Image-Guided Superficial Radiation Therapy (SRT) for NMSC and Keloids

David J. Goldberg, MD, JD

Skin Laser and Surgery Specialists

Schweiger Dermatology Group

Icahn School of Medicine at Mount Sinai

Image-Guided SRT: Advancing Non-Surgical Treatment of NMSC session is supported by an educational grant from SkinCure.

Financial Disclosures

Consultant for Sensus Healthcare

I serve as a consultant for Sensus Healthcare, providing expert guidance on superficial radiation therapy technology and clinical applications.

ACGME Fellowship Director Director

I previously directed an ACGME-accredited Micrographic Surgery and Cutaneous Oncology Fellowship program, training the next generation of skin cancer specialists.

SRT Consensus Group Member

I am an active member of the SRT Consensus Consensus Group, contributing to evidence-evidence-based guidelines and best practices practices for radiation therapy in dermatology.

The Spectrum of NMSC Treatment Approaches

Non-melanoma skin cancer treatment requires a comprehensive understanding of available modalities. Each approach offers distinct advantages for specific clinical advantages for specific clinical scenarios, patient populations, and tumor characteristics.

Mohs Micrographic Surgery

Gold standard surgical technique with tissue-sparing precision and precision and real-time margin assessment, achieving cure rates up to rates up to 99% for basal cell carcinoma.

Other Destructive Methods

Alternative approaches including electrodesiccation and curettage, curettage, cryotherapy, and excisional surgery offer viable options for options for appropriate lesions.

PD-1 and Hedgehog Inhibitors

Systemic pharmacologic therapies targeting specific molecular molecular pathways, reserved for advanced or metastatic disease not disease not amenable to local treatment.

Superficial Radiation Therapy

Non-invasive treatment modality utilizing low-energy X-rays to eliminate malignant cells while preserving surrounding healthy tissue and minimizing scarring.

1920S ERA

The Dawn of SRT: A Century of Innovation Begins

100+ Years Ago

Pioneering Dermatologists Develop Fractionated SRT

Visionary dermatologists initiated groundbreaking research and development of fractionated superficial radiation therapy, establishing the foundation for a revolutionary approach to non-melanoma skin cancer treatment. This early innovation represented a paradigm shift in dermatologic oncology, offering patients their first non-surgical option for definitive cancer treatment.

The pioneering work of these early dermatologists established radiation therapy as a legitimate a legitimate first-line treatment modality, with documented cure rates demonstrating clinical demonstrating clinical efficacy that would stand the test of time.

Early SRT Cure Rates

80-90%

NMSC Cure Rates

For non-melanoma skin cancers treated with early fractionated SRT protocols

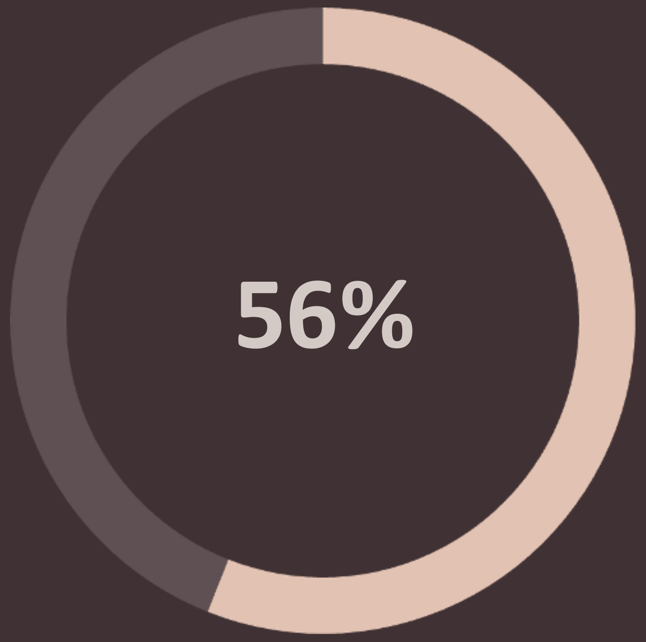
1930S-1970S ERA

SRT Emerges as Standard of Care in Dermatology

For Decades

SRT Establishes Itself as First-Line Treatment

Throughout the mid-20th century, superficial radiation therapy and surgical
surgical resections served as the primary treatment modalities for non-
non-melanoma skin cancer, providing dermatologists and patients with both
with both non-surgical and surgical first-line treatment options. This dual
dual approach allowed for individualized treatment planning based on patient
on patient preference, tumor characteristics, and anatomic location.



Adoption Rate

US dermatologists offering SRT in the 1970s

1970S ERA

The Surgical Revolution: Mohs Technique Optimized

50+ Years Ago

Mohs Micrographic Surgery Transforms Transforms NMSC Treatment

Mohs Surgery Cure Rates

99%

Basal Cell Carcinoma

Superior outcomes for BCC treatment

95%

Squamous Cell Carcinoma

Excellent results for SCC management

1980S-2014 ERA

Mohs Surgery Becomes the New Gold Standard

For 35+ Years

The Mohs Era: SRT Relegated to Second-Line Status

- **Treatment Hierarchy Shift:** SRT moved to a second-line NMSC treatment option, primarily utilized when surgery was not feasible or desired by the patient.

2015 ERA

The Renaissance: Image-Guided SRT Arrives

~10 Years Ago

Revolutionary HRDUS Technology Transforms SRT

In 2015, superficial radiation therapy experienced a renaissance with the integration integration of HRDUS

2016-PRESENT

The Modern Era: IGSRT as First-Line Noninvasive Care

In Recent Years

The landscape of non-melanoma skin cancer treatment has evolved dramatically in recent years, with image-guided superficial radiation therapy ushering in a new therapy ushering in a new era of noninvasive, standard of care. This transformation represents a full-circle return to dermatology's roots in radiation therapy, now radiation therapy, now enhanced with sophisticated imaging technology.

Understanding Superficial Radiation Radiation Therapy

Modern SRT Equipment Technology

Variable Peak Voltage Capability

Calibrated variable peak voltages of 50, 70, and 100 kilovolts peak (kVp). This variable energy capability allows clinicians to precisely match the radiation penetration depth to the specific tumor characteristics and anatomic location.

The ability to modulate peak voltage enables treatment optimization optimization for tumors at different depths within the skin, from from very superficial lesions requiring minimal penetration to slightly to slightly deeper tumors requiring increased energy levels. This This versatility ensures comprehensive tumor destruction while while minimizing dose to underlying healthy structures.

