Rhenium SCT for non-melanoma skin cancer: Topline Results from EPIC Skin, An international Phase 4 prospective single arm multicentre study

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Dr Cody Allison, OncoBeta

Global Regulatory Status of Rhenium SCT

Rhenium-SCT is not approved or cleared by the U.S. Food and Drug Administration. Data and materials are for scientific and educational purposes only and should not be interpreted as establishing safety or effectiveness for any indication in the United States.

Globally Rhenium-SCT is:

- MDR-approved in EU – MDR 796214 R000
- AEMPS approved Class IIb Medical Device in Spain – PD/2022/6247(D)
- ARTG-registered in Australia; ARTG Number 400142
- HAS registration medical device in Singapore – Product Number: MDPR251103W0003
- SAHPRA authorised in South Africa – 00003410MD_v1
- Medsafe in New Zealand – 230302-WAND-70RGWT

Abbreviations: MDR: Medical Device Regulation EU: European Union; AEMPS: Agencia Española de Medicamentos y Productos Sanitarios; ARTG: Australian Register of Therapeutic Goods; HSA: Health Sciences Authority; SAHPRA: South African Health Products Regulatory Authority

Disclosures

- This study is a clinical investigation of the OncoBeta product, Rhenium-SCT.
- Cody Allison and Sasha Grubman are employed by OncoBeta Therapeutics.
- Gerhard Dahlhoff reports administrative support, article publishing charges, equipment, drugs, or supplies, statistical analysis, travel, board membership, consulting or advisory, and writing assistance were provided by OncoBeta GmbH. Gerard Dahlhoff is Chief Medical Officer of Oncobeta gmbh.
- Giuseppe Cardaci reports article publishing charges, equipment, drugs, or supplies, statistical analysis, and writing assistance were provided by OncoBeta GmbH. Giuseppe Cardaci reports a relationship with OncoBeta GmbH that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement.
- Saima Vohra reports a relationship with OncoBeta GmbH that includes: consulting or advisory, funding grants, non-financial support, and travel reimbursement.
- Siddhartha Baxi reports a relationship with OncoBeta GmbH that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement. Siddhartha Baxi is Medical Director of Oncobeta Australia.
- Martin Heuschkel reports a relationship with OncoBeta GmbH that includes: consulting or advisory and funding grants. Martin Heuschkel reports a relationship with Terumo Deutschland GmbH that includes: consulting or advisory, funding grants, and travel reimbursement. Martin Heusckhel reports a relationship with Novartis that includes: consulting or advisory and funding grants. Martin Heuschkel reports a relationship with Boston Scientific Corporation that includes: consulting or advisory, funding grants, and travel reimbursement.
- Angela Hong reports a relationship with OncoBeta and Telix Pharmaceuticals Limited that includes: consulting or advisory.
- Siroos Mirzaei and Nicola Mulholland report a relationship with OncoBeta GmbH that includes: travel reimbursement.
- Julia Tietze reports a relationship with OncoBeta GmbH that includes: consulting or advisory
- All discussions refer to investigational purposes only.

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Today's Program

Title	Presenter
EPIC Skin: Clinical Background and Study Design	Dr Cody Allison
Rhenium SCT in NMSC: 24-month Clinical Efficacy results from EPIC Skin	A/Prof Siddhartha Baxi
Rhenium SCT in NMSC: 24-month Safety results from EPIC Skin	A/Prof Siddhartha Baxi
Clinical Relevance of Rhenium SCT in NMSC	A/Prof Siddhartha Baxi
Question/Answer Session	A/Prof Siddhartha Baxi, Dr Cody Allison

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01

EPIC Skin: Clinical Background and Study Design

Dr Cody Allison

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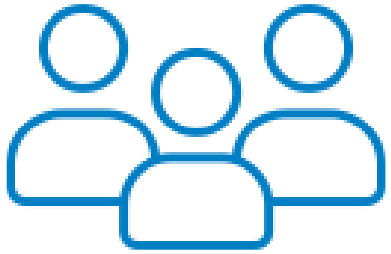
Non-Melanoma Skin Cancer (NMSC): A global view

#1 most common cancer

most frequent cancer in all white/light-skinned population by incidence[2]; officially #5 across all ethnicities (after lung, breast, colorectum, prostate)[2]



8.6M new lesions annually

(fastest growing cancer globally) in > 4.6m individuals [1] X 1.5 incidence growth projection by 2044[3]

Rates are increasing, likely due to[4]:

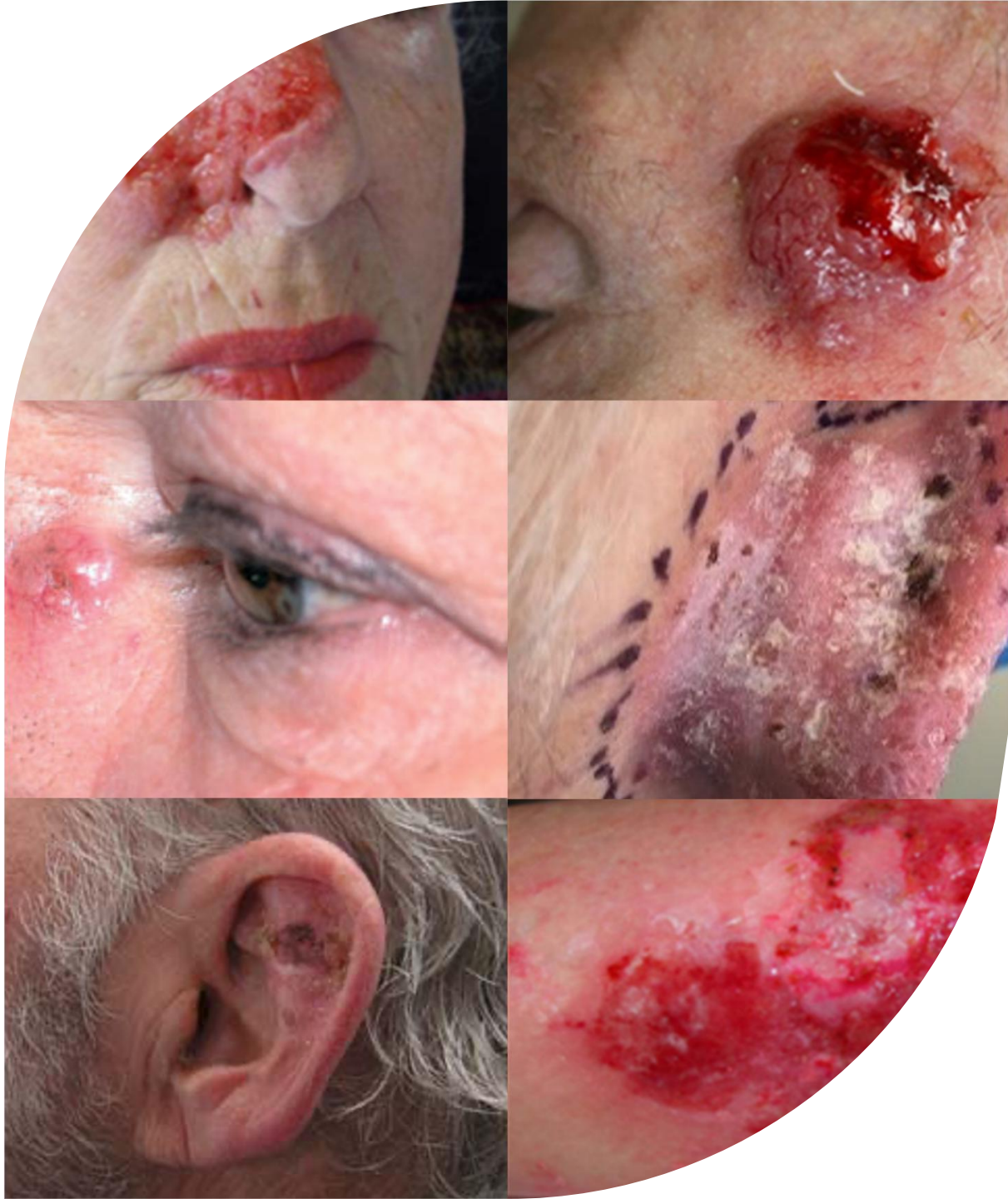
- Earlier detection
- Increased sun exposure
- Longer life spans

References: References: 1 https://link.springer.com/article/10.1186/s12885-025-13864-z ; 2 https://pubmed.ncbi.nlm.nih.gov/26833519/ ; 3 https://pubmed.ncbi.nlm.nih.gov/35907848/; 3. Cancer.Net. Skin Cancer (Non-Melanoma): Statistics. February 2021. https://www.cancer.net/cancer-types/skin-cancer-non-melanoma/statistics (accessed July 2021). Abbreviations: BCC: Basal cell carcinoma; NMSC: Non-melanoma skin cancer; SCC: Squamous cell carcinoma.

NMSC: Can have a dramatic impact on quality of life[1]

NMSC can be **difficult to treat** due to:

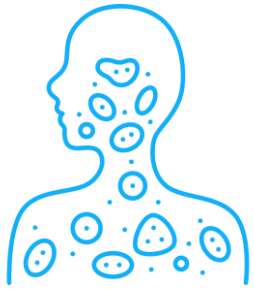
- Lesion size and location (face, lips, ears, etc.)
- Treatment can **be unsatisfactory** due to:
- Disfigurement
- Loss of function
- Need for reconstruction
- Recurrence
- Pain
- Complications
- Waiting lists and/or recovery time



Reference: Philipp-Dormston et al. Patient-reported health outcomes in patients with non-melanoma skin cancer and actinic keratosis: results from a large-scale observational study analysing effects of diagnoses and disease progression. J Eur Acad Dermatol Venereol. 2018;32(7):1138-1146. doi: 10.1111/jdv.14703. Images courtesy of Cipriani, C. - S. Eugenio Hospital, Rome, IT; Sedda, A. - S. Eugenio Hospital, Rome, IT; Castellucci, P - IRCCS Azienda Ospedaliero-Universitaria, Bologna, IT.

Treatment options in NMSC

Treatment Approach	Strengths	Trade-offs
Mohs / Excision[1-4]	Highest cure rates / Immediate removal	Scarring/reconstruction/disfigurement risk (cosmesis / functionality); down-time; patient suitability; costs, multiple lesions, anatomically difficult locations, patient comorbidities or preference.
Ablation & topicals[1-4]	Cheap, office-based convenience for select lesions / high-risk patients	Selection limitations; poorer efficacy/retreatments, patient compliance issues
Radiotherapy[1-5]	Effective, nonsurgical option with excellent cosmesis	Extensive treatment time, scheduling/logistics



Significant unmet need

- >80% patients underestimate surgical scars[6]
- 60% delay in seeking treatment[7]
- ~50-day median time to seek treatment[8]
- 15% poor ECOG status limiting treatment options[9-10]

References:
[1]Peris et al. Eur J Cancer. 2023;192:113254; [2]Stratigos et al. Eur J Cancer. 2023;PLS, [3]Schmults et al J Natl Compr Canc Netw. 2023; 21(11):1181-1203; [4]Bordeaux et al Version 1.2026 NCCN Guidelines for Squamous Cell Skin Cancer; [5]Likhacheva et al. Pract Radiat Oncol. 2020;10:8–20. [6]Fix et al. 2020. JAMA Netw Open; [7] MSCAN/ACD 2025, Australia's National Skin Cancer Scorecard 2025; [8]Deva et al. 2023. International Journal of Integrated Care; [9]Broderick et al., 2014; [10]Szturz et ela. 2016

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Rhenium-SCT (skin cancer therapy) utilises a radioactive isotope, rhenium-188, in the form of a paste to treat NMSC in a single session.

There are four components to the medical device:

1. **The OncoBeta® Carpoule** is a patented device that contains the rhenium-188 paste, and has a brush to allow for precise treatment application.
2. **The OncoBeta® Applicator** ensures controlled release of the rhenium-188 paste allowing for application to the lesion in a homogenic manner.
3. **The OncoBeta® Base Station** is used to store, mix, load, and change the carpoules, whilst providing shielding for maximum radiation protection, and
4. **The OncoBeta® Measurement Station** is a specially designed portable dose calibrator to allow for accurate radiation activity measurement to determine treatment times using VARSKIN tables developed by the NRC, which incorporate activity applied, treatment area, and lesion depth.

Rhenium-SCT®

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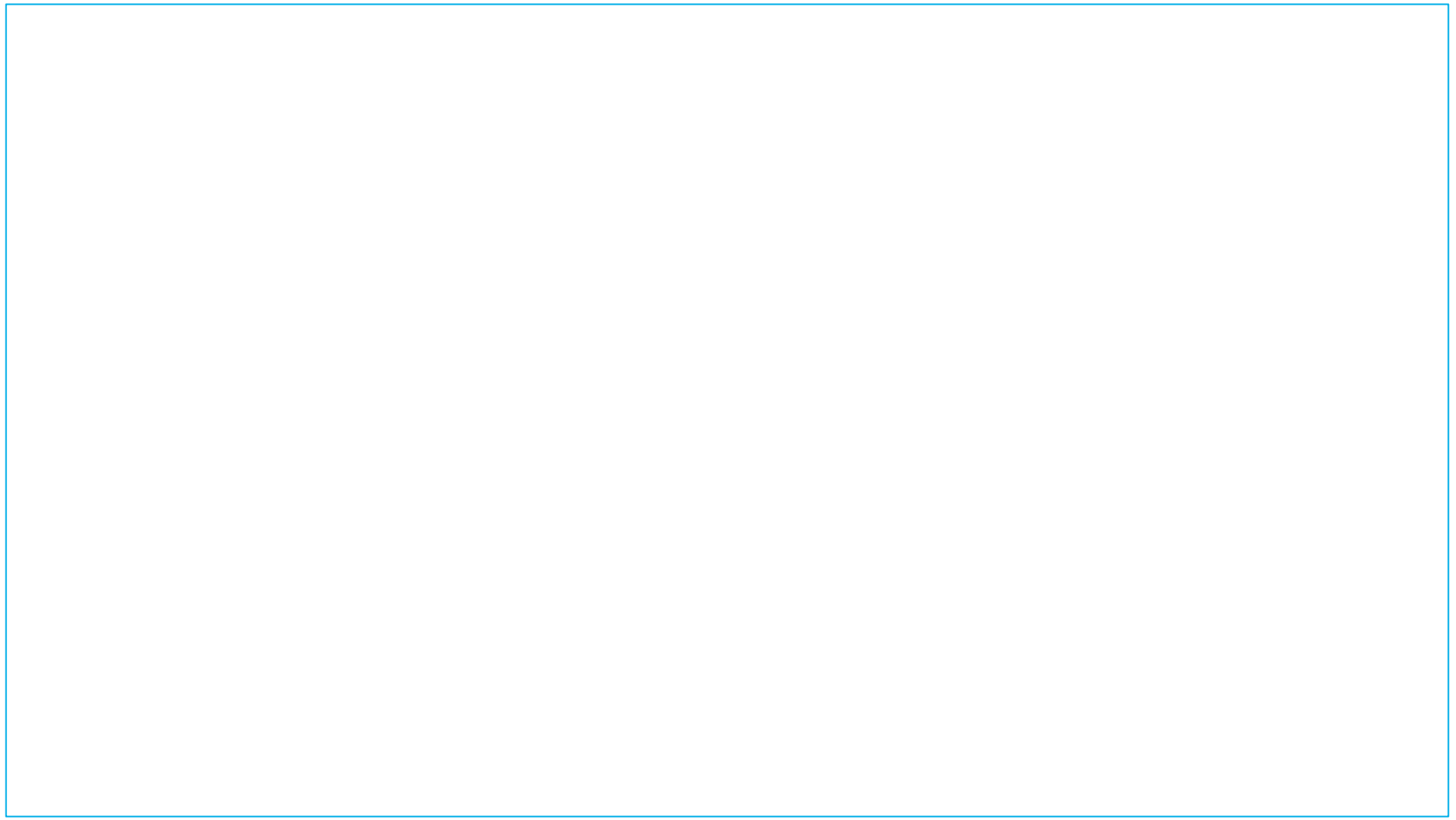
Rhenium-SCT: Demonstration



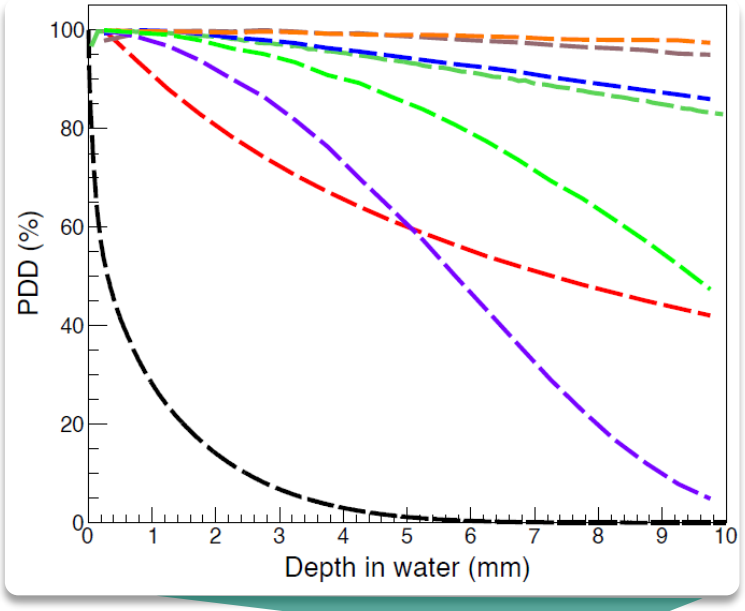
Rhenium 188 epidermal radioisotope therapy

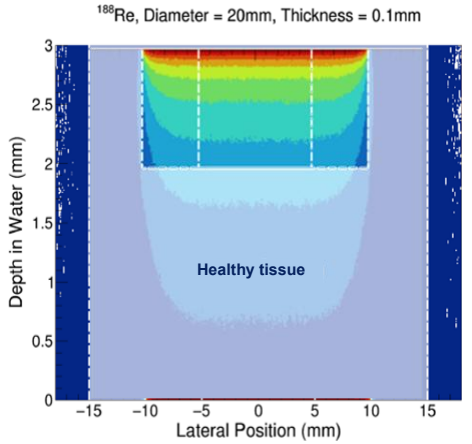
A healthy tissue-sparing isotope with steep dose falloff

17-hour half-life, emitting 100% beta energy (2.12 MeV maximum beta energy; mean 764 KeV), additionally yielding 155 keV gamma emissions in 15% of decays[1,2]

The main gamma component does not contribute significantly to the radiation dose[1,2]

92% of beta particles emitted from rhenium-188 decay are deposited within the first 3mm of skin.[2]





- **Dose Conformality[3]** Rhenium-SCT delivers a highly conformal, surface-focused radiation dose with rapid, contained fall-off; ideal for superficial, irregular lesions in sensitive areas (Independent Monte Carlo Modelling, right)
- **Steeper lateral dose gradient[3]** compared to 4-6MeV electron beams and 30-150 keV photon spectra.
- **Application Robustness[3]** Simulated variations in paste thickness and application had minimal, predictable effects on dose delivery

1. OncoBeta® Rhenium-188-Compound Instructions For Use. 2. Cipriani C et al. Int J Nucl Med 2017;114–22 3. David Bolst, University of Woolongong, manuscript in preparation; Centre for Medical Radiation Physics (CMRP) Abbreviations: NMSC: non-melanoma skin cancer

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Rhenium-SCT Clinical Data Timeline

2008

- First rhenium-188 publication for NMSC.
- Sedda et al. 53 patients; Mean 51 months follow-up
- Retrospective efficacy and cosmesis.

