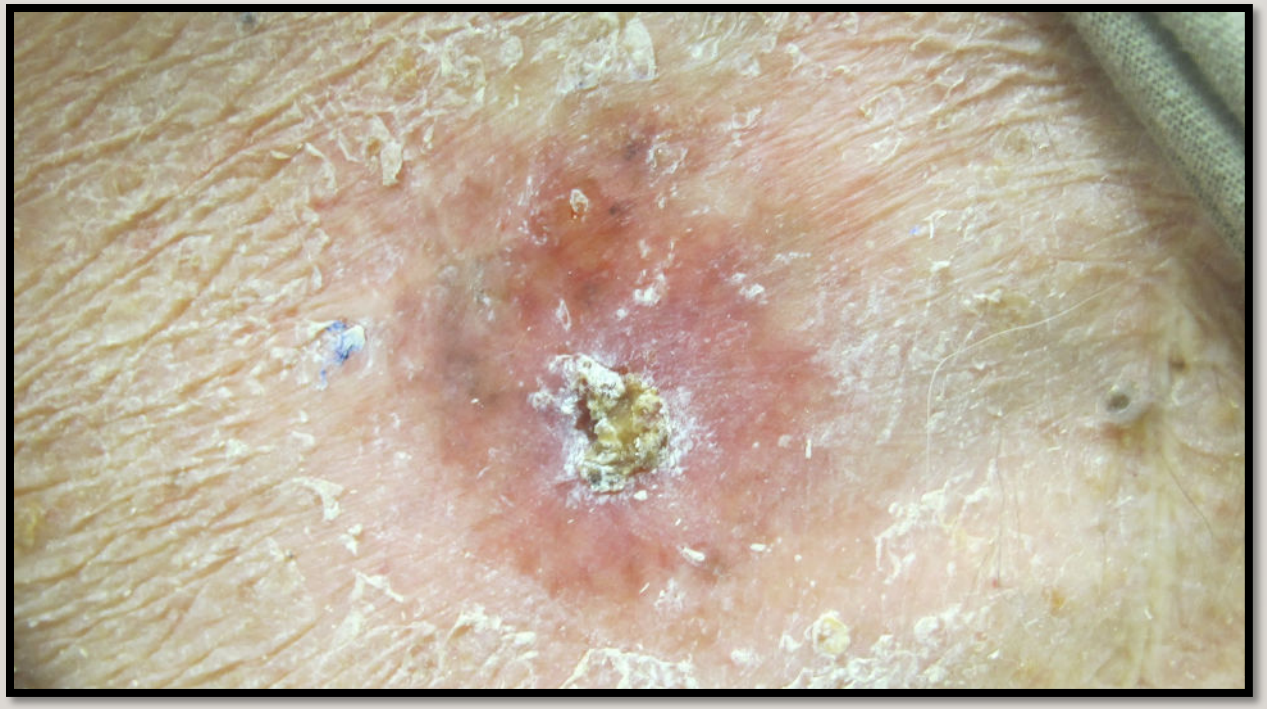


BCC R CHEST



BCC R CHEST

BCC R CHEST POST SRT:4 WEEKS



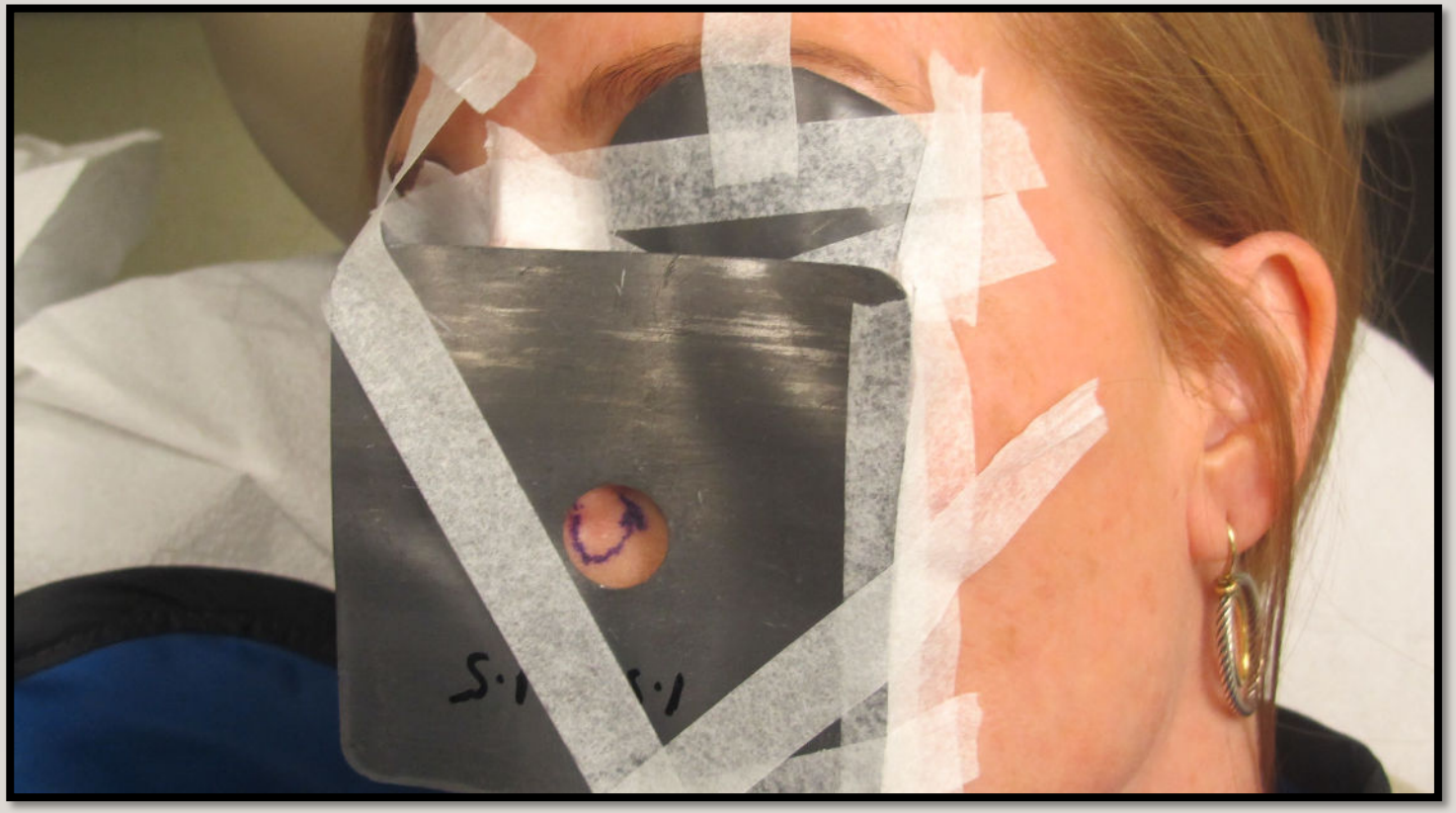
BCC L TEMPLE


5.0 x 5.0


STATUS
TREATMENT
READY
50 kV
10.0 mA
820 cGy/min
0.1 mm Al FILTRATION
0.42 mm Al HVL
APPLICATOR #10
DIAMETER
5.0cm
SSD
15cm
DOSE
397.1 cGy SET
0.0 cGy ACTUAL