Automated Safety Features

Intelligent Treatment Termination

Modern SRT units incorporate sophisticated safety systems that automatically terminate radiation delivery when the prescribed cumulative dose has been reached. This intelligent automation eliminates eliminates the risk of human error in dose administration and ensures ensures patients receive exactly the prescribed radiation dose—no more, no more, no less.

Clinical Advantages of Modern SRT

Ease of Administration

Effective Lesion Targeting

Tissue-Sparing Technology

Clinical Applications of SRT

FDA-Approved Indications

SCC, BCC, Keloids

Evidence-Based Clinical Outcomes

Landmark Clinical Study Results

A landmark study by Cognetta et all in JAAD in 2012, established the benchmark for SRT outcomes.

1,715 primary nonaggressive non-melanoma skin cancers treated with the SRT-100 device. The study demonstrated an cure demonstrated an cure rate of 98%..

Fundamental Treatment Objectives

Balancing Cure and Quality of Life

Effective tumor and patient selection represents a critical determinant of treatment success.
Focus on size, location, histologic subtype, and depth—but also patient-specific factors such as age, comorbidities, functional status, cosmetic concerns, and personal preferences.

NMSC Histologic Subtypes Most Commonly Treated with SRT

Basal Cell Carcinoma

Squamous Cell Carcinoma

Anatomic Versatility of SRT

Comprehensive Coverage Across All Body Sites

SRT can be effectively utilized to treat tumors on virtually all skin surface areas, from the scalp to the scalp to the lower extremities, making it an exceptionally flexible treatment modality.

Anatomic Sites with Superior SRT Cosmetic Outcomes

Scalp

Radiation avoids the cosmetic challenges of surgical reconstruction on the scalp, scalp, particularly in patients with alopecia or sparse hair coverage.

Eyelid

Preserves delicate periocular anatomy and avoids the functional complications that can that can occur with surgical reconstruction of the eyelid.

External Ear Canal and Helix

Maintains the complex three-dimensional structure of the ear without the distortion that can result from surgical excision and reconstruction.

Nasal Ala

Preserves the natural contour and function of this aesthetically critical structure without structure without the need for complex nasal reconstruction.

Oral Commissure

Avoids distortion of the oral commissure that can impair function and create asymmetry with surgical approaches.

Lower Extremities

Circumvents the wound healing challenges and complications that frequently occur with surgical excision on the lower legs, particularly in elderly patients.

Clarifying Radiation Therapy Terminology

Understanding the Distinctions

Considerable confusion exists regarding the differences between various radiation therapy modalities used in dermatology.

The primary modalities—superficial radiation therapy, electron beam beam therapy, brachytherapy, and electronic brachytherapy—differ differ fundamentally in their physics, energy levels, penetration depths, depths, equipment requirements, and clinical applications.

SRT Versus Other Radiation Modalities: Key Differences Differences

SRT vs. Grenz Ray

Superficial radiation therapy utilizes significantly higher energy levels and achieves deeper tissue penetration compared to Grenz ray therapy, which employs ultra-soft X-rays with minimal penetration depth suitable only for very superficial lesions.

Brachytherapy Technique

Brachytherapy employs radioactive sources positioned within or in direct contact with the the tumor tissue, requiring specialized radiation radiation safety protocols, regulatory oversight, and oversight, and radioactive source management not management not necessary with SRT.

Electron Beam Therapy

Electron beam therapy utilizes a medical linear accelerator to generate high-energy electron beams. This approach requires substantially more complex and expensive equipment compared to SRT devices.

Clinical and Economic Advantages of SRT

Superior Clinical Outcomes

Comparative studies have established that SRT delivers higher cure rates and superior cosmetic outcomes compared to both brachytherapy and electron beam therapy for appropriately selected non-melanoma skin cancers. These advantages stem from SRT's optimal energy spectrum and dose distribution characteristics.

Cost-Effectiveness

SRT represents a significantly more cost-effective approach than alternative radiation modalities.

SRT for Large Tumors

Simplifying Complex Reconstructions

Large non-melanoma skin cancers

Specific Anatomic Advantages of SRT

Lower Extremity and Facial Aesthetic Benefits

Critical Treatment Planning Parameters

Margin Selection for Optimal Outcomes

Basal Cell Carcinoma Margins

For basal cell carcinoma, clinical margins of 8-10 8-10 millimeters are commonly employed in in clinical practice. This margin width reflects the reflects the known patterns of subclinical extension for BCC and aligns with surgical margin margin recommendations.

Squamous Cell Carcinoma Margins

Squamous cell carcinoma typically requires slightly wider wider margins, with 10 millimeters representing the standard recommendation. This reflects SCC's higher risk of risk of subclinical extension compared to most BCC subtypes.

Technical Considerations in SRT Treatment Planning

01

Minimal Lateral Dose Fall-Off

The beam characteristics and delivered delivered dose profile of superficial radiation therapy demonstrate only a 1-only a 1-millimeter lateral edge drop-off drop-off (penumbra) at the treatment treatment site boundary. This sharp dose gradient enables precise targeting targeting of the tumor while sparing sparing adjacent normal tissue.

02

Optimized Radiation Field

03

Treatment Field Sizing

The initial measurement of tumor size size should encompass the clinically clinically visible lesion plus an additional additional 2-5 millimeter margin circumferentially around the lesion. With these margins, almost all lesions lesions will have final treatment field field sizes exceeding 2 centimeters in in diameter.

Ideal Patient Populations for SRT

Elderly Patients and Poor Surgical Candidates

Additional Patient Selection Criteria for SRT

Anticoagulation Therapy

Unlike surgical approaches, superficial radiation therapy does not require require patients to discontinue anticoagulants or antiplatelet agents. This This represents a major safety advantage for patients at high risk for thromboembolic events if anticoagulation is interrupted.