2020

- Retrospective rhenium-188 study of 50Gy to base of lesion
- 55 lesions / 52 patients; Mean 13.6 months. Efficacy & Safety.
- Cipriani et al.

2021

- Prospective Re-SCT study.
- 60 lesions / 50 patients; 3x doses. 24-months follow-up
- Castellucci et al.

2023

- Dermatologists-led prospective 12-month Re-SCT outcomes.
- 40 lesions / 22 patients; Efficacy, cosmesis and PROs. Tietze et al.

2024-2025

- 3x publications + 1 in prep Kronert et al.
- Global, Phase 4, Prospective EPIC-Skin study.
- 225 lesions / 180 patients; Efficacy, cosmesis, toxicity
- 2-pubs; Baxi et al. (6m) ; Cardaci et al. (12m)
- 24-month analysis in progress.

2025

- Difficult-to-treat BCC 64 patients; Chessa et al.
- Retrospective 3-year independent Re-SCT outcomes, 124 patients Castellucci et al.

Reviews:

- Independent review GEC-ESTRO BRAPHYQS Lozares et al
- Independent meta-analysis of 7 non-overlapping rhenium-188 studies Sadeghpour et al
- 94% complete response rate in NMSC lesions

Sedda et al. Clin Exp Dermatol. 2008;33:745–749. Cipriani et al. J Dermatol Treat. 2022;33:969–975. Castellucci et al. Eur J Nucl Med Mol Imaging. 2021;48:1511–1521. Tietze et al. Clin Nucl Med. 2023;48:869–876. . Baxi et al. J Nucl Med. 2024;65:1450–1455. Cardaci et al. Adv Radiat Oncol. 2025;10:101802. Krönert et al Healthcare 2024, 12, 921. Chessa et al. Dermatol Pract Concept. 2025;15:4993. Castellucci et al. J Nucl Med. 2025;00:1–6. Lozares et al. Radiother Oncol. 2025;190:109708. Sadeghpour et al. Front Med. 2025;12:1707729.Abbreviations: NMSC: non-melanoma skin cancer; Re-SCT: Rhenium Skin Cancer Therapy; PROs: patient-reported outcomes; GEC: Groupe Européen de Curiethérapie; ESTRO: European Society for Therapeutic Radiology and Oncology; BRAPHYQS: BRAchytherapy PHYsics Quality Assurance System. ; BCC: Basal cell carcinoma.

EPIC-Skin International Prospective Study

A global, multicenter, single-arm, Phase 4 post-marketing clinical study

- Patients deemed unsuitable for surgery based on clinical determination, screened by plastic surgeons and dermatologists
- **Clinical practice in NMSC radiotherapy is heterogeneous**, with no single standard comparator modality.
- Rhenium-SCT is applicable across multiple clinical scenarios, making **direct head-to-head comparison to a single modality inappropriate**.
- **A pooled historical reference** was therefore selected to contextualise outcomes.
- EPIC Skin was **powered for non-inferiority** to established complete response rates in superficial disease.
- The study design was **informed by multiple formative datasets** and prospectively structured to assess durability, safety, cosmesis, and patient experience.

7 sites; 5 countries
(South Africa, Australia, UK, Germany, Austria)

0, 6-, 12-, 24-month
time points

Stage I / II, BCC / SCC;
- De novo / Recurrent
- 1 - 3 lesions;
- Up to 8cm^2 area; < 3mm deep

Efficacy, cosmesis, toxicity, Safety, QoL, PROs

Rhenium-Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer. (EPIC-Skin); ClinicalTrials.gov ID NCT05135052
Abbreviations: Re-SCT: Rhenium Skin Cancer Therapy; PROs: patient-reported outcomes; BCC: Basal cell carcinoma; SCC: Squamous cell carcinoma; QoL: quality of life

02

Rhenium SCT in NMSC: 24-month Clinical Efficacy results from EPIC Skin

A/Prof Siddhartha Baxi, Genesiscare

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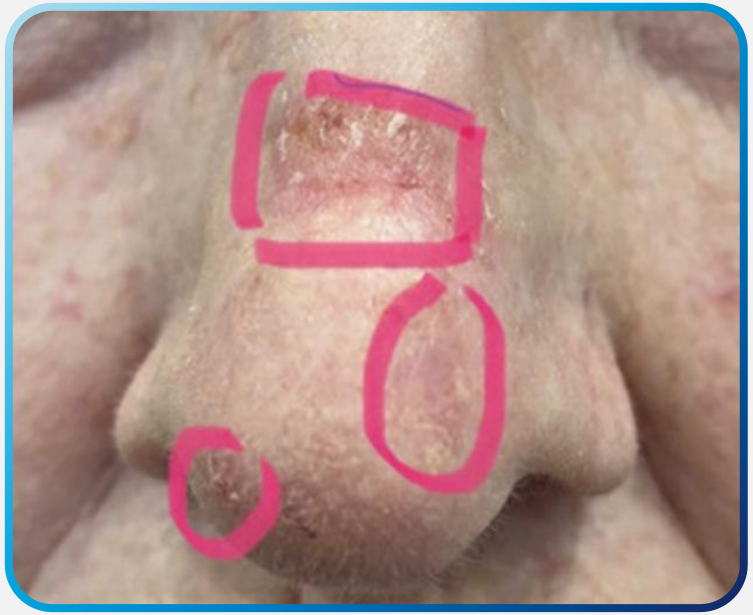
Patient Cases:

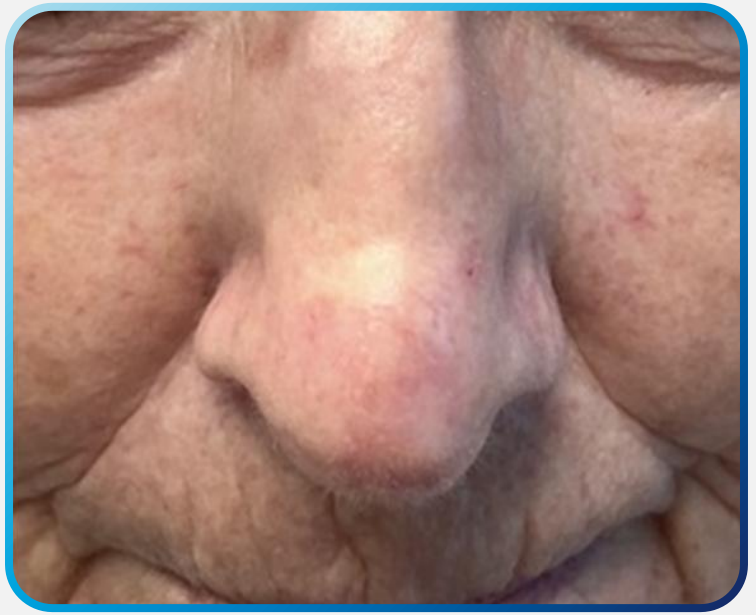
De Novo Treatment of Multiple Lesions Simultaneously

Female, 72 years-old

- Fitzpatrick II – ECOG 0
- BCC (1.9 mm deep; 6cm^2 area)
- Nose – multi-focal
- Worsening after multiple prior 5-FU applications
- Referred for Radiotherapy opinion due to substantial disease burden and risk of poor surgical outcomes.



Before



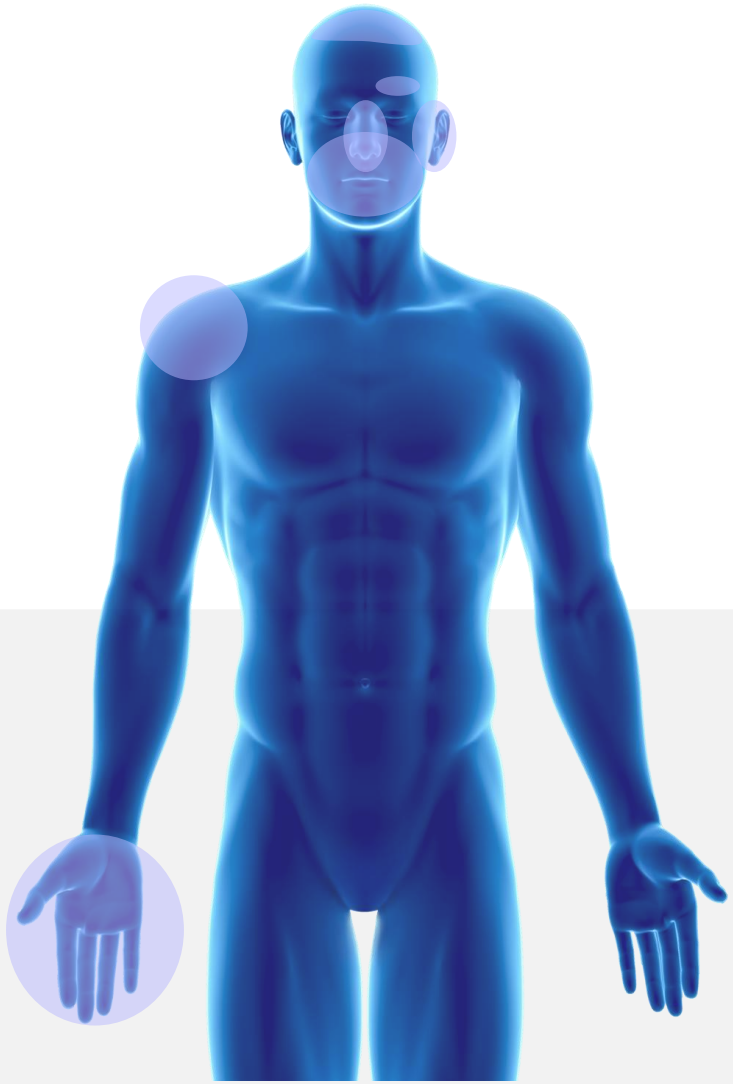
After

Case courtesy of Sid Baxi, Australia

Rhenium-SCT: Inclusion

Inclusion:

- Adults with Stage I or II Basal cell carcinoma (BCC)/Squamous cell carcinoma (SCC), node negative clinically
- < 3mm deep (punch or excisional biopsy verified)
- < 8cm^2 (~3cm diameter)
- 1-3 lesions
- Not suitable for surgery; patient consent



Exclusions

- Prior surgery/radiotherapy/laser to that lesion
- Malignant Melanoma
- Lupus and Scleroderma
- Locally advanced or suspected metastatic
- Lesions that cannot be appropriately shielded from healthy tissue (e.g. eyelid)
- Pregnancy and/or Lactation
- With Basal cell naevus syndrome, xeroderma, vitiligo and albinism
- Skin tumours that involve nerves or bony structures
- Any ongoing treatment for malignancy, or in the last 4 weeks prior to study entry

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EPIC-Skin: Study design

Primary outcome measure

- Complete Response (CR) assessed using Modified Visual RECIST tool at 24 months

Secondary outcome measure

- SKINDEX-16 QoL Questionnaire
- Comfort of Treatment questionnaire
- Cosmetic outcomes by VAS

Other outcome measure

- Safety as assessed by CTCAE v5.0

Abbreviations: Re-SCT: Rhenium Skin Cancer Therapy; vRECIST: visual Response Evaluation Criteria in Solid Tumors; SKINDEX-16: QoL: quality of life; VAS: Visual Analogue Scale; CTCAE: Common Terminology Criteria for Adverse Events

Study Endpoints

Primary Outcome

- To assess the proportion of treated lesions achieving complete response (CR) as per Modified Visual RECIST.

Secondary Ouctome

- To assess changes from baseline in Quality of Life (QoL)
- To assess treatment comfort
- To assess cosmetic outcomes

Safety endpoint

- To assess the adverse event rate by severity and relationship to Rhenium-SCT,
- To assess the rate of radiation dermatitis, skin ulceration, alopecia, skin induration, hypo/hyperpigmentation, and telangiectasia

Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors

Study Populations

Full Analysis Set (FAS)

The full analysis set (FAS) will be comprised of all subjects who provided consent and were enrolled in the study.

This population will be used to describe baseline characteristics.

Intent to Treat Set (ITT)

The intent-to-treat (ITT) set we be comprised of all subjects in the FAS who received treatment (Rhenium-SCT) for whom at least one item of efficacy data is available. Efficacy data consists of Modified Visual RECIST evaluations performed after Day 0, Quality of Life (QoL) assessments done after Day 0, assessments of treatment comfort, and/or assessment of cosmetic effects done after Day 0.

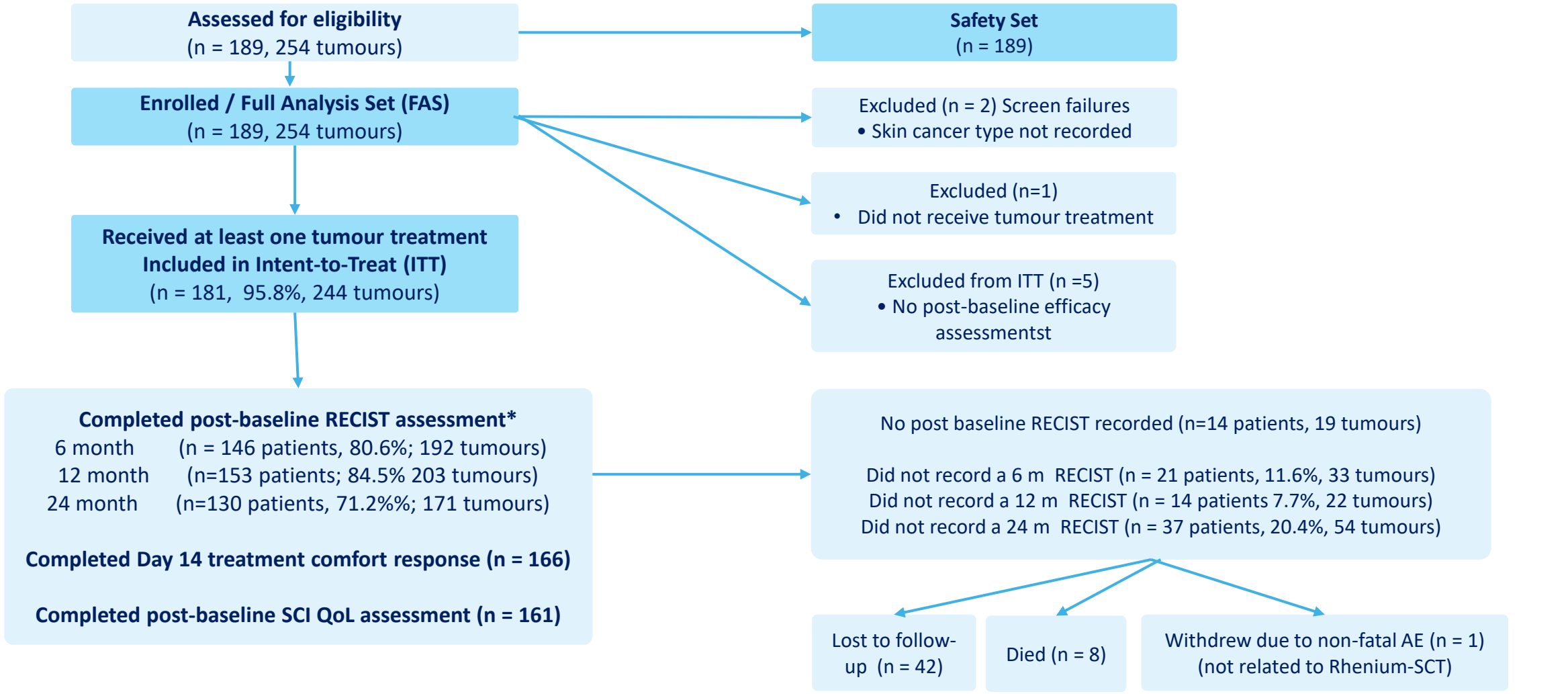
This population will be used to assess primary and efficacy outcome measures

Safety Set

The Safety Set (SS) will be comprised of all subjects who have received treatment and for whom at least one item of safety data is available.

Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors

Study Flow Diagram



Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors. *Proportion of ITT population for each analysis.