BCC L INFRANASAL AREA

BCC L INFRANASAL AREA

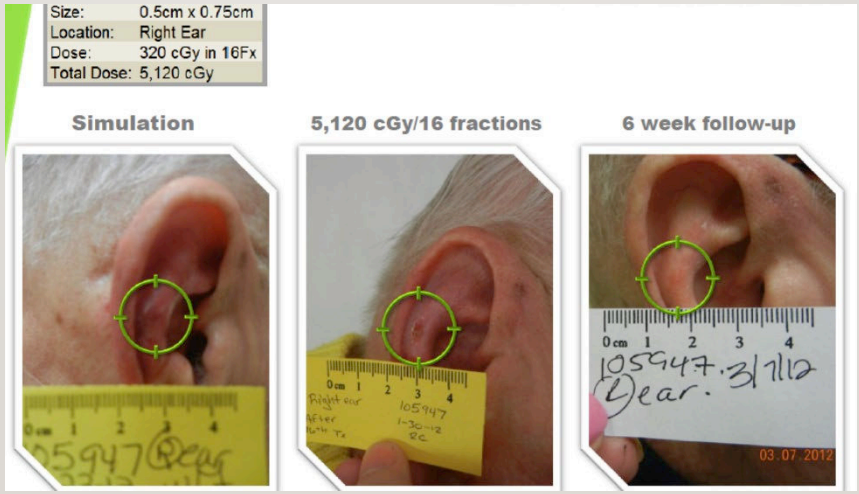


BCC NOSE


Size: 1cm x 1cm
Location: Nose
Dose: 571 cGY @ 7Fx
Total Dose: 4,000 cGy
At first treatment
2 weeks into SRT
3.5 months post SRT

SCC R HELIX

SCC R EAR


Size: 0.5cm x 0.75cm
Location: Right Ear
Dose: 320 cGy in 16Fx
Total Dose: 5,120 cGy
Simulation
5,120 cGy/16 fractions
6 week follow-up
03.07.2012

SCC L LEG


Size: 1.5cm x 1.5cm
Location: Left Leg
Dose: 350 cGY @ 12Fx
Total Dose: 4,200 cGy
2 weeks post SRT
4 weeks post SRT
2 months post SRT

COMPLICATIONS

- Temporary erythema almost all patients for 7-10 days
- Erythema usually related to dose of radiation
- Hyperpigmentation most common in Fitz V-VI patients
- Radiation dermatitis occasionally seen. Treatment with silicone gels

CONSENSUS

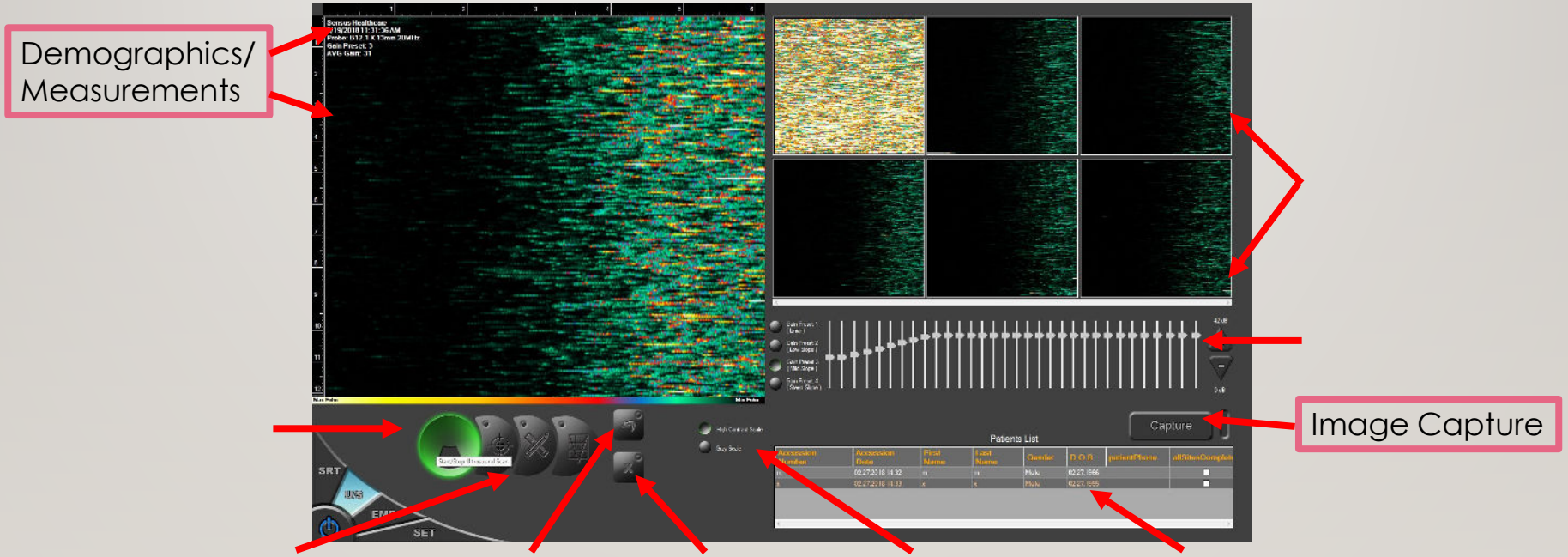
- There is insufficient evidence to support or refute specific topical therapies for prevention or management of radiation-induced skin changes
- There is no evidence that use of anti-inflammatory agents have any impact on cure rates
- Management of radiation dermatitis based on severity of damaged skin
- SRT induced radiation dermatitis mild