Poor Circulation

Wound Care Limitations

Surgical Anxiety

Contraindications to Superficial Radiation Therapy

Absolute Contraindications

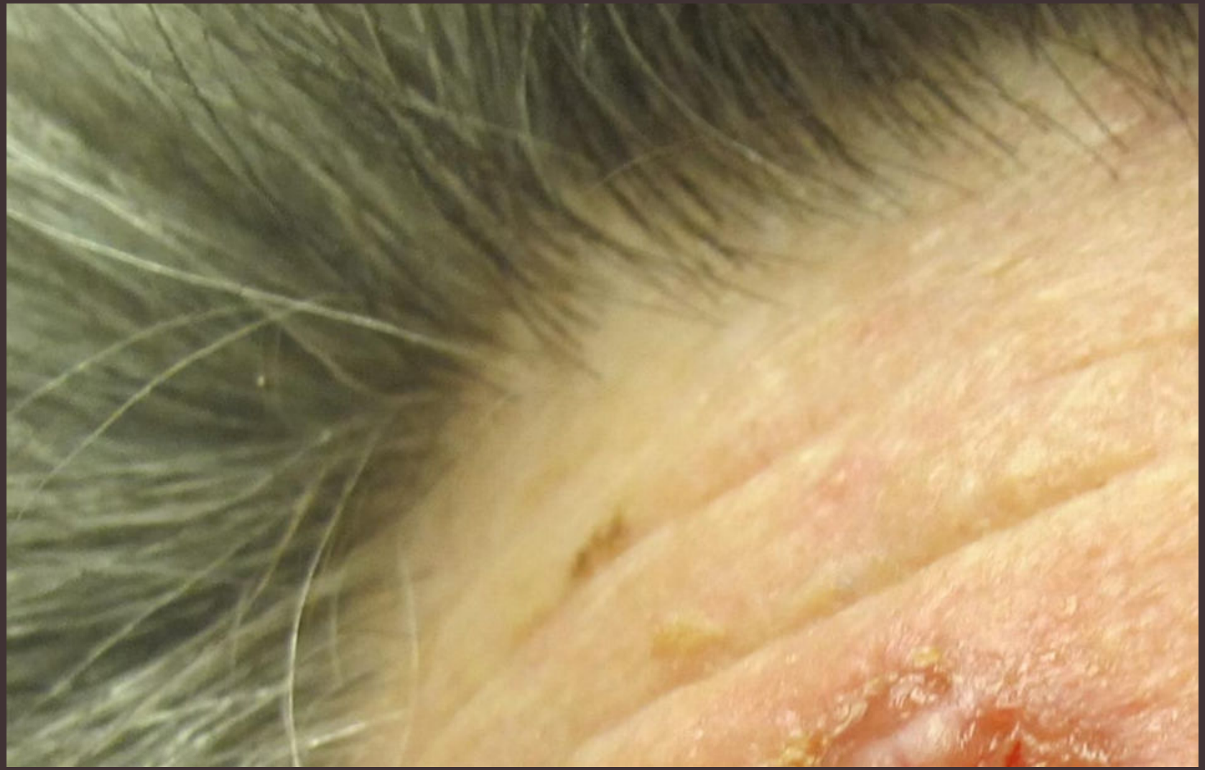
Cardiac Implantable Electronic Devices

Previous Radiation Therapy

Basal Cell Carcinoma

Clinical Case: BCC Right Forehead

Pre-Treatment and Intra-Treatment Documentation



Initial Presentation: Biopsy-confirmed basal cell carcinoma on right forehead demonstrating classic nodular appearance with rolled borders and central ulceration.

Mid-Treatment Assessment: Clinical response visible after several treatment fractions, treatment fractions, with reduction in tumor bulk and changes in surface characteristics indicating radiation effect.

This case demonstrates the typical clinical course of a forehead BCC undergoing superficial radiation therapy. The cosmetically sensitive location makes SRT an attractive option, an attractive option, avoiding the need for surgical excision and reconstruction in a highly visible area.