Patient Demographics and Baseline Characteristics (FAS, n=189)

71.5 years
Median age (range 27-95)

55.4%
>70 years

53.3%
were male

80%
Fitzpatrick Type I or II

Characteristics	Category	Overall n(%)
Age	Mean (range)	70.3 (27-95)
Age group	<40	3 (1.6%)
	40-49	6 (3.3%)
	50-59	29 (15.8%)
	60-69	44 (23.9%)
	70+	102 (55.4%)
	missing	5 (2.6%)
Gender	Male	98 (53.3%)
	Female	86 (46.7%)
	missing	5 (2.6%)
FitzPatrick skin type	I	41 (23%)
	II	101 (56.7%)
	III	32 (18%)
	IV	3 (1.7%)
	V	0 (0.0%)
	VI	1 (0.6%)
	missing	11 (5.8%)

Patient Demographics and Baseline Characteristics (FAS)

Characteristics	Category	Overall (N=189) n (%)
Country	Australia	67 (35.4%)
	South Africa	37 (19.6%)
	Austria	30 (15.9%)
	Germany	32 (16.9%)
	United Kingdom	23 (12.2%)
Number of Lesions[1]	1	137 (74.9%)
	2	32 (17.5%)
	3	14 (7.7%)
Surface area of Lesion[2]		Mean lesion size: 2.27cm^2
Depth of Lesion[2]		Mean lesion depth: 1.40 mm
Treatment Time		Mean treatment time: 119 min (SD 61.0 min)

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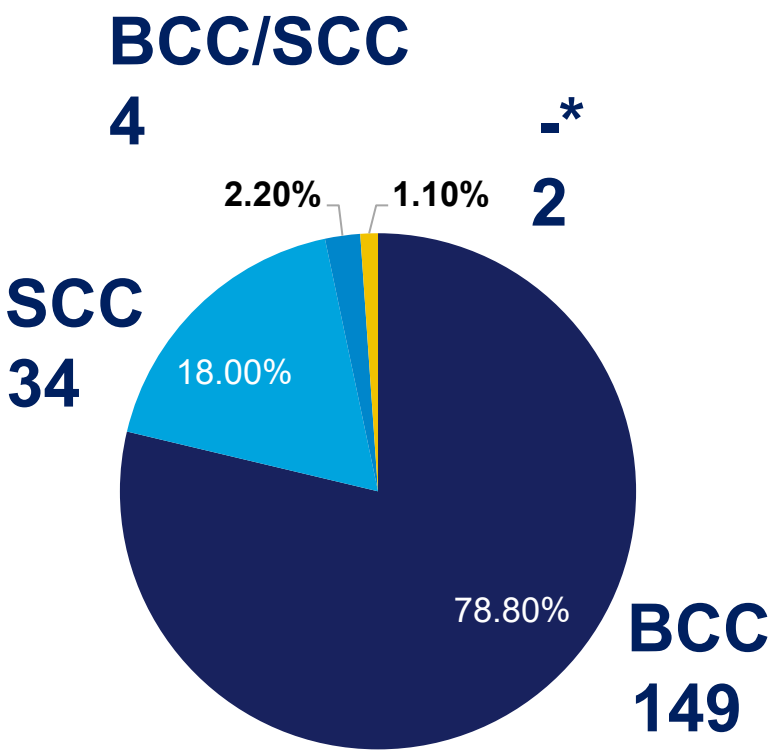
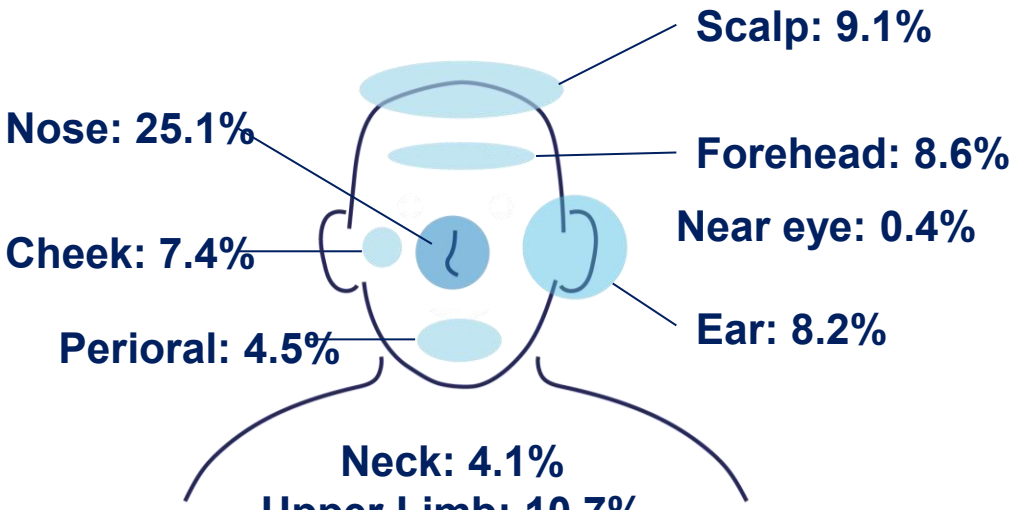
* Population is those patients that had at least one treatment (N=183); Overall 227 lesions contained information on surface area. FAS: full analysis set

Lesion Characteristics

Tumour Type



Lesion Locations



*Two patients did not have the type of skin cancer (BCC/SCC) recorded. These patients were both screen failures
Of the 183 patients with information in the tumour_details dataset, 137 had a single lesion recorded (74.9%), 32 had two lesions (17.5%), and 14 had three lesions (7.7%).

Primary Outcome

ITT vRECIST assessment at 24 months

Category	All Tumours	BCC Tumours	SCC Tumours
Complete response	**162/171 (94.7%)**	**123/131 (93.9%)**	**39/40 (97.5%)**
Partial response	6/171 (3.5%)	6/131 (4.6%)	0 (0.0%)
Stable disease	2/171 (1.2%)	1/131 (0.8%)	1/40 (2.5%)
Progressive disease	1/171 (0.6%)	1/131 (0.8%)	0 (0.0%)

Modified visual RECIST response categories for ITT patient tumours split by tumour type evaluated at 24-month follow-up visits. Total number of tumours at each time point is calculated in the ITT population with vRECIST evaluated

Missing data at not imputed at any time point. RECIST values missing for 73 lesions at 24 months.
Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors

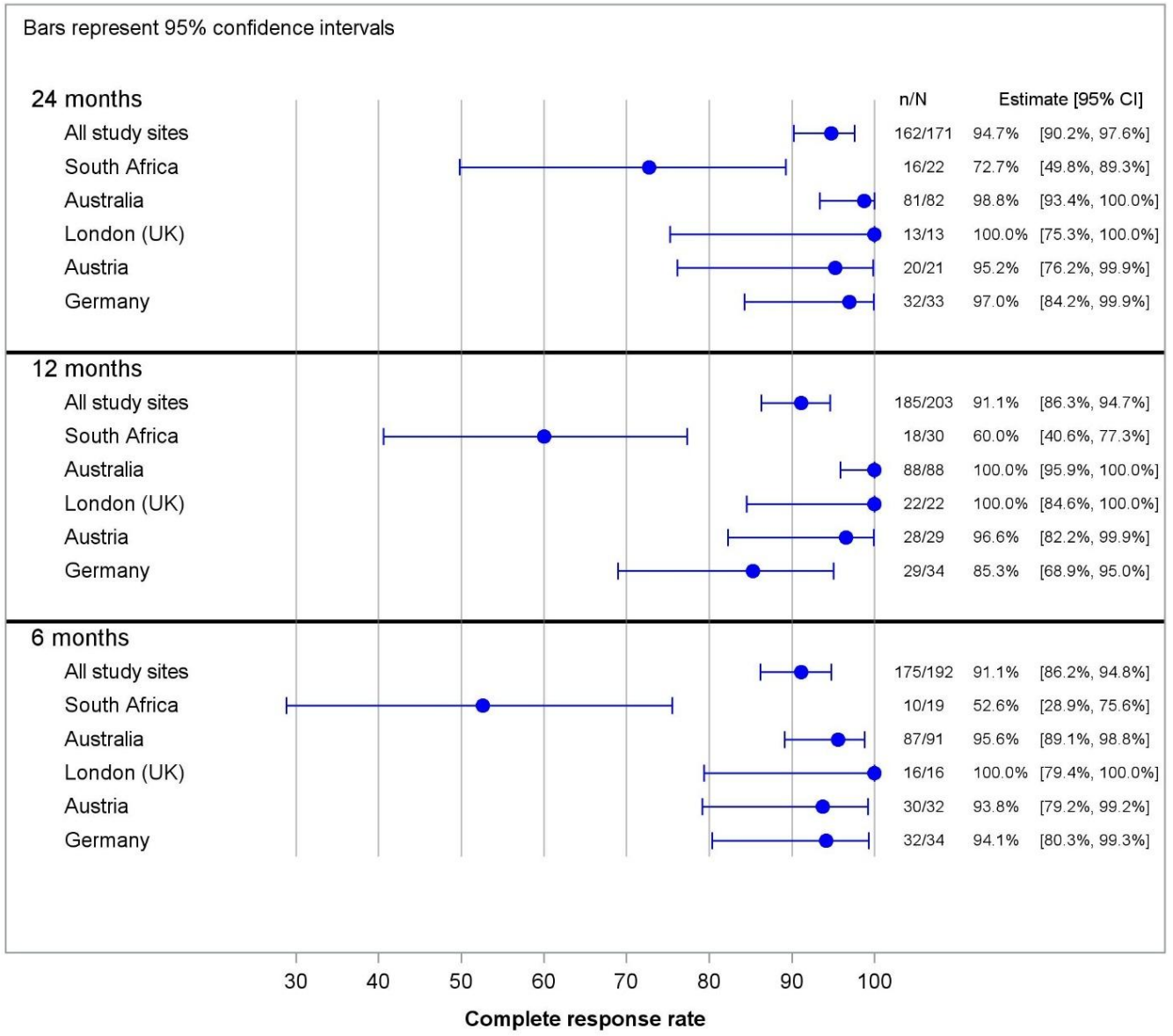
Complete Response over Time

Rhenium SCT achieved durable efficacy with maturing response as post treatment changes resolve

Category	6m 192 tumours 146 patients	12m 203 tumours 153 patients	24m 171 tumours 130 patients
Complete response	**175/192 (91.1%)**	**185/203 (91.1%)**	**162/171 (94.7%)**
Partial response	**15/192** (7.8%)	**10/203 (4.9%)**	**6/171** (3.5%)
Stable disease	**1/192** (0.5%)	**2/203** (1.0%)	**2/171** (1.2%)
Progressive disease	**1/192** (0.5%)	**6/203** (3.0%)	**1/171** (0.6%)

Modified visual RECIST response categories for ITT patient tumours evaluated at 6, 12, 24-month follow-up visits.
Total number of tumours at each time point is calculated in the ITT population with vRECIST evaluated
Missing data at not imputed at any time point. RECIST values missing for 52, 41, 73 lesions at 6, 12, and 24 months, respectively.
Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors, CR: Complete response, 6m: 6 months, 12m: 12 months, 24m: 24 months.

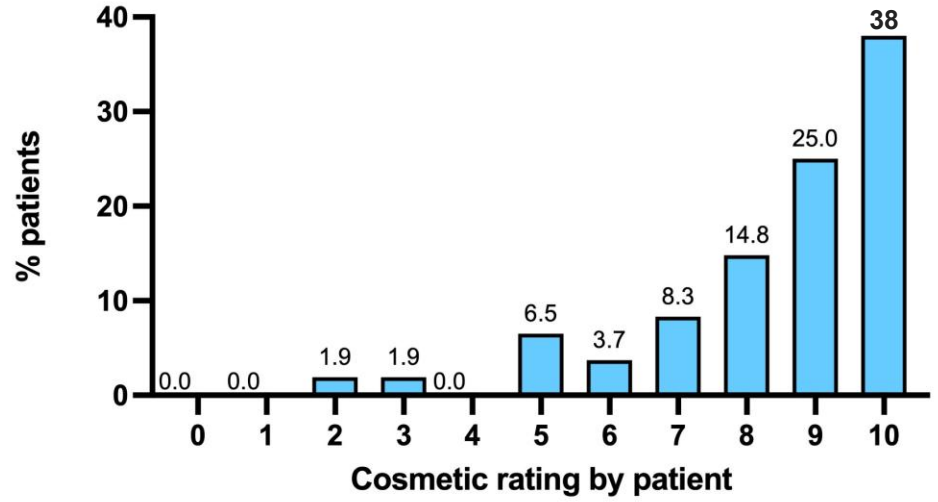
Complete response rates by geographic regions



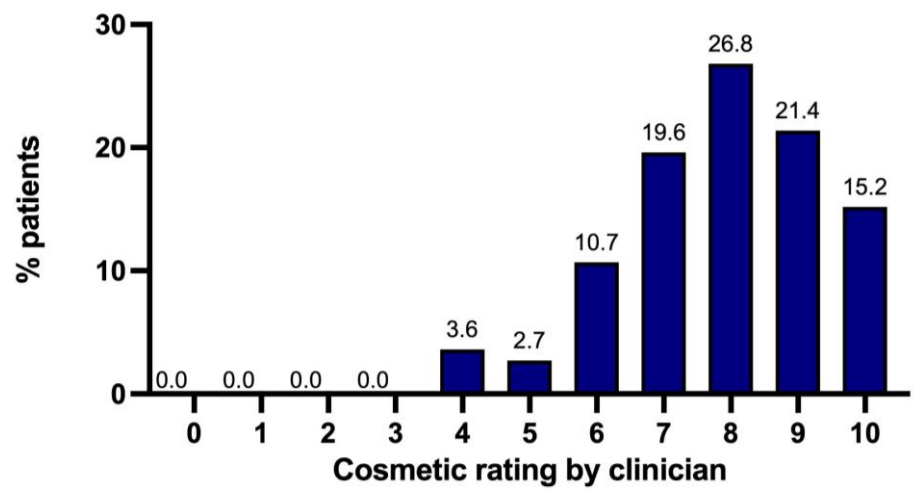
Secondary Outcome: Cosmesis

Patients and clinicians report favorable cosmesis outcomes that remained stable over 24m

Average patient cosmetic score: 8.5 (SD=1.88) N=108



Average clinician cosmetic score: 7.9 (SD=1.51) N=112



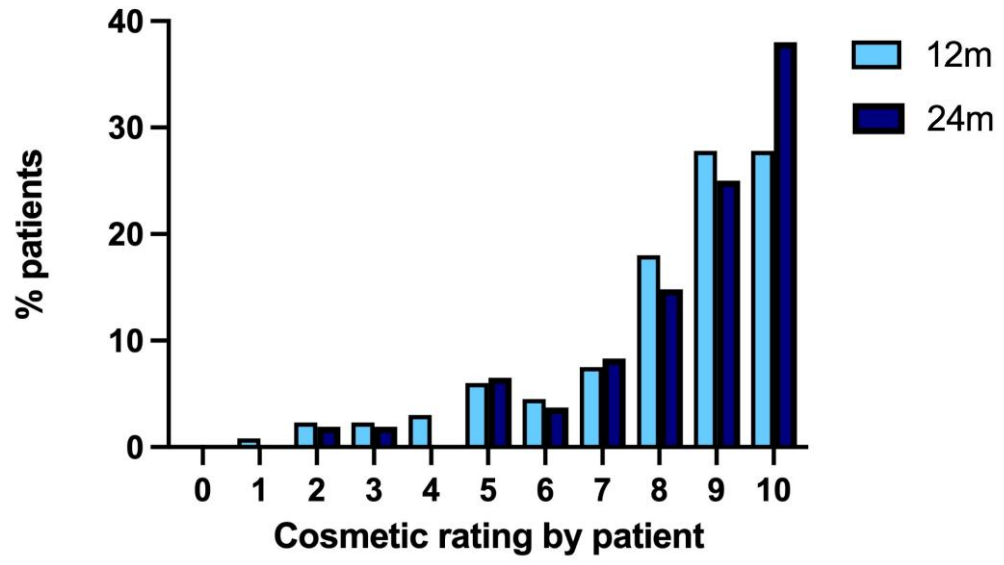
Both patients and clinicians provided an assessment of the cosmetic appearance of the wound at 24 months post-procedure.
This was done using a 10-point scale: 0 = very poor appearance; 10 = no visible wound

Secondary Outcome: Cosmesis

Patient and clinician assessment of cosmesis remains stable over 24m

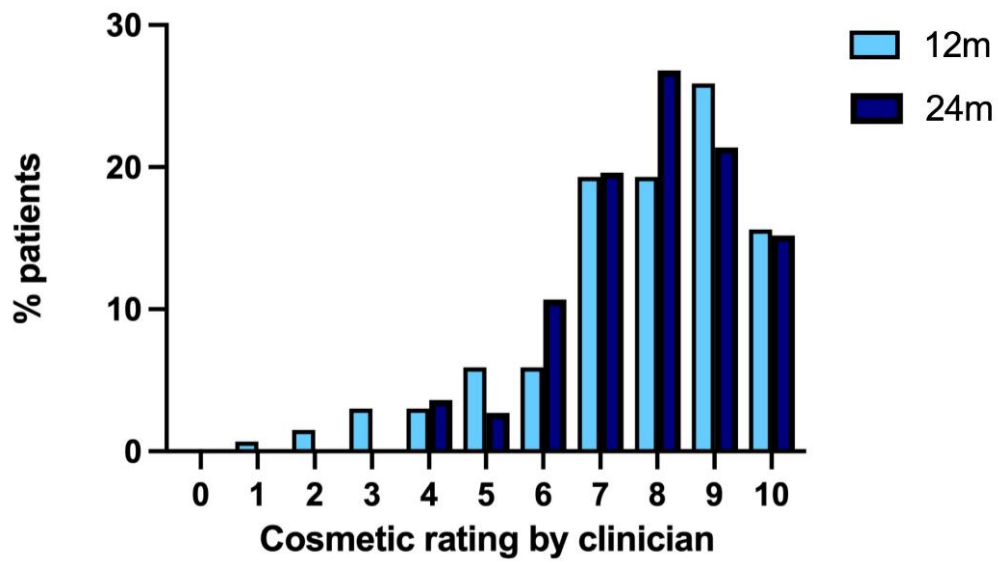
Average patient cosmetic score at 12m: 8.1 (SD=2.11) N=143

Average patient cosmetic score at 24m: 8.5 (SD=1.88) N=108



Average clinician cosmetic score at 12m: 7.7 (SD=1.97) N=147

Average clinician cosmetic score at 24m: 7.9 (SD=1.51) N=112



Both patients and clinicians provided an assessment of the cosmetic appearance of the wound at 24 months post-procedure.
This was done using a 10-point scale: 0 = very poor appearance; 10 = no visible wound

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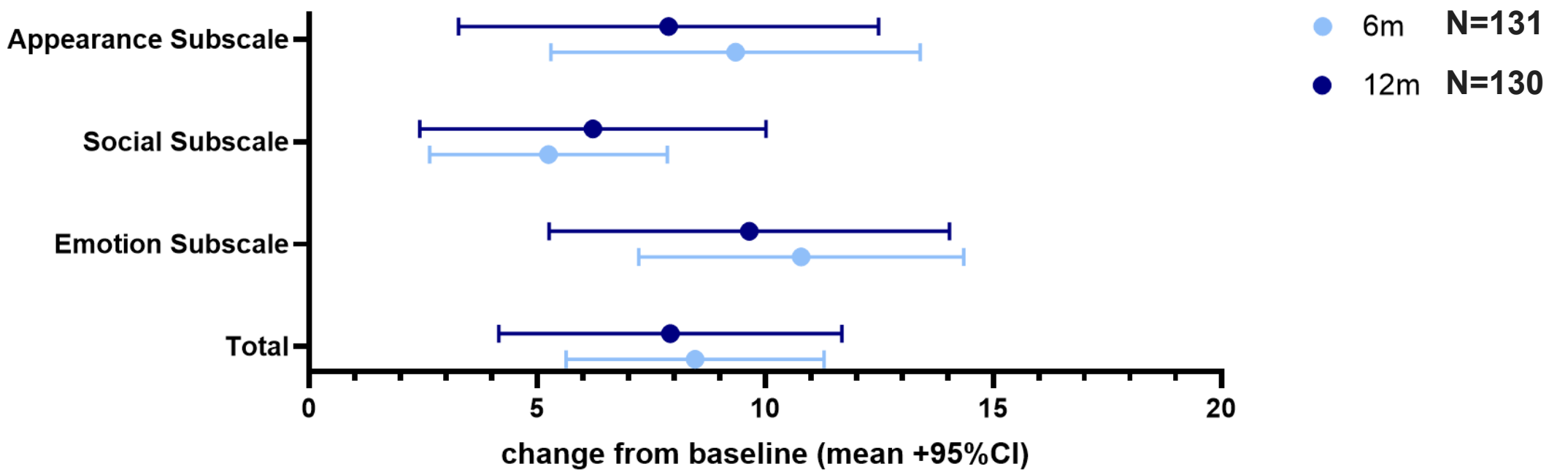
Secondary Outcome: Comfort of Treatment and Quality of Life

Patients report no pain and improved skin-directed quality of life following treatment with Rhenium-SCT

Comfort of Treatment

Of 166 patients with a response on the Day 14 treatment comfort assessment, no pain or discomfort was reported.