RADIATION DEMATITIS

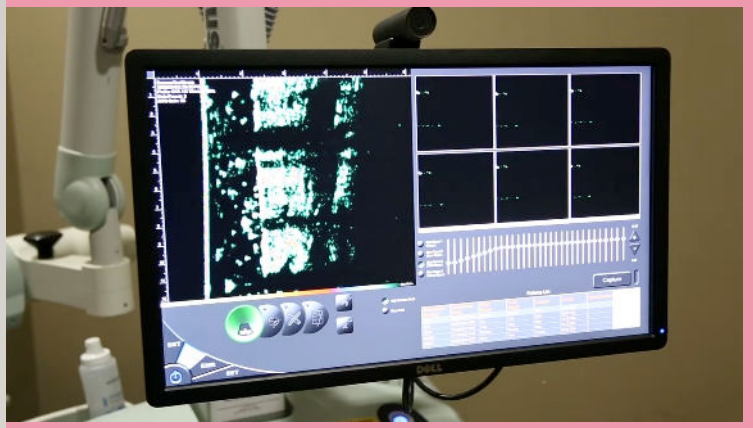
2 days of silicone gel treatment

HIGH FREQUENCY ULTRASOUND (HFUS) IMAGE GUIDANCE

Ultrasound Display



IGSRT REPRESENTS A SIGNIFICANT INNOVATION IN NONINVASIVE NMSC TREATMENT



Unlike SRT, IGSRT combines high-resolution dermal ultrasound (HRDUS) imaging and SRT

- ✓ Can see and measure lesions at every stage[1,2]
- ✓ Allows for adaptive, needs-based dosing according to tumor response throughout the course of treatment[1,2]
- ✓ Enables precision targeting of cancer cells[1,2]
- ✓ Maximizes efficacy while minimizing toxicity in alignment with ALARA (as low as reasonably achievable)[1-3]

References: 1. Dermatology Association of Radiation Therapy. DART clinical guidelines for nonmelanoma skin cancer: Appropriate use criteria for the treatment of early-stage cutaneous squamous cell carcinoma (SCC) using image-guided superficial radiation therapy Version 1.2024. Available at: https://dermassociationrt.org/guidelines **2.** Dermatology Association of Radiation Therapy. DART clinical guidelines for nonmelanoma skin cancer: Appropriate use criteria for the treatment of early-stage basal cell carcinoma (BCC) using image-guided superficial radiation therapy Version 1.2024. Available at: https://dermassociationrt.org/guidelines **3.** Centers for Disease Control and Prevention. Radiation and your health: radiation safety. Available at https:// www.cdc.gov/nceh/radiation/safety.html. Accessed April 25, 2024.

IGSRT EFFICACY AND SAFETY IS DEMONSTRATED IN NUMEROUS CLINICAL STUDIES

IN THE TREATMENT OF NMSC:

IGSRT with HRDUS imaging has been shown to deliver:[1-5]

- ✓ **99%+** cure rates for BCC and SCC
- ✓ **99%+** patient satisfaction
- ✓ **0.2%** reported recurrence to tumor registry in 120,000+ lesions treated to date (76 BCC, 67 SCC)
- ✓ **0** secondary cancers reported

BCC=basal cell carcinoma; SCC=squamous cell carcinoma.