Clinical Case: BCC Right Forehead - 4 Month Follow-Up

Excellent Cosmetic Outcome Following SRT

BCC Right Chest

Pre-Treatment Presentation

BCC Right Chest

BCC Right Chest

BCC Right Chest - 4-Week Follow-Up

Early Post-Treatment Outcome

BCC Left Temple

BCC Left Infranasal Area

Pre-Treatment Evaluation

Clinical Case: BCC Nasal Tip

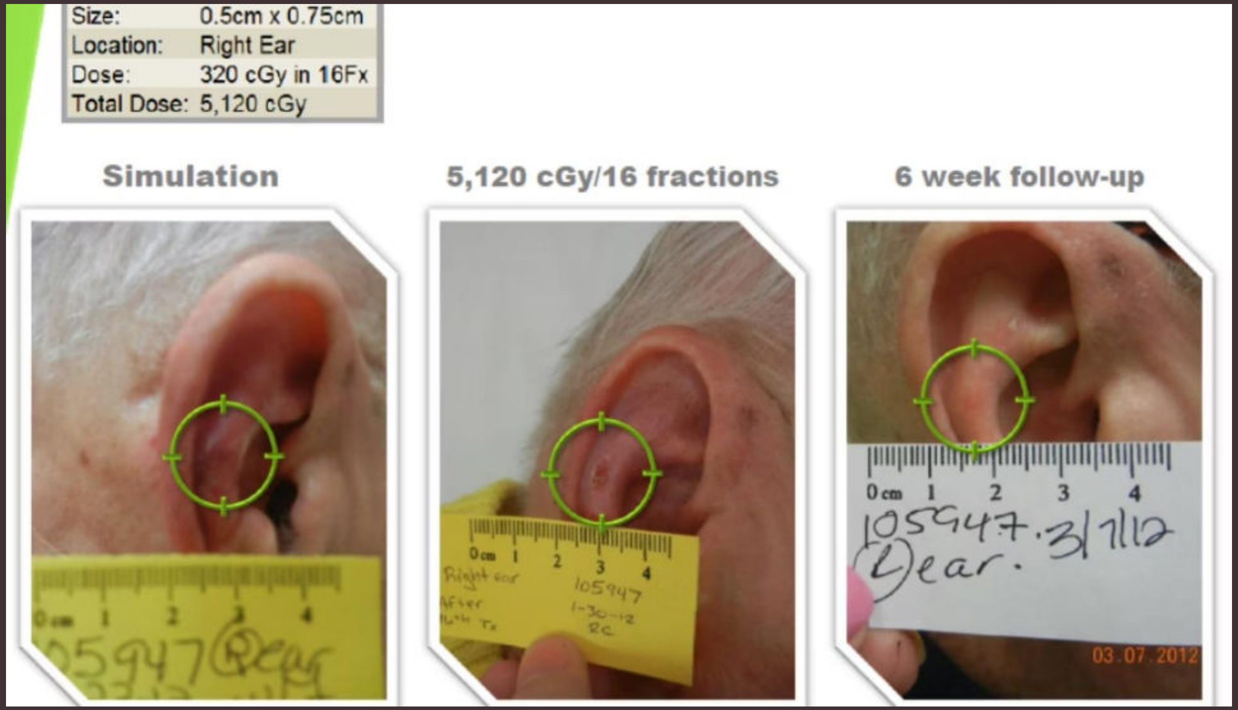
Nasal Tip Lesion Treatment

SCC Right Helix

Squamous Cell Carcinoma of the Ear

Clinical Case: SCC Right Ear

Right Ear SCC Treatment



Clinical Case: SCC Left Leg

Lower Extremity SCC Management

Managing Acute Radiation Effects

Common Side Effects

Temporary Erythema

Hyperpigmentation

Radiation Dermatitis Management

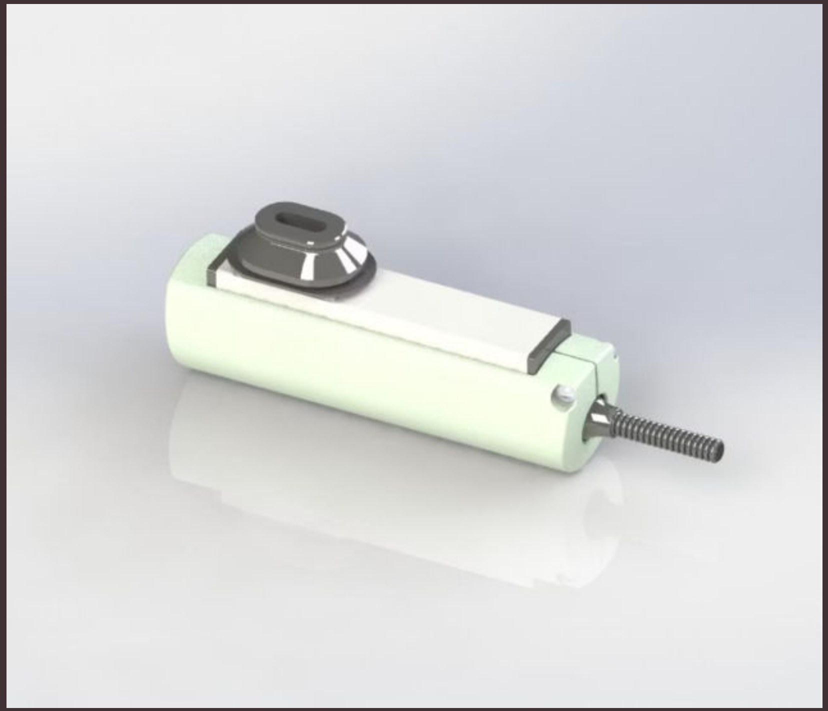
Clinical Case: Radiation Dermatitis Management

Rapid Response to Silicone Gel Treatment

Before Treatment

After 2 Days of Silicone Gel

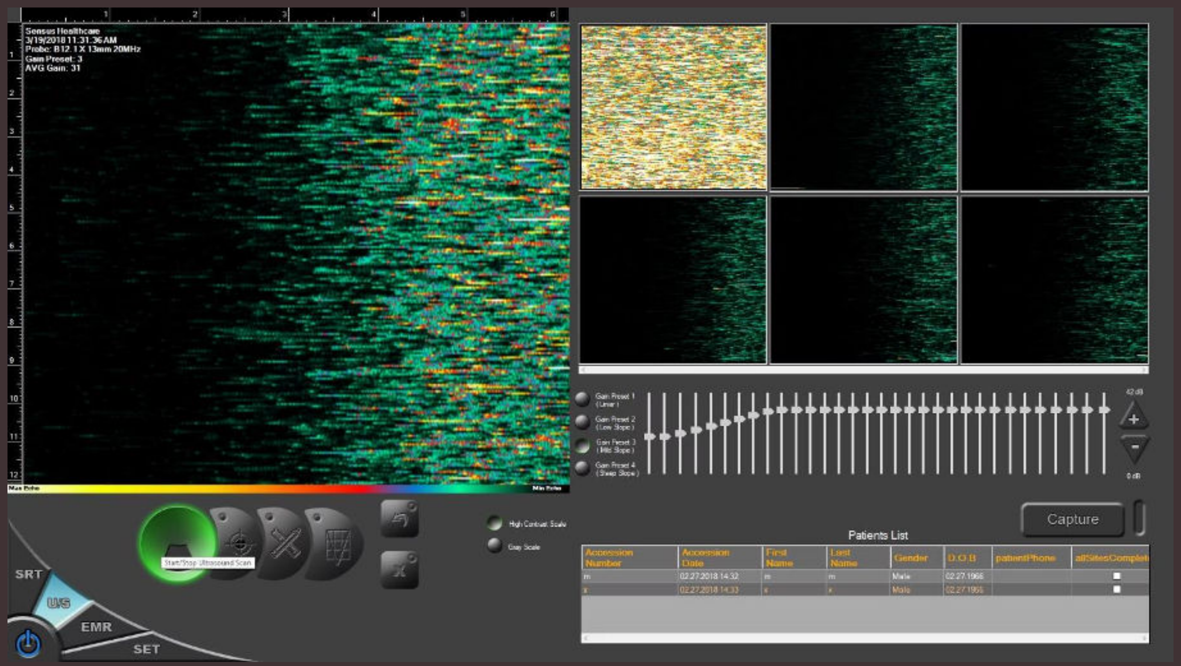
High-Frequency Ultrasound Image Guidance