Skin Cancer Index questionnaire Quality of Life



Estimated change from baseline to 6-month and 12-month follow-ups for SCI subscales of the SKINDEX-16 QoL instrument, adjusted for baseline subscale scores. Adjusted repeated measures analysis. *While no MCID exists for the SCI scale, the study describing the instrument found a +9.0 point difference post Mohs surgery (Rhee et al Laryngoscope 2007 Mar;117(3):399-405). Subsequent studies found a +2.36 point difference for Mohs surgery (Sanchez et al J Dermat Treat 2020, 31:5, 491-493), which was deemed statistically significant and consistent with earlier studies (Zhang et al 2018 J Am Acad Dermatol 78(6):1060-1067), and a non-significant -0.6 point difference for excision on the Total scale (Sanchez et al J Dermat Treat 2020, 31:5, 491-493).

Summary

EPIC-Skin Phase IV Study

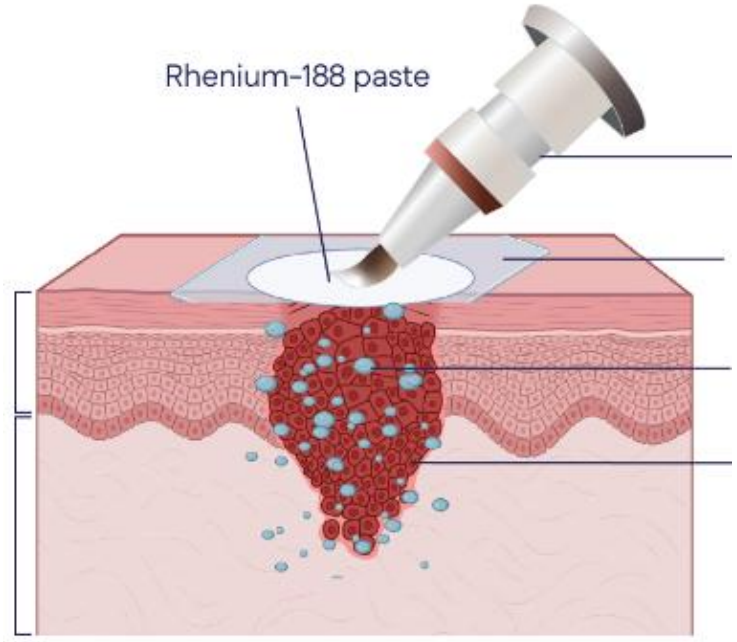
Rhenium-SCT
Single-session 50Gy treatment

24-month outcomes

189 patients
(Median: 72 years)

BCC or SCC
1-8cm^2; < 3mm deep

171 tumors
with 24m month follow-up



Efficacy
94.7% complete response

Treatment Comfort
100% no pain during procedure

QoL
+7.92 meaningful* improvement in SKINDEX -16 scores from baseline

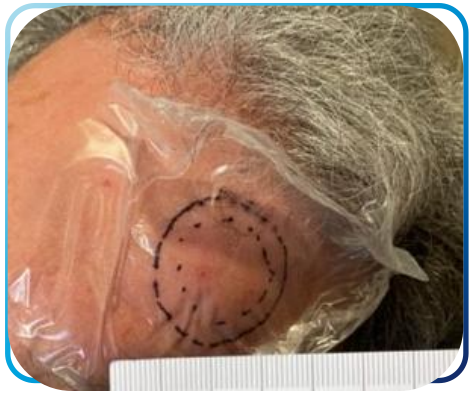
Cosmesis
8.5/10 Patient-rated mean

7.9/10 Clinician rated mean

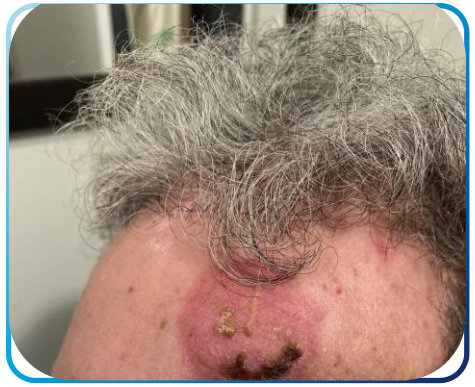
*While no MCID exists for the SCI scale, the study describing the instrument found a +9.0 point difference post Mohs surgery (Rhee et al Laryngoscope 2007 Mar;117(3):399-405). Subsequent studies found a +2.36 point difference for Mohs surgery (Sanchez et al J Dermat Treat 2020, 31:5, 491-493), which was deemed statistically significant and consistent with earlier studies (Zhang et al 2018 J Am Acad Dermatol 78(6):1060-1067), and a non-significant -0.6 point difference for excision on the Total scale (Sanchez et al J Dermat Treat 2020, 31:5, 491-493).

EPIC Clinical Cases

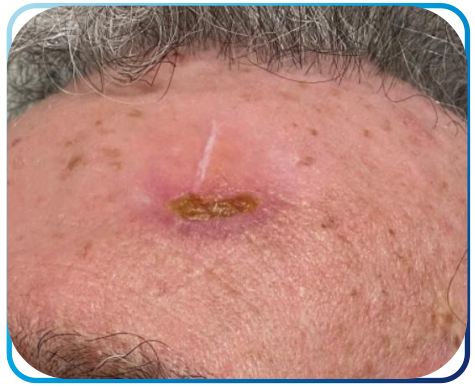
004_multiple facial lesions



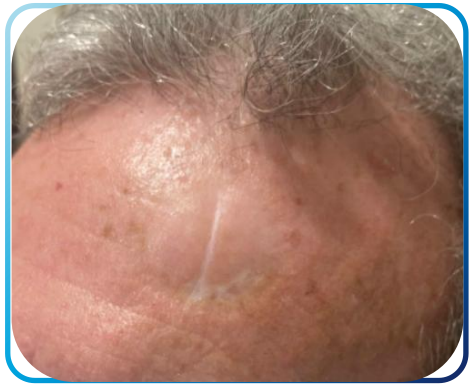
Baseline



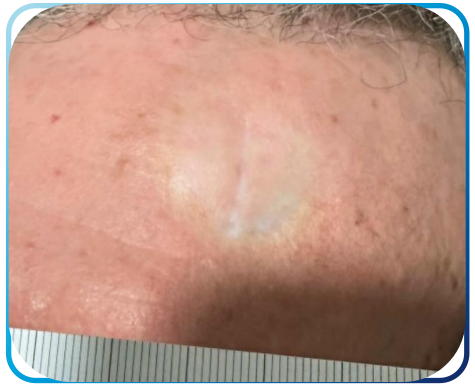
Day 14



Month 3



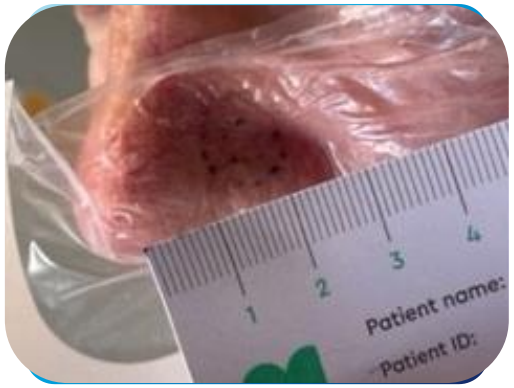
Month 6



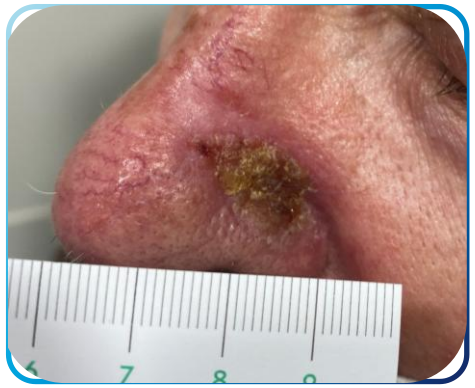
Month 12

EPIC Clinical Cases

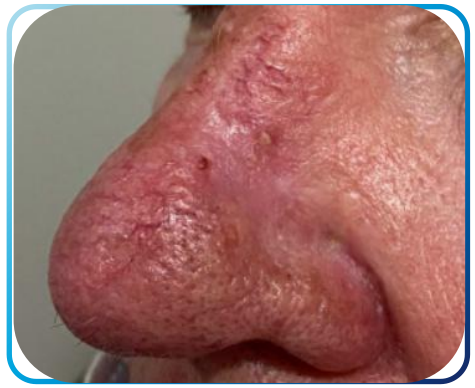
004_multiple facial lesions



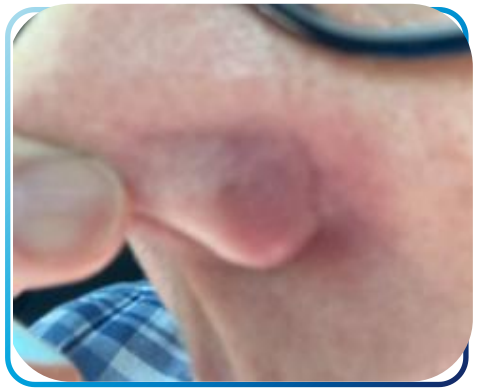
Baseline



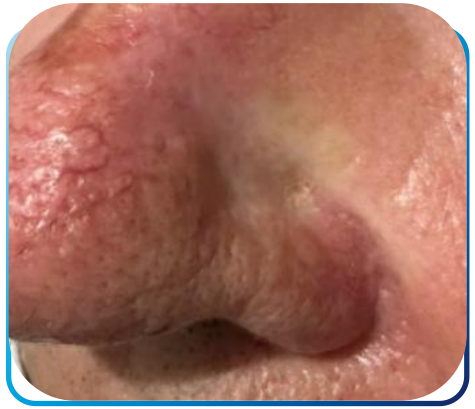
Day 14



Month 3



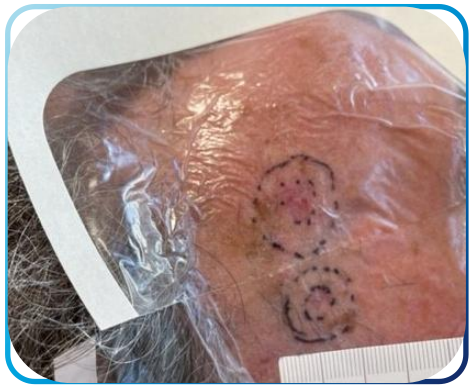
Month 6



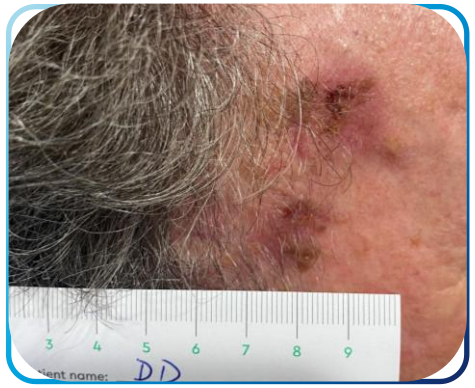
Month 12

EPIC Clinical Cases

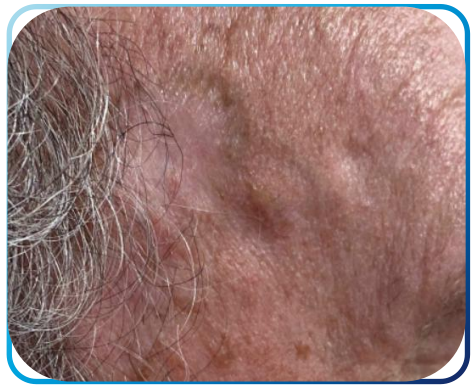
004_multiple facial lesions



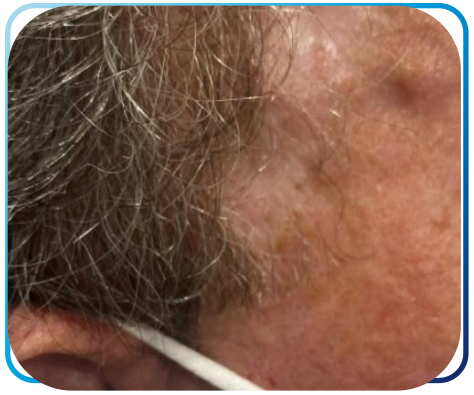
Baseline



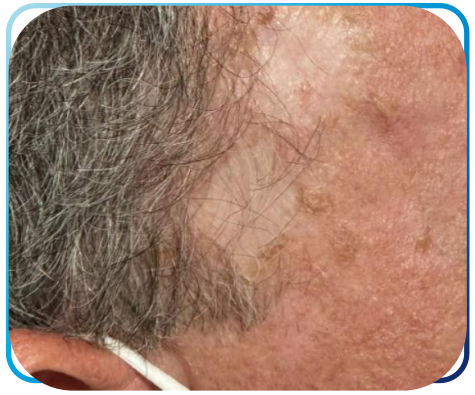
Day 14



Month 3



Month 6



Month 12

03

Rhenium SCT in NMSC: 24-month Safety results from EPIC Skin

A/Prof Siddhartha Baxi, Genesiscare

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Adverse Events

	Overall n=189	
	Patients[a,b] (%)	Events[c] (%)
Any adverse events	73 (38.6%)	169
Severity		
Mild	55 (29.1%)	104 (61.5%)
Moderate	30 (15.9%)	50 (29.6%)
Severe	5 (2.6%)	7 (4.0%)
Fatal	8 (4.2%)	8 (4.7%)
Relationship to IP		
Unrelated	17 (9.0%)	21 (12.4%)
Possible	12 (6.3%)	12 (7.1%)
Probable	51 (27.0%)	131 (7.8%)
Missing	5 (2.6%)	5 (3.0%)
Serious event		
No	65 (34.4%)	158 (93.5%)
Yes	9 (4.8%)	9 (5.3%)
Missing	2 (1.1%)	2 (1.2%)
Event leading to withdrawal		
No	65 (34.4%)	161 (95.3%)
Yes	6 (3.2%)	6 (3.6%)
Missing	2 (1.1%)	2 (1.2%)

- **There were 169 AE reported in 73 patients (38.6% of patients reporting at least one AE):**
  - 104 mild (G1) / 50 moderate (G2) / 7 severe (G3) events
  - 6 events leading to study withdrawal (unrelated to IP)
- **Relationship to IP was noted as probable for 131 events, possible for 12 events, unrelated for 21 events, and was missing for 5 events.**
- **9 SAE were included in the study data:**
  - 1 possibly related to the IP (skin induration - moderate)
  - 8 unrelated to IP (7 were fatal SAE)
- **No treatment emergent, treatment related adverse events led to withdrawal from study**

An SAE is any untoward medical occurrence that at any dose (including overdose): Medical Device (MDR 2017/745)
Serious adverse event (SAE) is any adverse event that led to any of the following:
a) death, b) serious deterioration in the health of the subject, that resulted in any of the following:
1) life-threatening illness or injury, 2) permanent impairment of a body structure or a body function, 3) hospitalization or prolongation of patient hospitalization; 4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function; 5) chronic disease; c) fetal distress, fetal death or a congenital physical or mental impairment or birth defect.
NOTE 1 Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event. Any adverse events that do not satisfy these descriptions are defined as being non-serious

[a]Patients = number of patients with at least one event of this type. Patients are counted up to once in each row. Events = number of events of this type. Patients may contribute multiple events to each row. Percentages are based on the number of patients in the safety set[b], or total number of Adverse events[c]. Abbreviations: G1: AE: Adverse Event, Grade 1; G2: Grade 2; G3: Grade 3; IP: Investigational Product; SAE: Serious Adverse event;

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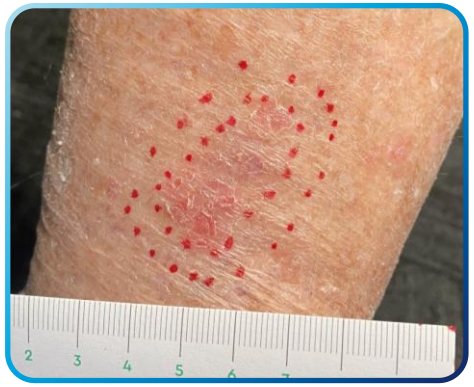
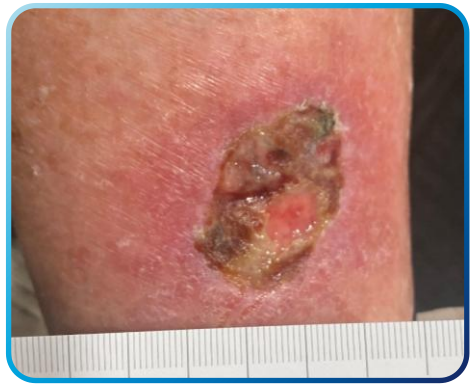
Serious Adverse Event: skin induration, EPIC Clinical Cases