References: 1. Tran A, Moloney M, Kaczmarski P, Zheng S, et al. Analysis of image-guided superficial radiation therapy (IGSRT) on the treatment of early-stage non-melanoma skin cancer (NMSC) in the outpatient dermatology setting. *J Cancer Res Clin Oncol.* 2023;149(9):6283-6291. doi:10.1007/s00432-023-04597-2 **2.** Yu L, Moloney M, Beers R, Serure D. Enhancing cosmesis while achieving high cure rates for early-stage non-melanoma skin cancer in the outpatient dermatology clinic using novel non-invasive modality. *Am J Biomed Sci & Res.* 2021;12(6):525-532. doi:10.34297/AJBSR.2021.12.001803 **3.** Moloney M, Kaczmarski P, Zheng S, et al. Updated results of 3,050 non-melanoma skin cancer (NMSC) lesions in 1,725 patients treated with high resolution dermal ultrasound-guided superficial radiotherapy: a multi-institutional study. Available at https://assets.researchsquare.com/files/rs-4047823/v1/8d4bc9c2-33bc- 4368-8ae8-cb090b640de5.pdf. Accessed on April 25, 2024. doi.org/10.21203/rs.3.rs-4047823/v1 **4.** McClure EM, Sedor G, Jin Y, Kattan MW. Image-guided superficial radiation therapy has superior 2-year recurrence probability to Mohs micrographic surgery. *Clin Transl Radiat Oncol.* 2023;43:100678. doi:10.1016/j.ctro.2023.100678 **5.** Yu L, Moloney M, Tran A, Zheng S, Rogers J. Local control comparison of early-stage non-melanoma skin cancer (NMSC) treated by superficial radiotherapy (SRT) and external beam radiotherapy (XRT) with and without dermal image guidance: A meta-analysis. *Discov Oncol.* 2022;13:129. doi.org/10.1007/s12672-022-00593-z

Heavy NMSC Case Loads Lead to the High Rates of Burden & Burnout

Growing prevalence of NMSCs places a heavy burden on Mohs surgeons

~5.4M cases of NMSC are diagnosed in the United States each year[1]

- **3.6M** BCC and **1.8M** SCC

Significantly increases in prevalence have been seen over the **last 20 years**[1]

- **35% increase** for BCCs and **133%** for SCCs

A 2023 survey of ACMS Mohs surgeons revealed high rates of pain, injury, and distress (n=473)[2]

~90% reported moderate to severe concerns with musculoskeletal injuries[2,3]

- Most common issues reported included neck, lower back, shoulder, and upper back pain

70% reported experiencing psychological or emotional stress or burnout[2,3]

- Common cause of emotional distress was patient care-related anxiety

Of those who reported musculoskeletal disorders or emotional distress[2,3]

- Only **40.56%** and **46.67%**, respectively, felt they had the knowledge and the resources to manage them

References: 1. Ciuciulete AR, Stepan AE, Andreiana BC, Simionescu CE. Non-melanoma skin cancer: Statistical associations between clinical parameters. Curr Health Sci J. 2022; 48(1):110-115. doi: 10.12865/CHSJ.48.01.16: 10.12865/CHSJ.48.01.16 **2.** Liang CA, Levine VJ, Dusza SW, et al. Musculoskeletal disorders and ergonomics in dermatologic surgery: A survey of Mohs surgeons in 2010. *Dermatol Surg.* 2012 38(2):240-248. doi: 10.1111/j.1524-4725.2011.02237.x. Epub 2011 Dec 30. **3.** Nelson R. Mohs surgeons have high rates of emotional and physical stress. Available at: https://www.medscape.com/viewarticle/mohs-surgeons-have-high-rates-emotional-and-physical-stress-2024a10008r6?form=fpf. Accessed June 4, 2024.

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CONSENSUS GUIDELINES

- Nestor MS, Berman BB, Goldberg D, Cognetta AB, Gold M, Roth W, Cockerell CJ, Glick B
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