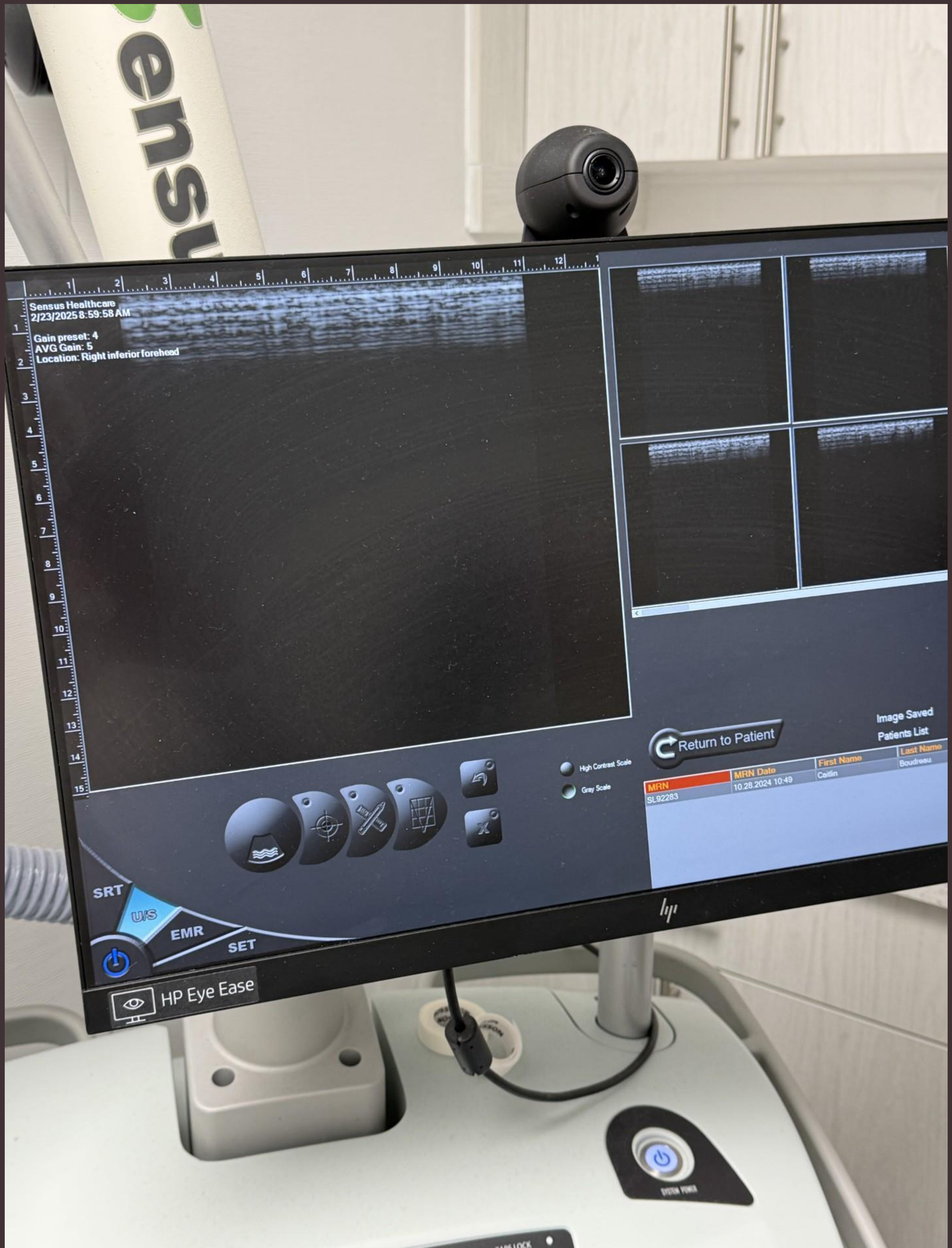
DermaScan C Technology

The integration of high-frequency ultrasound imaging with superficial radiation therapy represents a transformative innovation that has revolutionized treatment precision and outcomes. The DermaScan C system exemplifies this advanced imaging capability.

DermaScan C Display Interface




First Name Caitlin
Last Name Boudreau
MRN SL92283
Therapy ID 1
Site Name Right inferior forehead
Custom Shield [cm²] X 1.7 Y 1.7
Provider David Goldberg MD
Sex F M
DOB Friday, September 12, 1986
Ongoing
Background & Prognosis
BCC
Size of lesion 1.5x1.5
Identification Photo
Lesion Topography
BED 0
DOSE 0
TIME (minutes) 0.53
TOTAL FRACTION 14
Current Diameter: SSD:
Capture
List of Sessions
Treatment
No. Time Stamp kV mA Applicator Type SSD [cm] Diameter [cm] Elapsed Time [Min] Prescribed Dose [cGy] Delivered Dose [cGy] Cumulative Dose [cGy] Manual Dosimetry Provider Performed By
10 11/27/2024 09:17:02 AM 50 10 2 15 1.5 0.53 396.97 396.97 3969.7 David Goldberg MD M.Lolis
11 12/03/2024 10:42:51 AM 50 10 2 15 1.5 0.53 396.97 396.97 4366.67 David Goldberg MD D Goldberg
12 12/06/2024 09:22:29 AM 50 10 2 15 1.5 0.53 396.97 396.97 4763.64 David Goldberg MD D Goldberg
13 12/10/2024 10:41:21 AM 50 10 2 15 1.5 0.53 396.97 396.97 5160.61 David Goldberg MD D Goldberg
14 12/13/2024 10:36:46 AM 50 10 2 15 1.5 0.53 396.97 396.97 5557.58 David Goldberg MD M.Lolis
Dosimetry Summary
Last Session Date & Time: 12/13/2024 10:36:46 AM
Total Sessions: 14
Last Session Elapsed Time: 0.53 Min
Last Delivered Dose: 396.97 cGy
Last Applicator: # 2 @ Diameter = 1.5 cm, SSD = 15 cm
Cumulative Dose: 5557.58 cGy
Ultrasound Photo 1 Ultrasound Photo 2 Ultrasound Photo 3 Ultrasound Photo 4 Ultrasound Photo 5 Ultrasound Photo 6 Ultrasound Photo 7 Ultrasound Photo 8
Photo 1 Photo 2 Photo 3 Photo 4 Photo 5 Photo 6 Photo 7 Photo 8
Export / Print
Create Report
Copy Site
Delete Site
1/1
No. Site Name Total Fx Complete Fx Partial Fx
1 Right inferior forehead 14 14 0
Save
Exit
HP Eye Ease


Sensus Healthcare
2/23/2025 8:59:58 AM
Gain preset: 4
AVG Gain: 5
Location: Right inferior forehead
High Contrast Scale
Gray Scale
Return to Patient
Image Saved
Patients List
MRN MRN Date First Name Last Name
SL92283 10.28.2024 10:49 Caitlin Boudreau
SRT
U/S
EMR
SET
HP Eye Ease