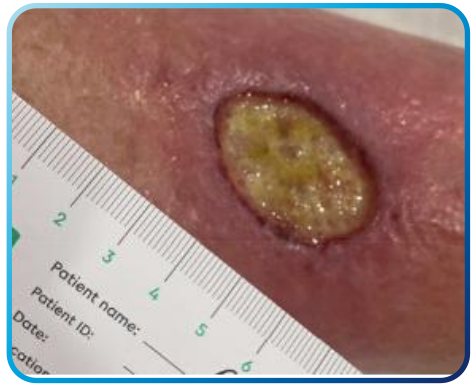
005_moderate ulceration, moderate dermatitis, moderate induration, moderate pain, moderate infection (unrelated)



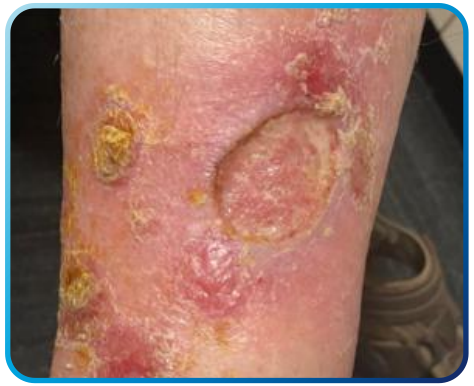
Baseline



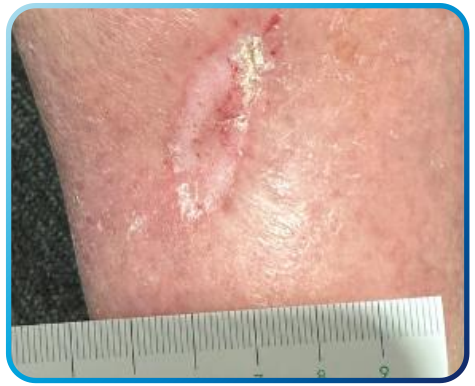
2 weeks



3 months



6 months



24 months

Severe Treatment-emergent Treatment-related AEs

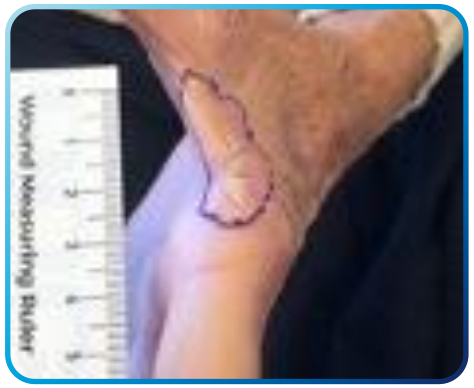
MedDRA coded term	Overall (N=189 Patients)	
	Patients (%)	Events
Any adverse event	4 (2.1%)	6
Skin and subcutaneous tissue disorders	3 (1.6%)	5
Skin induration	2 (1.1%)	2
Skin ulcer	2 (1.1%)	2
Dermatitis	1 (0.5%)	1
Injury, poisoning and procedural complications	1 (0.5%)	1
Radiation skin injury	1 (0.5%)	1

- There were 6 Severe AEs reported in 4 patients.

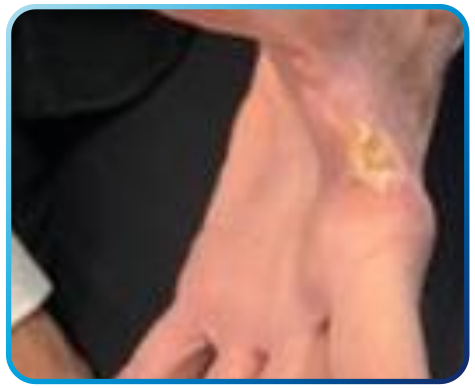
Abbreviations: MedRA: Medical Dictionary for Regulatory Activities
Severe Adverse Events: Grade 3 severe or medically significant but not immediately life threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL2
Treatment related AE are those which, in the opinion of the investigator, were possibly, probably, or definitely related to the study IP
P = the number of patients experiencing at least one of this type of event. Percentages are based on the number of patients that had the event at least once
E = the total number of events experienced during the study. Patients may contribute multiple times if the event was experienced on more than one occassion

Severe Adverse Effects: EPIC Clinical Cases

011_Severe radiation skin injury (radiation dermatitis) at 2 weeks

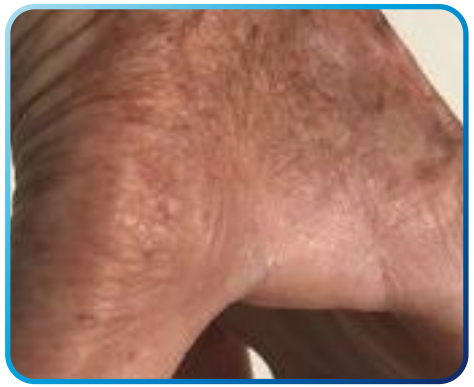


Baseline



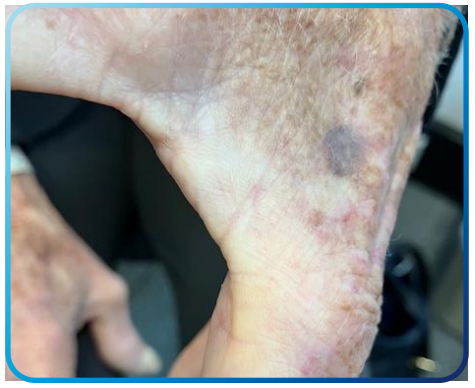
2 weeks

3 months



6 months

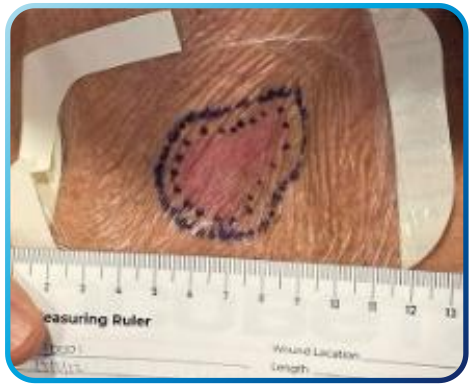
12 months



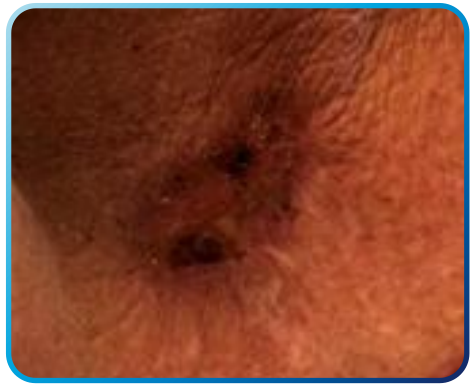
24 months

Severe Adverse Effects: EPIC Clinical Cases

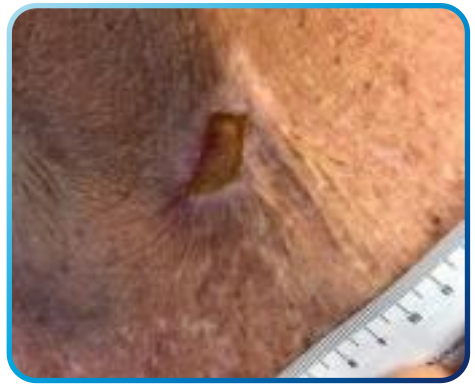
001_Severe Skin Induration/Fibrosis



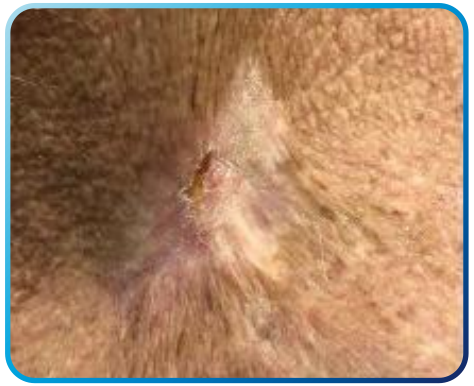
Baseline



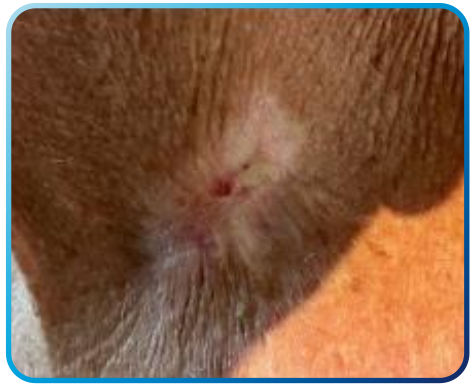
Day 14



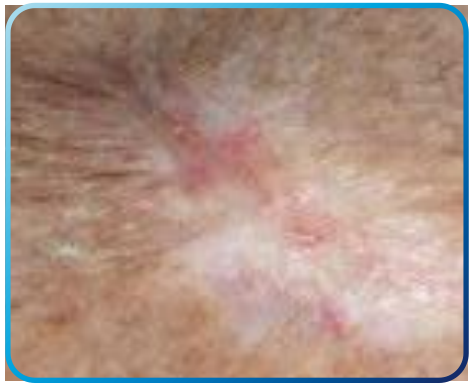
Month 3



Month 6



Month 12



Month 24

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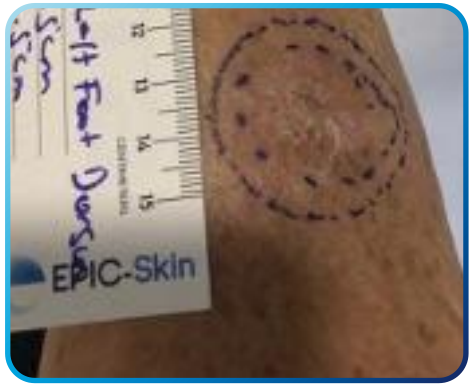
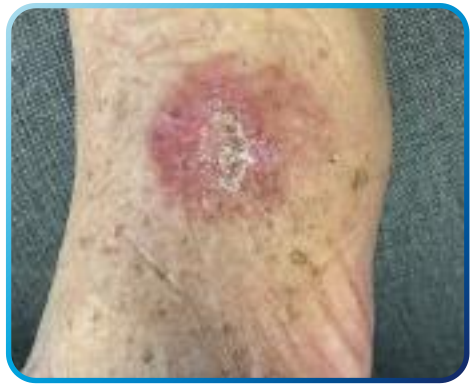
Severe Adverse Effects: EPIC Clinical Cases

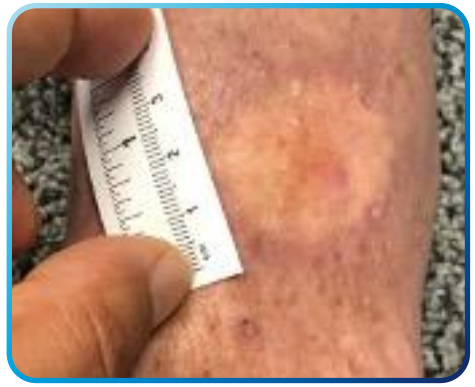
006_severe ulceration, dermatitis, hypopigmentation, telangiectasia



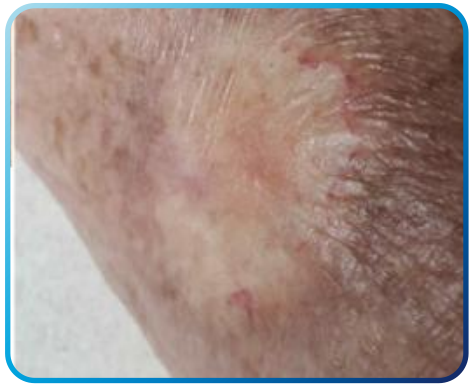
Baseline



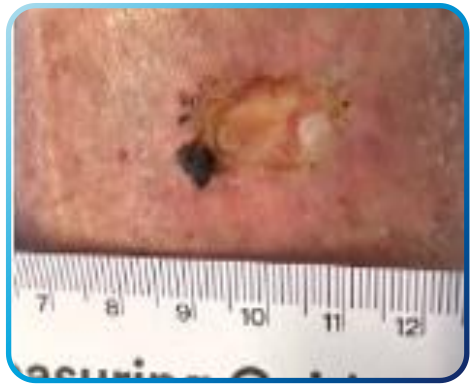
Day 14



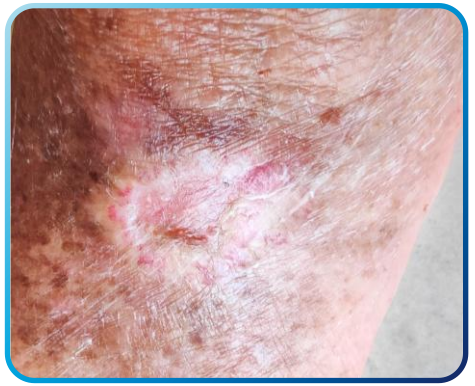
Month 3



Month 6



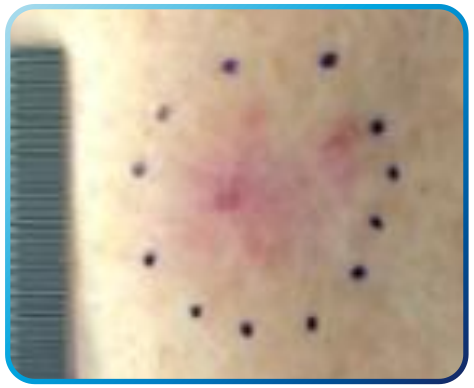
Month 12



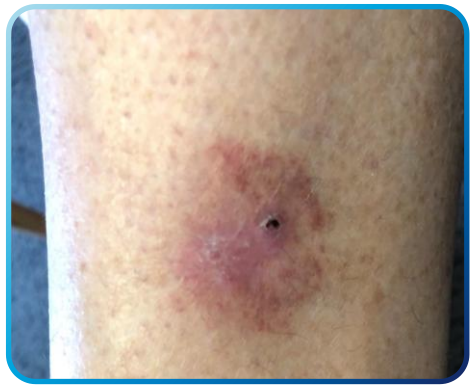
Month 24

Severe Adverse Effects: EPIC Clinical Cases

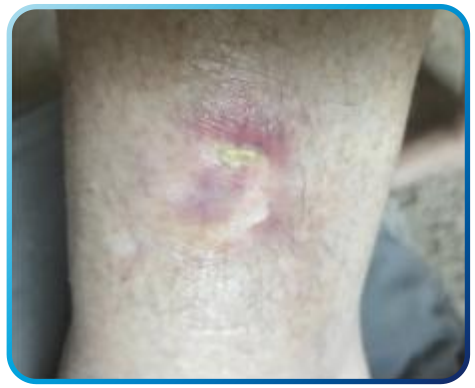
015_severe ulceration, severe dermatitis, severe induration



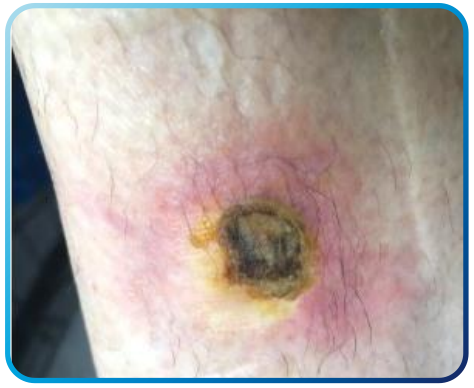
Baseline



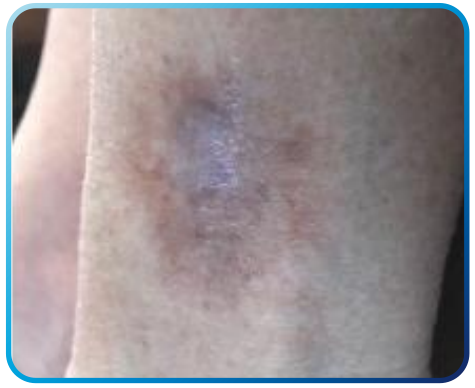
2 weeks



3 months



6 months



24 months

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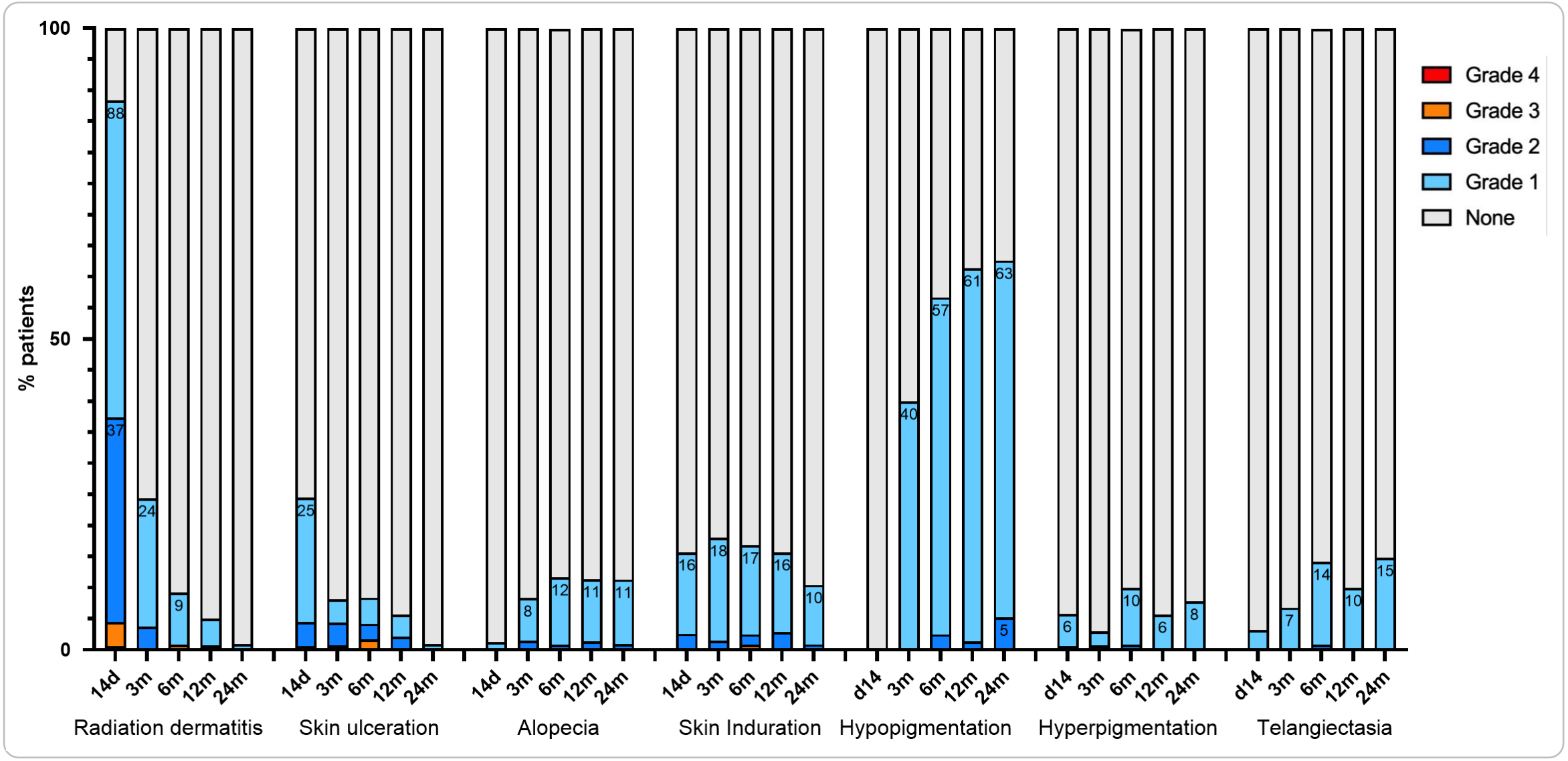
CTCAE Graded Adverse Events of Interest