Clinical Evidence Supporting IGSRT

Robust Data Demonstrating Superior Outcomes

99%+

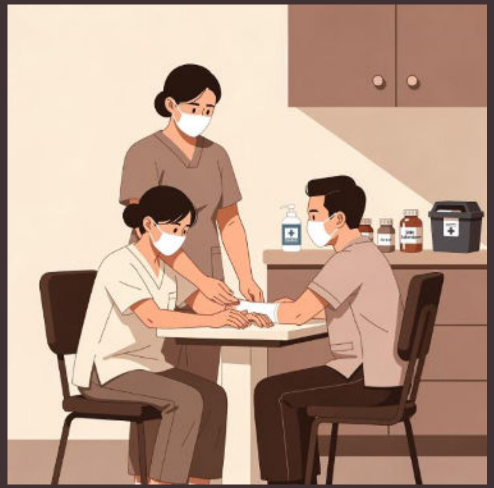
BCC Cure Rates

Exceptional efficacy for basal cell carcinoma

99%+

Patient Satisfaction

Outstanding patient-reported outcomes



0.2%

Recurrence Rate

In 120,000+ treated lesions

0

Secondary Cancers

No radiation-induced malignancies reported

The remarkably low recurrence rate of 0.2% documented in the tumor registry encompassing over 120,000 treated lesions (76 BCC, 67 SCC) provides compelling real-world evidence of IGSRT's effectiveness. The complete absence of secondary complete absence of secondary cancers in this large dataset addresses one of the primary historical concerns regarding radiation therapy for skin cancer.

Addressing the NMSC Burden on Mohs Surgeons

The Growing Challenge of High-Volume Caseloads

Impact on Mohs Surgeons

SkinCure Oncology: Expanding Access Nationwide

Building a National Network of Excellence

350+

Practice Partners

Growing network of dermatology practices offering IGSRT

43

States with Coverage

Contracted partners providing care in 43 states nationwide

1 in 3

American Access

Americans now live in a county where where GentleCure Experience is available

120,000+

Lesions Treated

NMSC lesions successfully treated in treated in 81,000 patients to date

Foundational Research

Key Reference: Practice and Educational Gaps

> Cognetta AB, Wolfe CM, Goldberg DJ, and Hong HG. Practice and Educational Gaps in Radiation Radiation Therapy in Dermatology. *Dermatologic Clinics.* 34: 319-333, 2016

Evidence-Based Clinical Guidelines

Consensus Statement on SRT in Dermatology

Nestor MS, Berman BB, Goldberg D, Cognetta AB, Gold M, Roth W, Cockerell CJ, Glick B. CJ, Glick B. *Journal of Clinical and Aesthetic Dermatology.* 12: 2019

Keloid Pathophysiology

Understanding Abnormal Wound Healing

Keloids represent benign dermal fibroproliferative tumors characterized by excessive collagen deposition and abnormal wound healing responses. Unlike hypertrophic scars Unlike hypertrophic scars that remain confined to the original injury site, keloids extend beyond the boundaries of the initial wound.

Cellular Mechanisms

The pathophysiology of keloid formation involves dysregulated fibroblast proliferation and collagen synthesis. In keloid tissue, fibroblasts continue to multiply to multiply even after the wound cavity has been filled, driven by aberrant growth aberrant growth factor signaling and impaired apoptotic mechanisms.

The collagen composition in keloid tissue consists predominantly of types I and III types I and III collagen, similar to normal skin but deposited in excessive quantities quantities with abnormal spatial organization. The characteristic thick, nodular nodular collagen bundles create the clinical appearance and functional problems problems associated with keloid scarring.

Clinical Significance

Keloids can cause significant functional impairment and psychological distress. distress. Beyond cosmetic concerns, keloids may be painful, pruritic, or restrict restrict movement when located over joints. The tendency for recurrence following following surgical excision alone makes keloid management particularly challenging. challenging.

Understanding the underlying pathophysiologic mechanisms provides insight into insight into why multi-modal treatment approaches—particularly combining combining surgery with radiation therapy—achieve superior outcomes compared to compared to single-modality interventions.

The Healing Process Failure in Keloids

Disrupted Apoptosis and Continuous Collagen Production

The fundamental problem underlying keloid formation represents a failure of normal wound healing regulation. In physiologic wound healing, cellular proliferation, collagen synthesis, and tissue remodeling proceed through orderly phases with appropriate termination signals. Keloid formation reflects disruption of this carefully orchestrated process.

1

Defective Apoptosis

Normal wound healing requires programmed cell cell death (apoptosis) to remove excess fibroblasts fibroblasts once tissue repair is complete. In keloids, keloids, certain growth factors attached to fibroblasts fibroblasts retard this programmed cell death, leading to persistent fibroblast proliferation.

2

Collagen Overproduction

The continued fibroblast activity results in excessive collagen production that forms characteristic striated bundles extending across the keloid scar. This disorganized collagen architecture differs fundamentally from normal dermal collagen organization.

3

Vascular Compromise

The striated collagen bundles progressively clog clog blood vessels at their distal ends, creating creating hypoxic and anoxic regions within the the elongated tissue mass. This vascular compromise compromise paradoxically stimulates further pathologic growth factor production.

This self-perpetuating cycle of abnormal healing, characterized by defective apoptosis, continuous collagen production, and progressive vascular compromise, explains the compromise, explains the high recurrence rates historically observed with surgical excision alone and the poor response to electron beam radiation with its suboptimal its suboptimal ionizing pattern.

Rationale for SRT in Keloids

Correcting the Healing Process Imbalance

Limitations of Surgery Alone

Radiation's Mechanism of Action

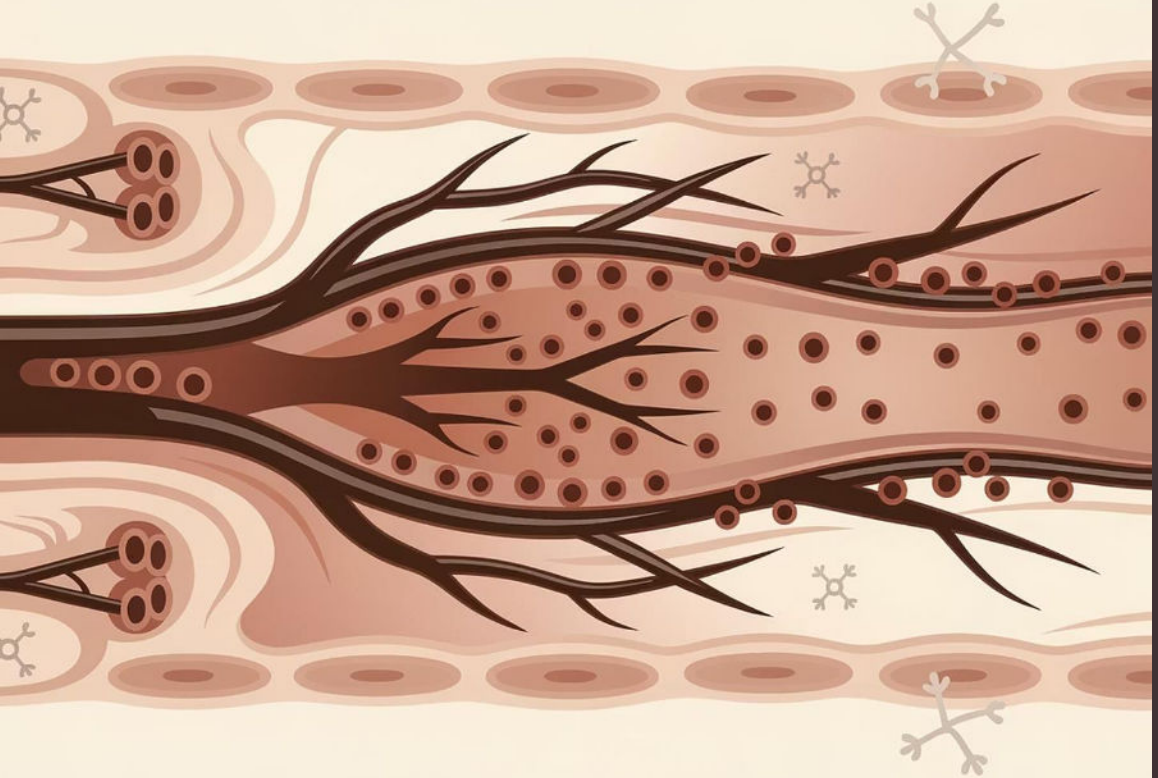
Optimizing Keloid Treatment Outcomes

The Case for Adjuvant Radiation Therapy

1. Surgical Excision
2. Near - Immediate SRT
3. Normalized Healing

Superficial Radiation Therapy for Keloids

Keloids represent benign dermal fibroproliferative tumors with no malignant potential, characterized by persistent fibroblast multiplication that extends beyond normal wound healing parameters.



Molecular Mechanisms of Keloid Persistence

01

Growth Factor Dysregulation

02

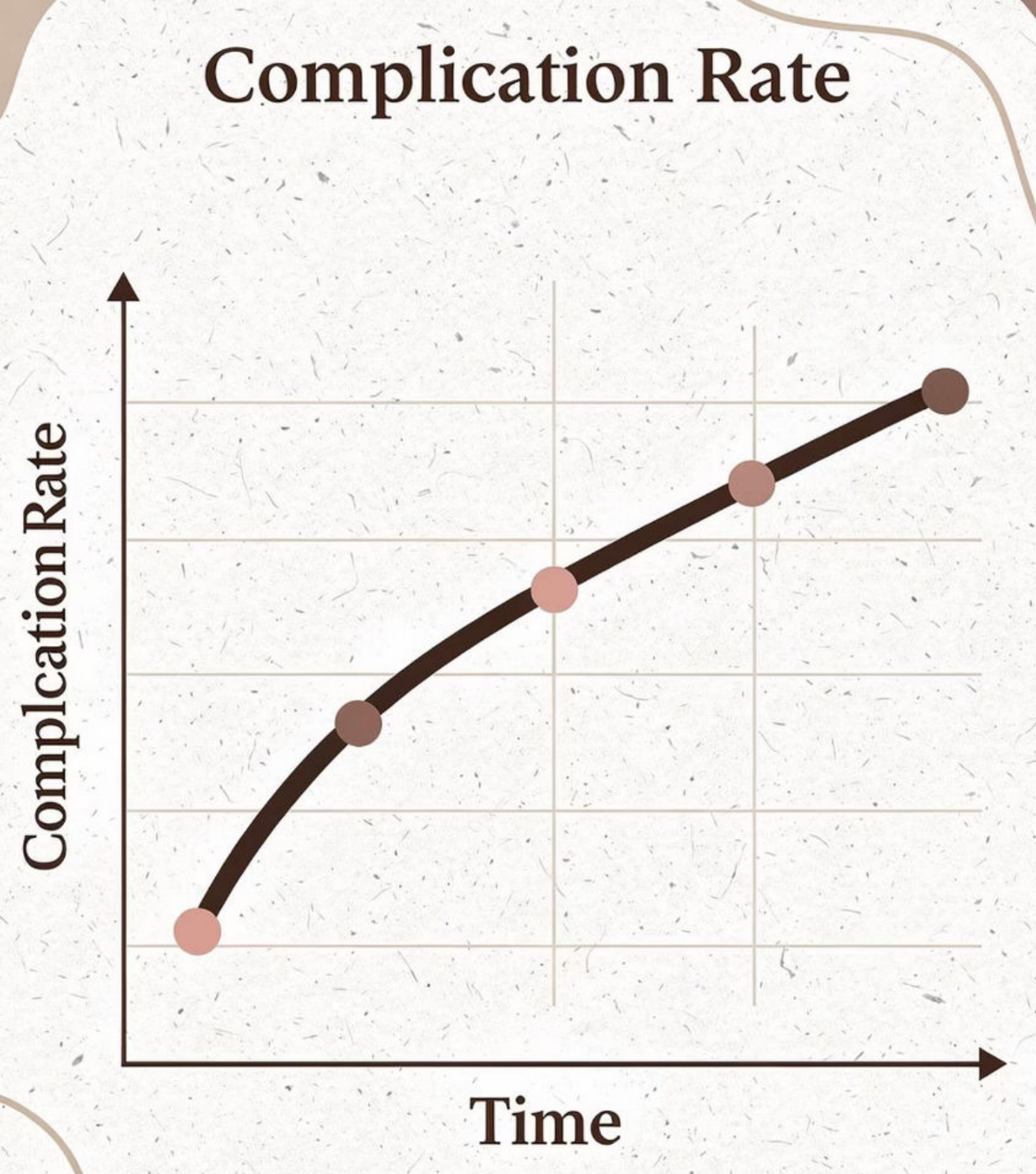
Vascular Obstruction

03

Treatment Resistance

The Rationale for Combined Therapy

Combined modality therapy addresses both the structural abnormality and the cellular dysfunction.