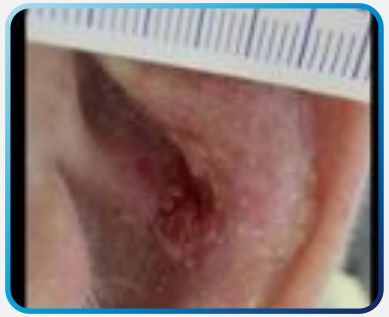


For each event type (radiation dermatitis, skin ulceration, alopecia, skin induration, hypopigmentation, hyperpigmentation, telangiectasia), only patients experiencing the event are graphed. Assessment for these events were undertaken at day 14, 3-month, 6-month, 12-month and 24-month visits. Abbreviations: CTCAE:Common Terminology Criteria for Adverse Events; d14: day 14, 3m: 3-month, 6m: 6-month, 12m: 12-month and 24m: 24-month

Late toxicities: Suspected recurrences

Biopsy confirmed in 1 out of 3 suspected clinical recurrences at 12 months in Tietze et al 2023

Suspicious lesion and biopsy results after 4 months and after 12 months (A–D). Lesion A appeared suspicious after 4 months, and a biopsy was taken. Lesions B–D appeared suspicious after 12 months. Only suspicious lesion D was confirmed to be residual/recurrent tumor.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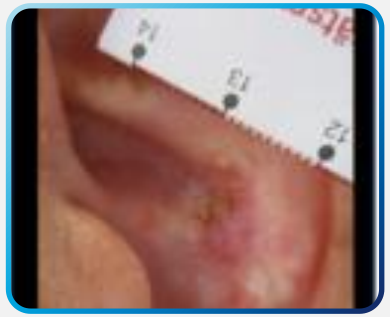
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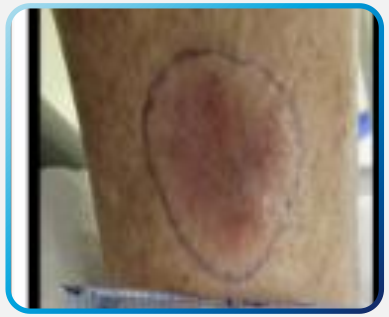
(A)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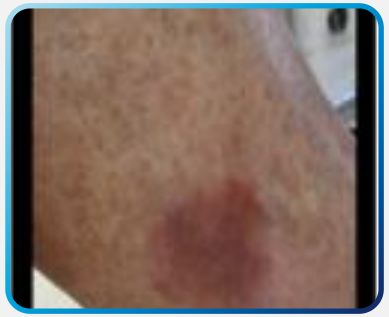
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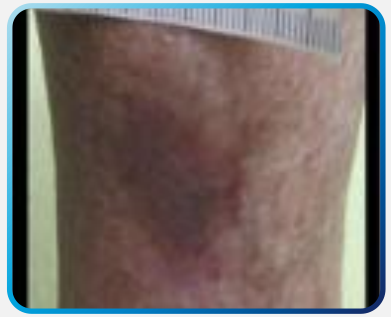
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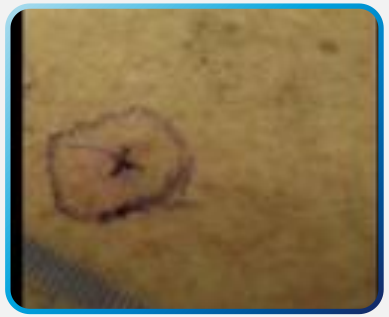
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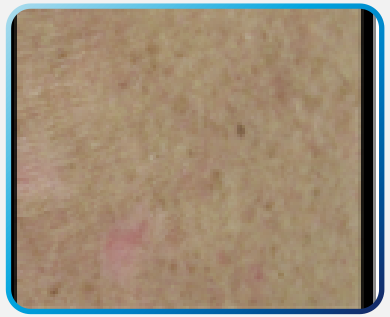
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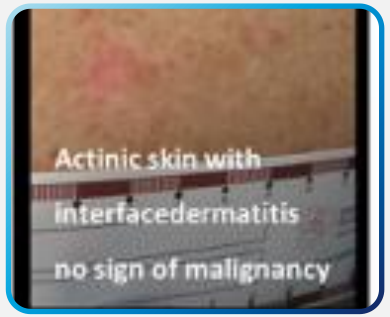

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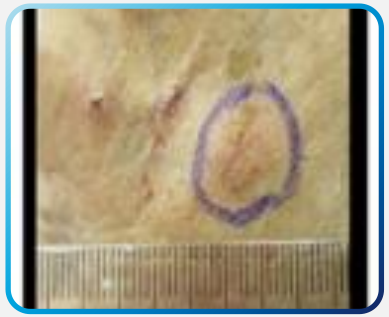
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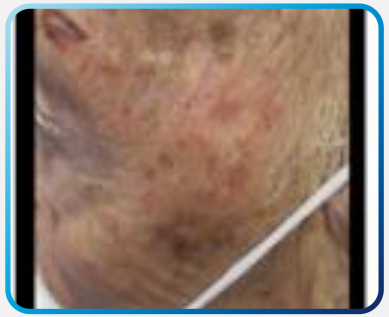
(D)

(D)

Tietze JK et al. Clin Nucl Med 2023;48:869–76

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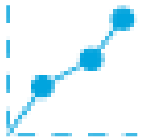
Summary of EPIC-Skin 24-month outcomes

The EPIC-Skin study's 24-month analysis demonstrates that Rhenium-SCT is a safe and effective treatment for BCCs and SCCs, which yields excellent cosmetic outcomes and significant improvements in patient quality of life.

Single session (~30-180min) radioisotope treatment

EPIC Skin enrolled BCC / SCC / IEC <3mm deep, up to 8cm^2 (2.5cm diameter).

Used clinically in lesions with difficult surgical options or unacceptable functional/cosmetic outcomes – Face / Ears / Noses / Peri-oral / Digits / (Penile)



Efficacy: The overall response rate was 98.2%,with a complete response rate of 94.7% (BCC: 93.9%, SCC: 97.5%)

- **QoL**: All average scores showed an increase in QoL from baseline.
- **Cosmesis**: Patients and Clinicians reported favorable cosmesis outcomes that remained stable over 24m
- **Patient Comfort**: 100% reported no pain or discomfort during the treatment session (n=166).

Safety: Manageable safety profile consistent with conventional radiotherapy.

- **Early toxicities** include radiation dermatitis (88.4%) and skin ulceration (24.5%).
- **Late toxicities** include hypopigmentation (57.4% Gr1/5.2% Gr2) and telangiectasia (14.8% Gr1)

04

Clinical Relevance of Rhenium SCT in NMSC

A/Prof Siddhartha Baxi, Genesiscare

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Supporting Literature: Independent Long-Term Experience

Independent retrospective data support durable local control and predictable safety profile with Rhenium-SCT

Study context

- Single-centre retrospective analysis
- 124 patients, 181 BCC/SCC lesions
- Mean lesion size 6cm^2 (range 1-34cm^2)
- 40% recurrent or previously treated lesions

Long-term outcomes

- **91.1% relapse-free rate at 36 months**
- Relapse risk increased with larger lesion size
- ~30% of recurrences occurred at treatment margins

Safety

- Adverse events were predominantly mild and self-limiting
- No late toxicity observed in a long follow-up subgroup (23 patients to 66 months)

Castellucci et al, Efficacy and Safety of Epidermal Radionuclide Therapy with 188Re Resin in Patients with Nonmelanoma Skin Cancers: Long-Term Data from a Single Center, J Nucl Med 2025; 00:1–6.

What matters to patients?

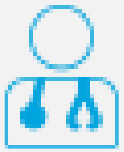
Rhenium-188 patients prioritise pain avoidance, treatment simplicity, and alternatives to surgery

Why patients choose Rhenium-SCT

- Pain avoidance: 84% participated to avoid pain and complications of surgery
- Lower treatment anxiety: Patients were significantly less afraid of Rhenium-SCT than surgery
- Single-visit treatment was valued, particularly after multiple prior procedures

Experienced pain (patients who had both treatments)

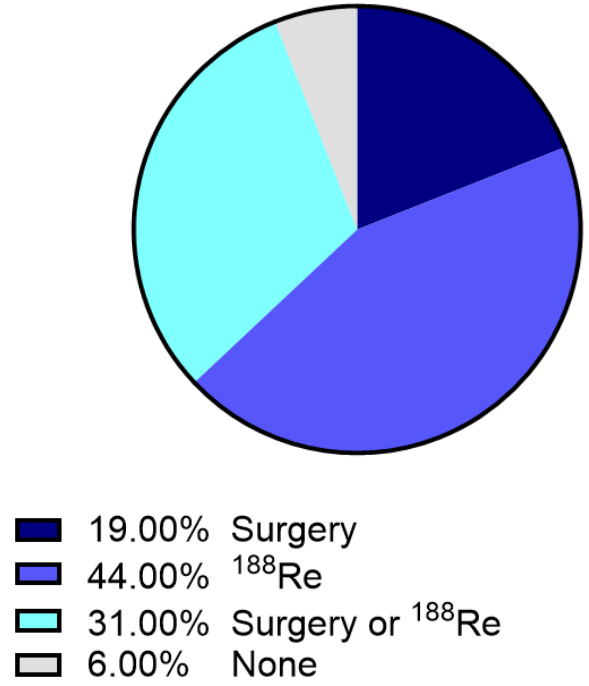
- Rhenium-SCT was associated with significantly lower pain scores than surgery
- During treatment
- And at 14 days post-treatment



Clinician-supported decision-making

- Dermatologists strongly supported Rhenium-SCT in ~50% of cases due to:
  - Lesion size
  - Sensitive anatomical locations
  - High expected surgical morbidity

Choice of treatment for a new NMSC



Krönert MIC, Schwarzenböck SM, Kurth J, Heuschkel M, Krause BJ, Emmert S, Tietze JK. Patient-Orientated Evaluation of Treatment of Non-Melanoma Skin Cancer with Rhenium-188 Compared to Surgery. Healthcare (Basel). 2024 Apr 29;12(9):921. doi: 10.3390/healthcare12090921. PMID: 38727478; PMCID: PMC11083370. Abbreviations

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Conclusions – From a Clinical Perspective

EPIC establishes Rhenium-SCT as an effective, well-tolerated option for appropriately selected superficial NMSC

EPIC is the first prospective dataset specifically designed to assess durability, safety, and efficacy of Rhenium-SCT in ≤3 mm lesion

Rhenium-SCT is an additional tool, not a replacement for surgery, for selected patients.

Best suited for thin (≤3 mm) BCC/SCC lesions, particularly when:

- Surgery is high morbidity, declined, or impractical
- Lesions are in cosmetically or surgically challenging locations
- Multiple or refractory lesions can be treated in a single visit

Durable tumour control is achieved when appropriate dose is delivered to tumour depth, with responses continuing to mature as post-treatment changes resolve.

Predictable healing and low procedural pain align with what many patients value compared with surgery or fractionated radiotherapy.

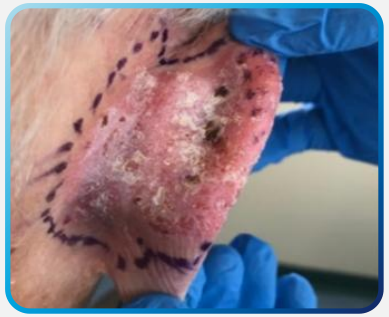
Rhenium SCT: another tool in the radiation oncology toolbox

Patient Cases:

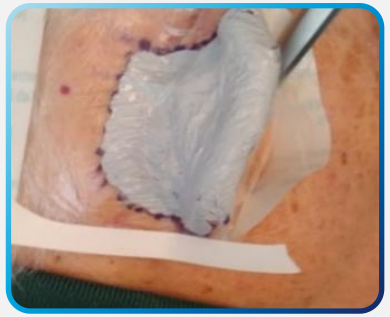
Lesions in areas with cosmetic considerations

Male, 93 years-old

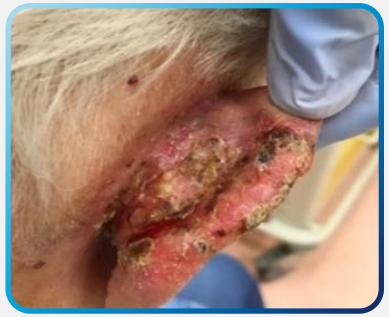
- Fitzpatrick I – ECOG 2
- SCC (2 mm deep; 11cm^2 area)
- Entire ear eminence
- No prior treatment
- Surgical comorbidities and inability to attend multiple RT sessions



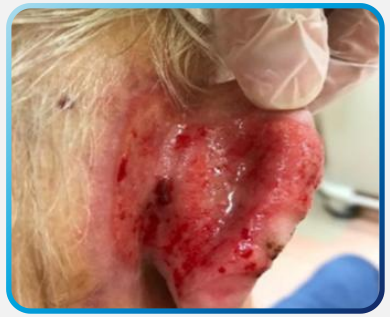
Pre-treatment



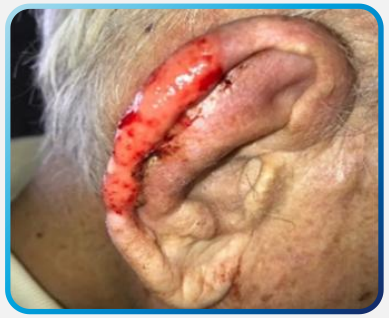
Pre-treatment



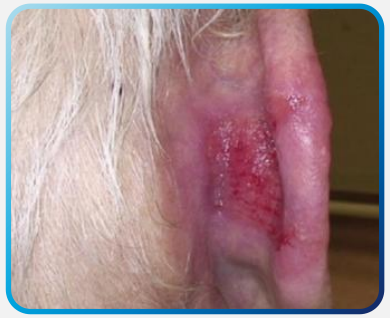
Day 14



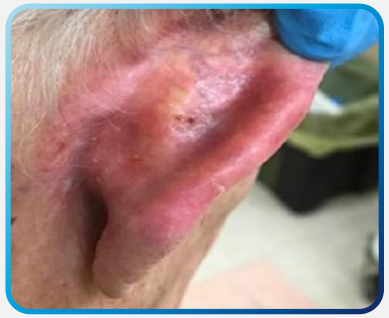
Day 30



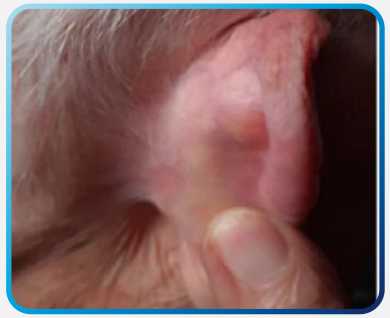
Day 30



Day 48



Day 90



1 Year

Castellucci P, Savoia F, Farina A, Lima GM, Patrizi A, Baraldi C, et al. Eur J Nucl Med Mol Imaging. 2021 May;48(5):1706. doi: 10.1007/s00259-021-05363-7

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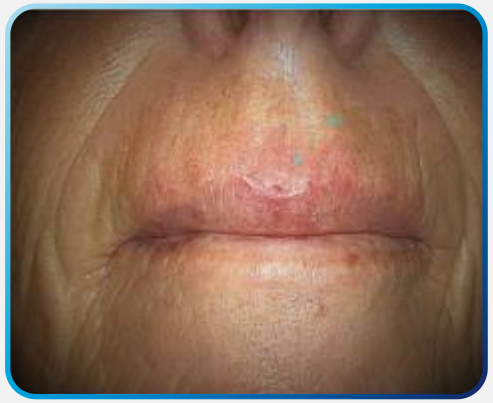
Patient Cases:

SCC lesion contraindicated for surgery

- 54-year-old Caucasian woman, no relevant medical history; 1-year history of dermatitis on the upper lip treated with topical steroids
- 20 mm erythematous infiltrated plaque on the labial philtrum and upper vermilion border.
- Dermoscopic examination: structureless white and pink background, a polymorphous vascular pattern characterized by hairpin and linear irregular vessels, and white circles around follicular
- Skin biopsy confirmed ulcerated, moderately differentiated 0.635 mm SCC.
- Surgery contraindicated due to technical difficulty of maintaining aesthetics due to location/dimension of lesion



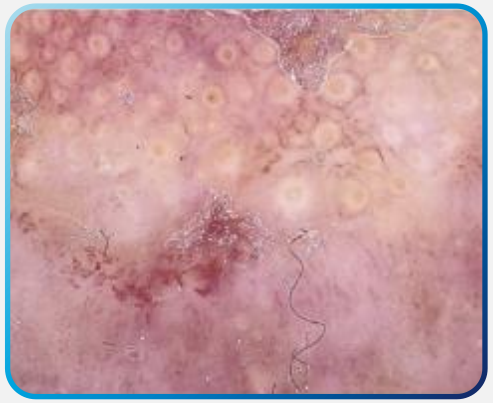


Figure 1. Patient at presentation. Erythematous infiltrated plaque on the labial philtrum and upper vermilion border. Dermoscopy shows a polymorphous vascular pattern and white circles around follicular openings

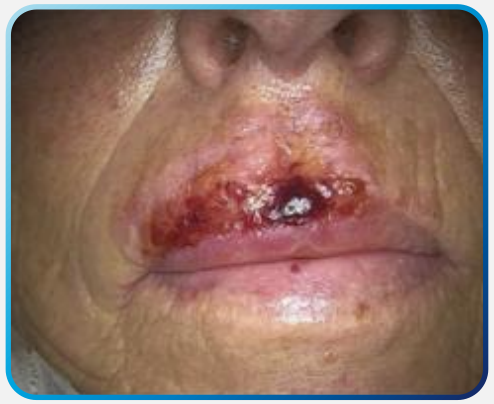
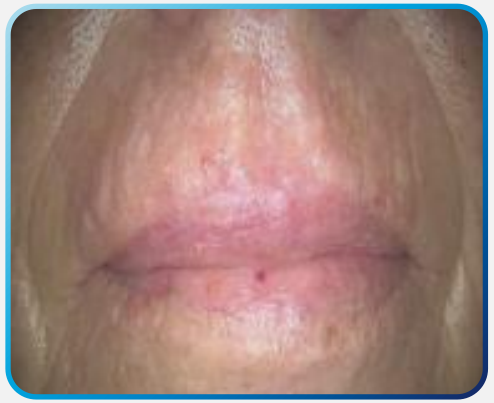


Figure 2. Erosions and blood crusts in the treated area after 4 weeks of treatment.



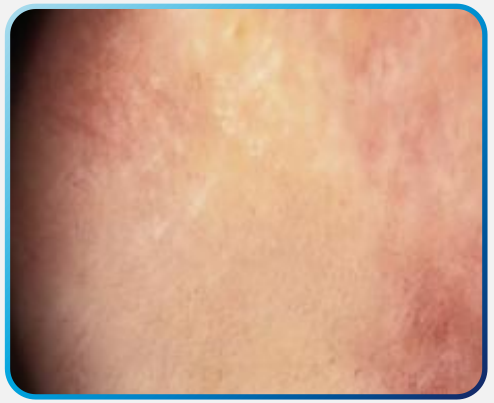


Figure 3. After 8 weeks of treatment

Sabbadini, Patta, Lorenzon, Farsad and Nobile 2023. Cutaneous squamous cell carcinoma of the lip successfully treated with rhenium-188 brachytherapy, Dermatology Reports 2023; volume 15

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05
Thank you for listening

Questions?

A/Prof Siddhartha Baxi, Genesiscare

Dr Cody Allison, OncoBeta

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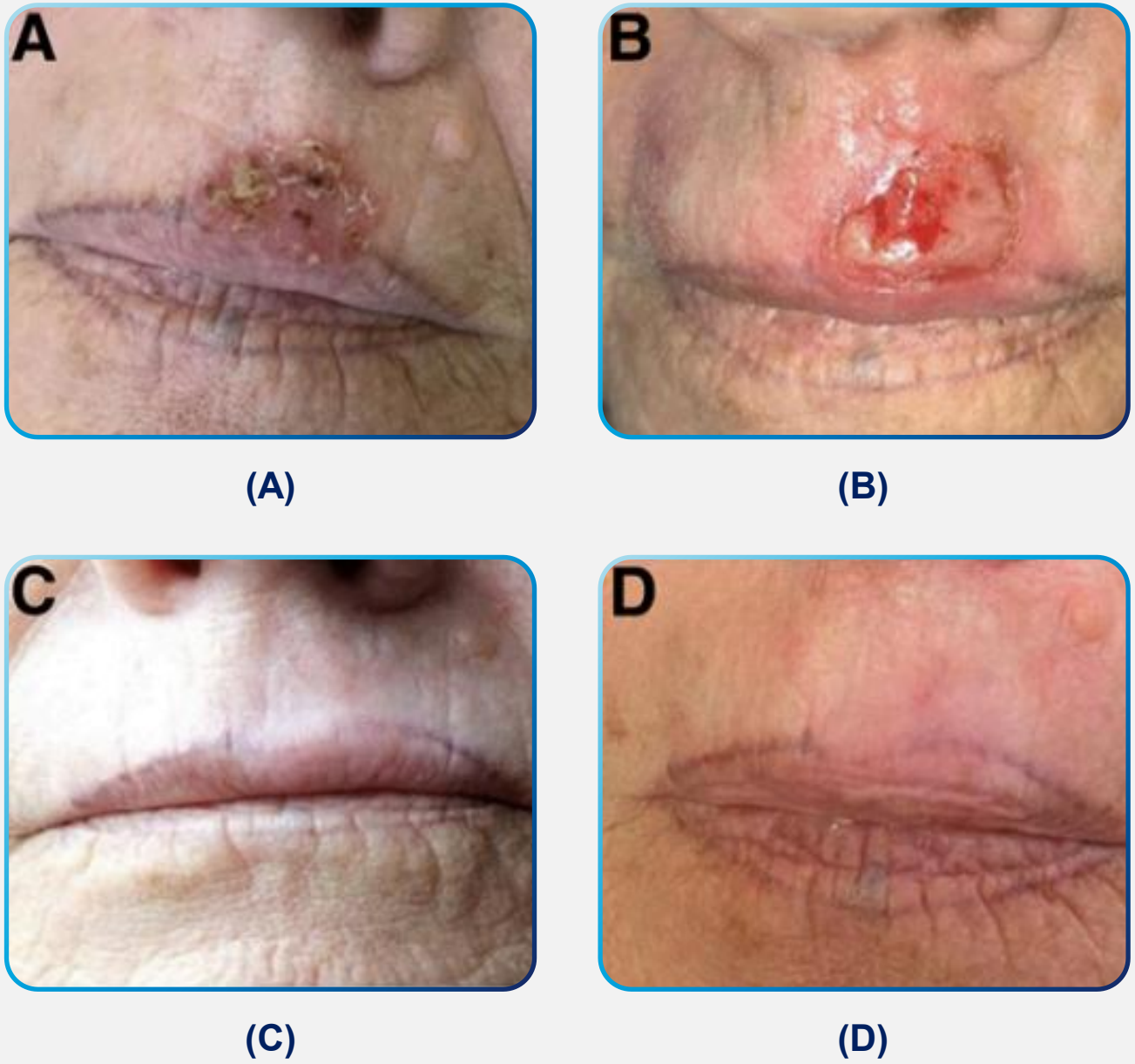
Patient Cases:

Lesions in areas with cosmetic considerations

Female, 78 years-old

- Fitzpatrick II – ECOG 0
- SCC (1.7 mm deep; 4cm^2 area)
- Upper lip (midline over philtrum)
- No prior treatment of lesions
- Surgeon referred due to concerns for functionality and asymmetry

78-y-old woman with relapse of SCC of upper lip, previously treated with cryotherapy. Lesion area, 4 cm2 ; thickness, 1.7 mm; administered dose, 190 MBq of 188Re resin; mean absorbed dose, 60 Gy; treatment time, 110 min. (A) Before treatment. (B) At 28 d after 188Re-ERT (CTCAE grade 3). (C) At 180 days after 188Re-ERT. (D) At 2 y after 188ReERT, faint depigmentation visible.



Castellucci et al, Efficacy and Safety of Epidermal Radionuclide Therapy with 188Re Resin in Patients with Nonmelanoma Skin Cancers: Long-Term Data from a Single Center, J Nucl Med 2025; 00:1–6.

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Monte Carlo Modelling Study

To understand the impact of Rhenium-188 on healthy tissue: comparing depth-dose profiles, evaluating lateral dose spread, and assessing the effects of modifying paste thickness.

Of the modelled modalities, ^{188}Re showed the steepest dose drop-off, minimising radiation to deeper healthy tissues while maintaining localised tumour control.

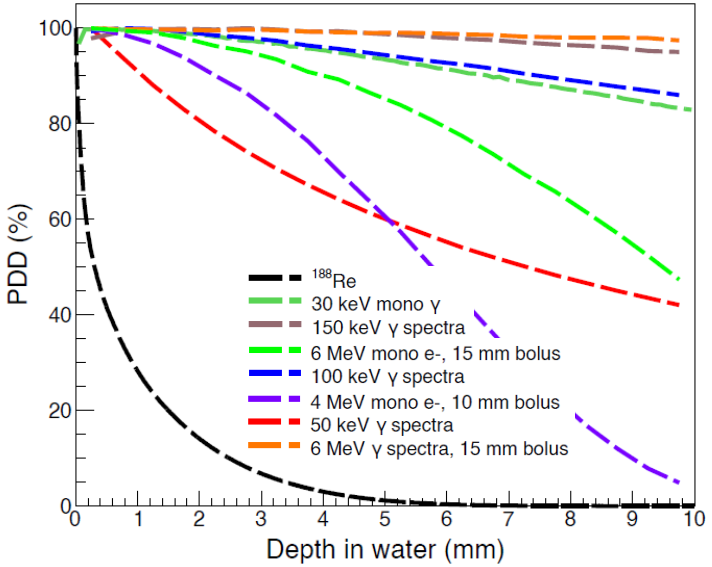

Fig 1. Modelled percentage dose deposition in water phantom of ^{188}Re, compared to clinically used conventional beams including 4-6MeV electron beams and 30-150KV gamma spectra.

Rhenium-SCT maintains a steep dose gradient, delivering consistent dose across the treatment surface area with a sharp lateral drop-off, minimising exposure to healthy tissue.

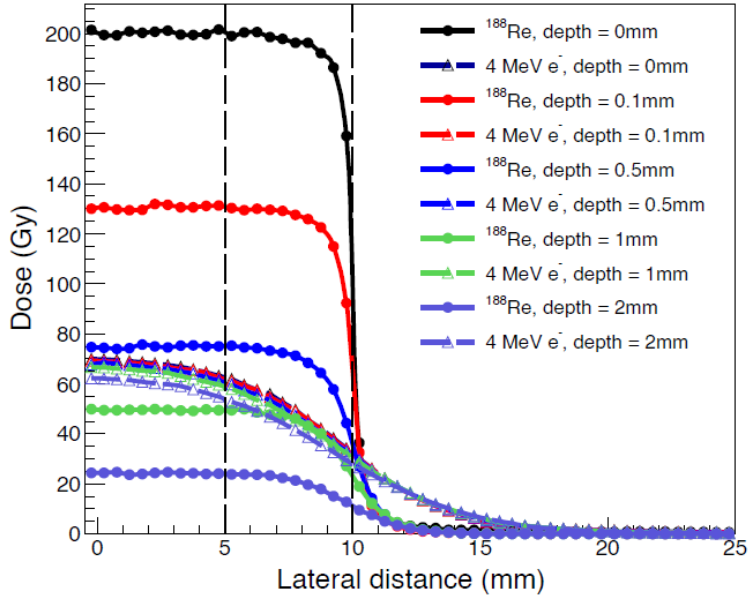

Fig 2. Modelled lateral dose deposition (50Gy dose delivered to the base of 1mm deep tumour, 10mm width, 5mm margins) at stated depth with ^{188}Re or 4MeV electron beam

Despite attenuation with increasing paste thickness, even the thickest clinically relevant application still delivered 95% of the prescribed dose; well within accepted radiotherapy dosing tolerances.

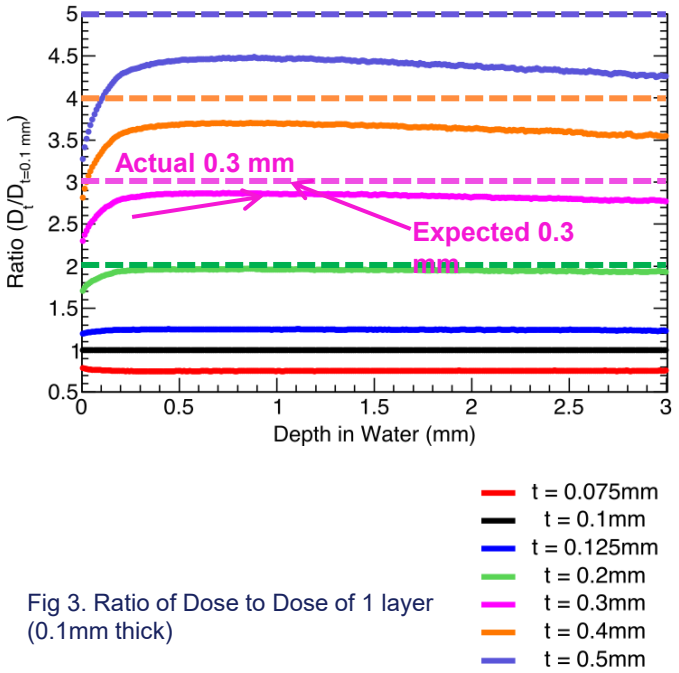

Fig 3. Ratio of Dose to Dose of 1 layer (0.1mm thick)

David Bolst, University of Woolongong, manuscript in preparation
Centre for Medical Radiation Physics (CMRP)

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The role of Rhenium-SCT in the RT Modality Spectrum

Modality	Indications	Pros	Cons	Considerations
SXRT (Superficial X-Ray Therapy)	• Superficial skin cancers up to ~8mm depth • Ideal for curved surfaces (e.g., nose, ears)	• Effective for small, localised tumours • Short treatment times • Good for elderly patients[1 2]	• Limited penetration • Not suitable for deep tumours • Multiple treatments required	• Best for patients unsuitable for surgery • Excellent for complex surface geometries • Consider long-term cosmetic outcomes[1 2]
Electron Beam Therapy	• Larger and more infiltrating skin tumours • Definitive and post-surgical adjuvant treatment	• Can treat deeper tumours • 3D dosimetry planning • Versatile for various tumour sizes[3]	• Larger field margins • Limited to relatively flat surfaces • Potential for higher OAR toxicity	• Ideal for larger tumours or post-surgical treatment • Best when anatomical geometry not complex • Consider fractionation schedule[3]
VMAT (Volumetric Modulated Arc Therapy)	• Complex, large volume skin cancers • Extensive cases of wide-field cancerisation	• Highly conformal dose distribution • Suitable for complex anatomical surfaces • Can treat very large regions with multiple levels of dose[4]	• Complex planning and treatment process • Risk of low dose bath to normal tissue and OARs • Daily treatments over weeks	• For advanced or extensive cases • When treatment precision is crucial • Consider treatment duration and complexity[4]
Rhenium-SCT	• Early-stage BCC and SCC, including recurrences • Lesions <8 cm² surface area / 3mm deep	• Single session treatment • Ideal for complex surfaces • Avoids OARs	• Expensive • Patient batching required • Special licensing • Shallow lesions	• Perfect for patients benefiting from single fraction • Excellent for those unsuitable for surgery or fractionated RT

Reference: 1. https://www.targetingcancer.com.au/radiation-therapy/superficial-radiation-therapy-sxrt/ 2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6415702/
3. https://www.oncolink.org/cancer-treatment/radiation/types-of-radiation-therapy/electron-beam-radiation-therapy 4. https://www1.racgp.org.au/ajgp/2023/august/role-of-volumetric-modulated-arc-therapy-in-skin-f

Skin reactions / typical healing timeline

- **Acute reaction grade correlates with:**
- Depth[1-3] : resolution of reaction = 32 days (mean depth 1.1 mm)[2];
- Surface area[1-3] : resolution of reaction = 65 days (mean area 5cm^2)[3]
- Anatomic Zone[3] : face heals quicker than lower limbs[3]
- Age[3]

; 1. Tietze JK et al. Clin Nucl Med 2023;48:869–76.; 2. Castellucci P et al. Eur J Nucl Med Mol Imaging 2021;48:1511–21 3. Cipriani C et al. Int J Nucl Med 2017;114–22. Images Courtesy of Sid Baxi

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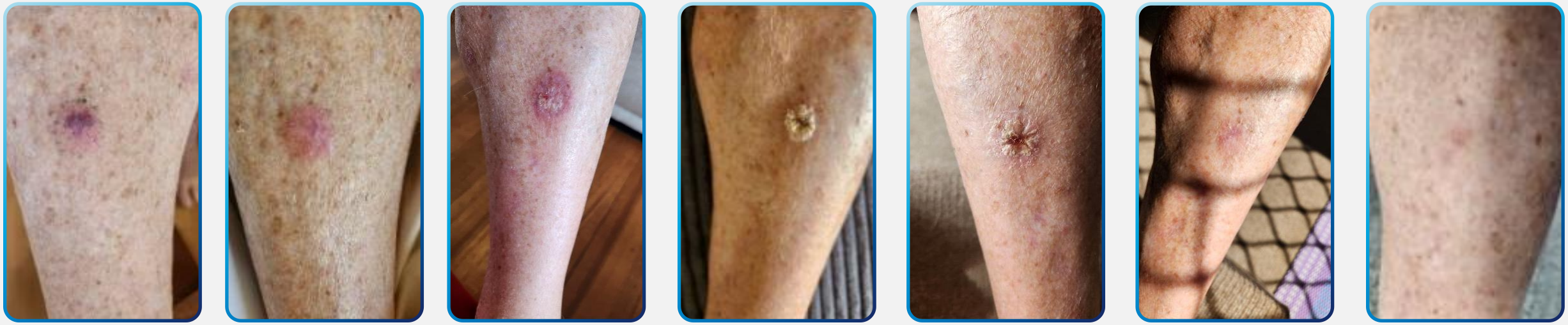

1. Tietze JK et al. Clin Nucl Med 2023;48:869–76.; 2. Castellucci P et al. Eur J Nucl Med Mol Imaging 2021;48:1511–21 3. Cipriani C et al. Int J Nucl Med 2017;114–22. Images Courtesy of Sid Baxi