Comparative Recurrence Rates

Clinical outcomes data demonstrate dramatic differences in keloid recurrence based on based on treatment modality selection. Evidence-based analysis reveals clear therapeutic therapeutic hierarchies:

45-100%	<50%	<10%
Surgery Alone	**Surgery + Steroids**	**Surgery + SRT**
Surgical excision as monotherapy results in unacceptably high recurrence rates ranging from 45% to 100% across published series.	When surgical excision combines with intradermal intradermal corticosteroid corticosteroid administration, the majority majority of studies report recurrence rates falling below 50%.	Surgical excision combined combined with Superficial Superficial Radiation Therapy Therapy yields recurrence recurrence rates less than 10%, representing optimal optimal therapeutic outcomes.

TREATMENT PROTOCOL

The Three-Step Keloid Management Protocol

Step 1: Surgical Excision

Step 2: Initial SRT Fraction

Step 3: Fractionation Completion

Timing: The 24-Hour Critical Window

1

0-24 Hours

Initial wound response phase. Fibroblasts begin infiltrating the surgical site.

2

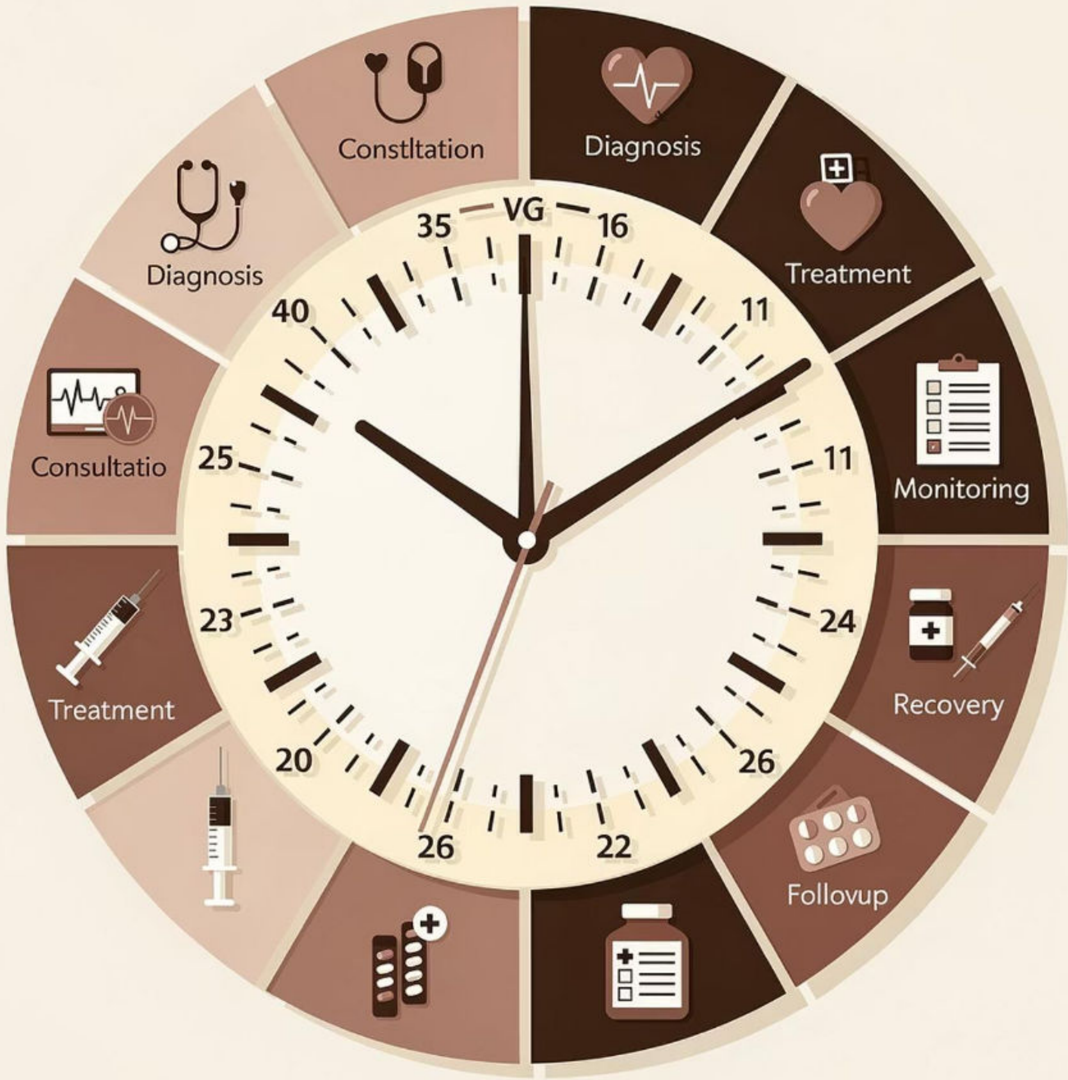
24-48 Hours

Peak fibroblast infiltration period. Optimal therapeutic window for first SRT fraction.
fraction.

3

72 Hours

Final treatment deadline. All SRT fractions must complete within this window.



Case Study 1: Pre-Excision Assessment

- Extended duration indicates established pathologic collagen architecture architecture requiring definitive intervention.

Excision Specifications

Primary Keloid

16 cm × 2 mm excised specimen

With Surgical Margin

18 cm × 12 mm total excision including appropriate margin

Case Study 1: SRT Treatment Setup

Clinical Setup Parameters

Three-Day Fractionation Protocol

- **Energy:** 100 kVp
- **Daily Dose:** 600 cGy per fraction
- **Total Dose:** 1800 cGy cumulative

Six-Week Outcome

Pre-Excision Evaluation

Excision Measurements

Keloid Tissue

15 cm × 3 mm primary lesion

Total Excision

17 cm × 13 mm with margins

Case Study 2: Post-Operative Result

Six Weeks Post-Operative Assessment

Facial Keloid: Baseline Appearance

Before Excision

Facial Keloid: One-Year Post-Treatment Outcome

12 Months After Superficial Radiation Therapy

12

Months Follow-Up

Extended observation period confirms durable treatment response

0%

Recurrence

No evidence of keloid reformation at one-year assessment