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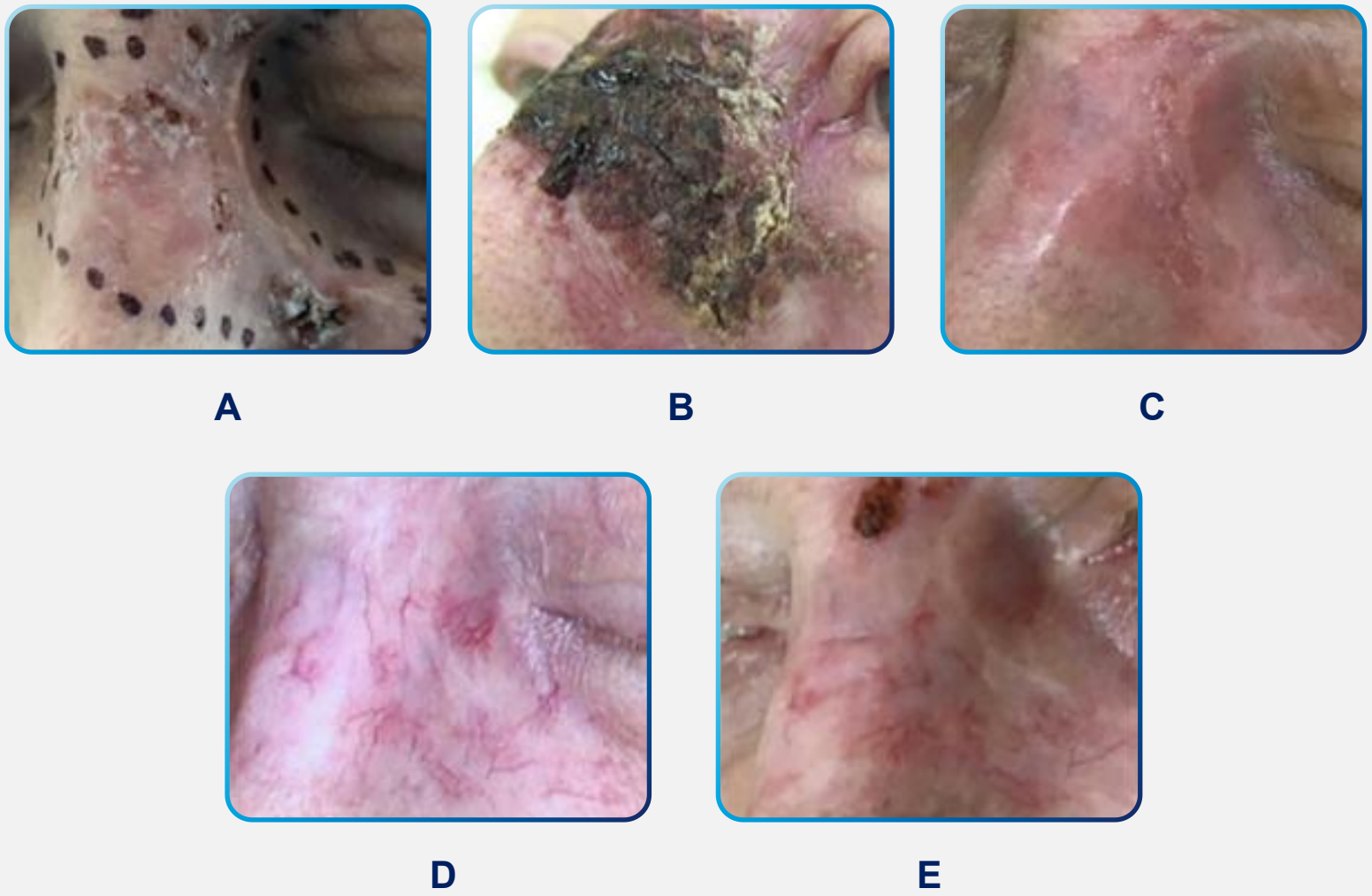
Late toxicities: Telangiectasia & Relapse

- 86yo F, relapse after surgery of morphoeic BCC, involving nose, left cheek, and partial left eyelid.
- Lesion area, 10 cm2 ; thickness, 0.6 mm; administered dose, 430 MBq of 188Re resin; mean absorbed dose, 54 Gy; treatment time, 61 min.
- (A) Before treatment: visible scar from previous surgery.
- (B) At 30 d after 188Re-ERT (CTCAE grade 3)
- (C) At 60 d after 188Re-ERT
- (D) At 120 days after 188Re-ERT: complete resolution of wound, with multiple telangiectasia and depigmentation.
- (E) At 180 days after 188Re-ERT: evidence of small relapse, subsequently treated with microinvasive surgery. Patient died of unrelated causes 2 y after 188Re-ERT

Castellucci et al 2025



Images taken from Castellucci et al, Efficacy and Safety of Epidermal Radionuclide Therapy with 188Re Resin in Patients with Nonmelanoma Skin Cancers: Long-Term Data from a Single Center, J Nucl Med 2025; 00:1–6.

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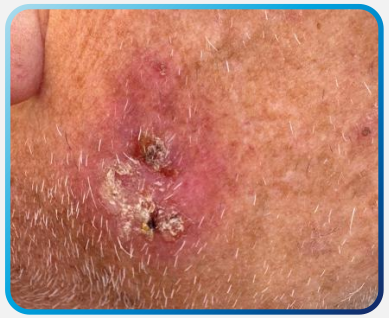
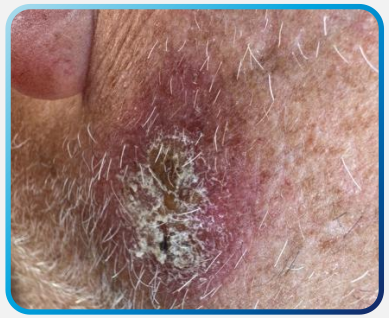
Late Toxicities:
Hypopigmentation

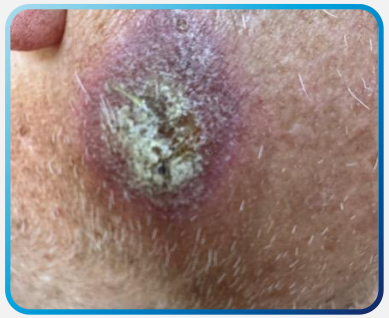
The lesion was treated with 882 MBq of Re-188 (75.06 MBq per cm2) which was left in situ for 72 minutes resulting in an absorbed dose of 50 Gy.



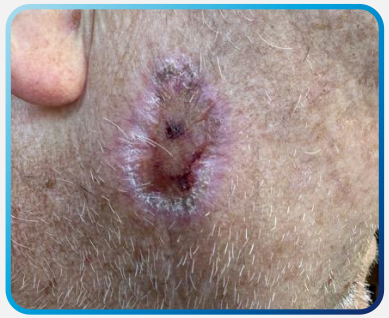
Week 0



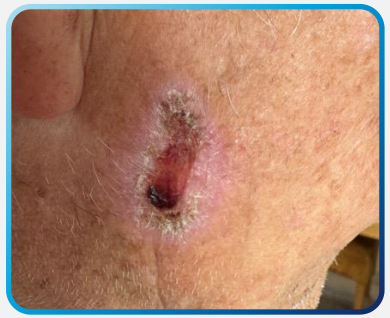
1 week



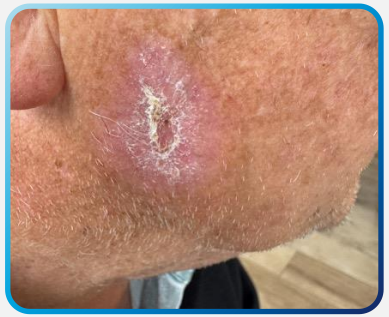
2 weeks



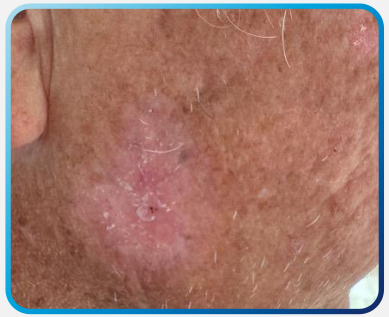
3 weeks



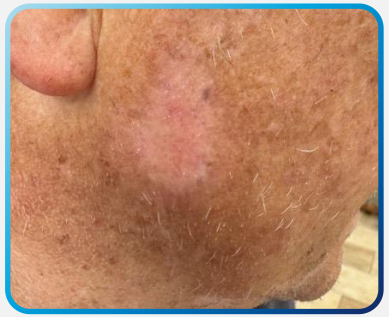
4 weeks



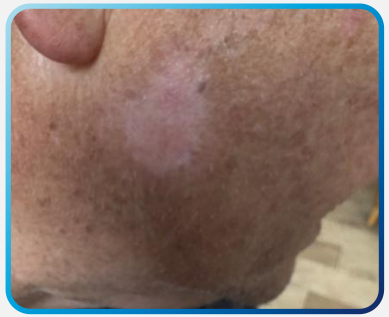
5 weeks



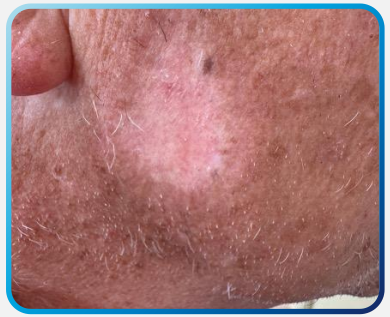
6 weeks



7 weeks



8 weeks



9 weeks

Case courtesy of: The London Clinic

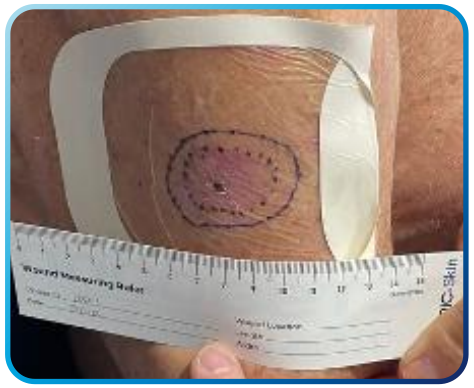
ONCOBETA®

Duration of Adverse Events

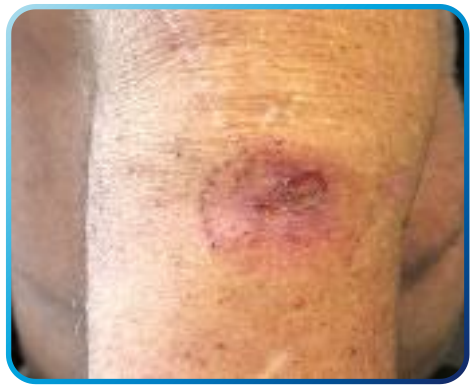
	Duration of Event						
AE description	Number of events	Known duration	Mean (SD)	Min-Max	Ongoing	<180 days	>=180 days
Dermatitis	24	19	98 (83.2)	10 - 359	5	24	0
Skin hypopigmentation	15	2	131 (72.8)	79 - 182	13	8	7
Pruritus	13	10	60 (42.3)	31 - 169	3	13	0
Scab	12	9	54 (30.2)	28 - 122	3	12	0
Skin ulcer	12	5	99 (98.2)	8 - 253	6	8	4
Radiation skin injury	11	6	90 (51.2)	19 - 169	5	11	0
Pain	10	7	51 (57.2)	9 - 169	3	10	0
Erythema	8	7	91 (137.7)	5 - 400	1	8	0
Thermal burn	5	1	33 (-)	33 - 33	4	5	0

EPIC Clinical Cases

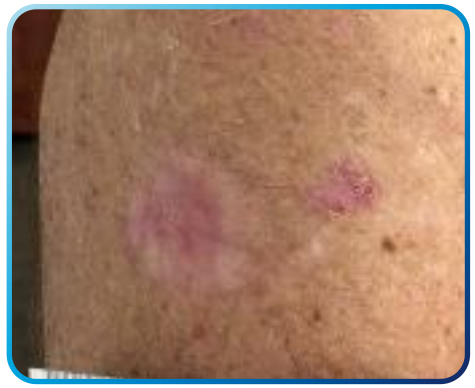
001, dermatitis, telangiectasia



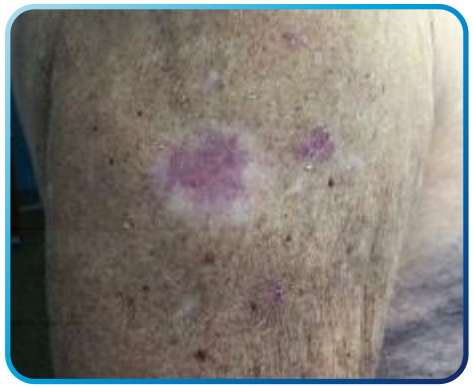
Baseline



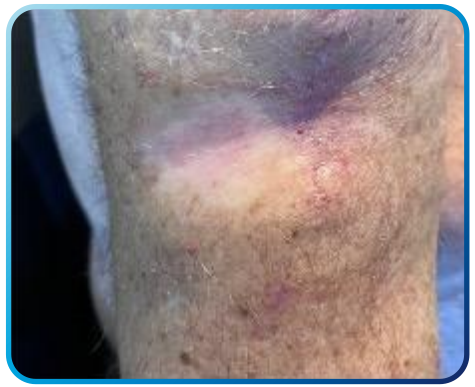
2 weeks



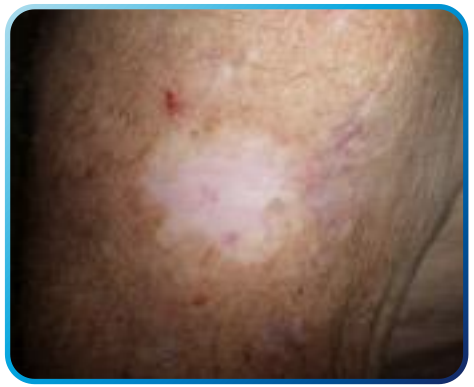
3 months



6 months

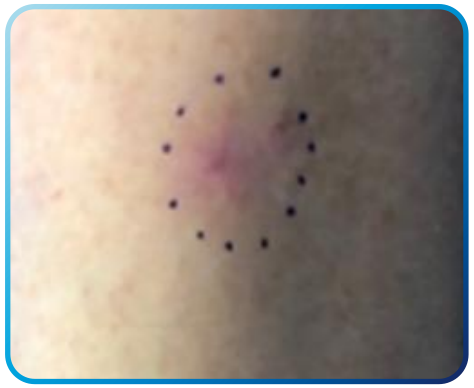


12 months

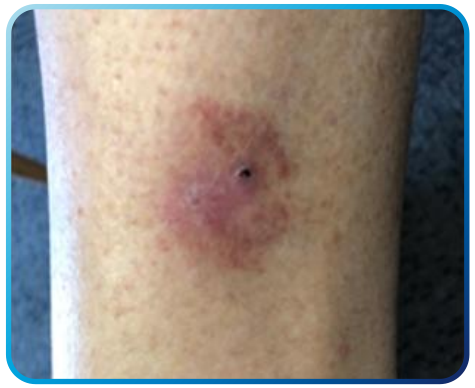


24 months

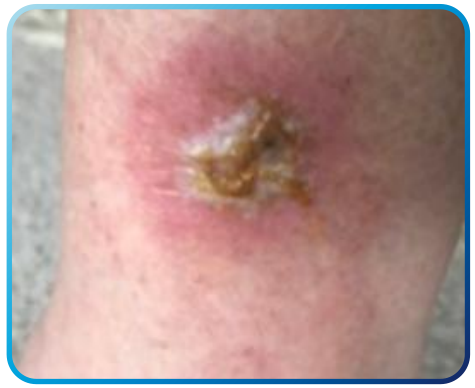
Serious Adverse Effects: EPIC Clinical Cases



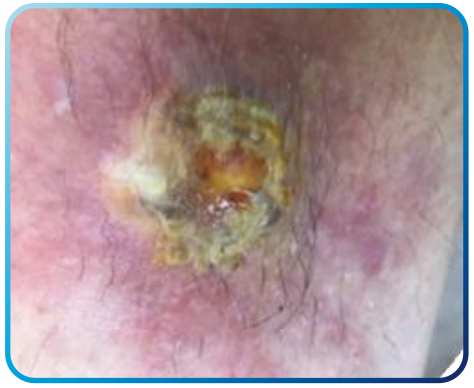
Month 0



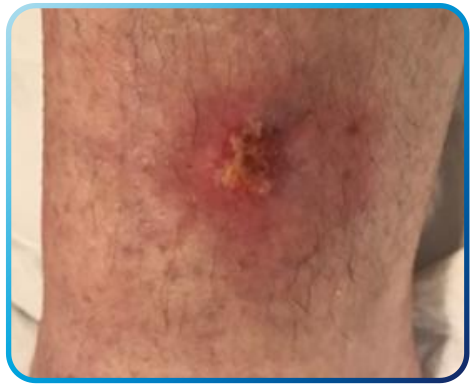
Month 1



Month 3



Month 4+

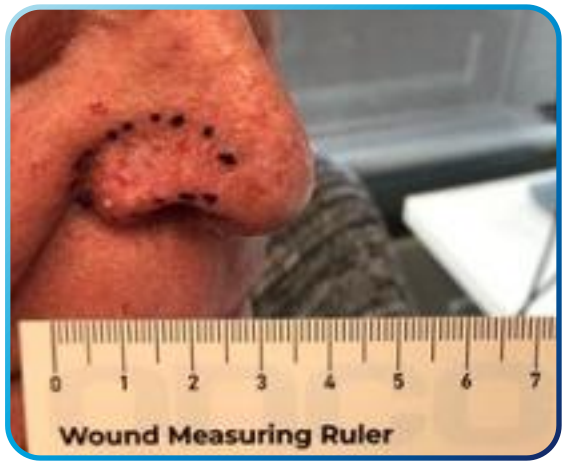


Month 12

ONCOBETA®

Early Skin Reactions: EPIC Patient Cases

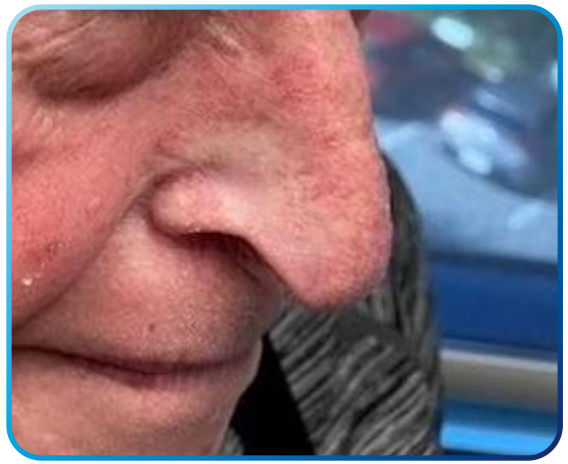
016_Moderate dermatitis



Baseline

2 weeks

3 months



12 months