Clinical Paper Summary

Efficacy, Safety and Patient Experiences of Rhenium-SCT® for Non-Melanoma Skin Cancer: 12 month outcomes from the EPIC-Skin Study

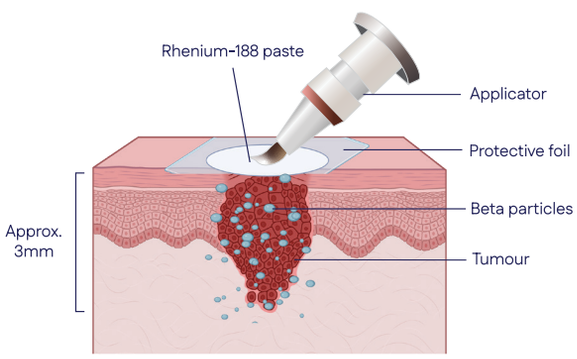
Cardaci G, et al. Advances in Radiation Oncology June 2025

Rhenium-SCT (Skin Cancer Therapy) is a single-session, non-invasive, radioisotope therapy for the treatment of shallow non-melanoma skin cancers (NMSC), specifically, basal cell carcinomas (BCC) and squamous cell carcinomas (SCC). Applied as a paste, Rhenium-SCT conforms to complex tissue surfaces allowing for precise, effective treatment, whilst ensuring tissue conservation.

The EPIC-Skin study represents the largest global prospective, post-market analysis, evaluating Rhenium-SCT for the treatment of NMSC. This 12-month interim analysis provides critical efficacy, safety, toxicity, cosmesis, and patient-reported outcome data.

The findings have been published in ASTRO's prestigious Advances in Radiation Oncology journal and include the first outcomes from Australian patients, with contributions from multiple local clinical sites.

Key Findings & Insights



Rhenium-SCT single-session 50 Gy treatment

Demographics

185 patients
(Age: Median 71.5 years (range: 27-95 years))

BCC and/or SCC; 1-8cm^2; ≤ 3mm deep.
1-lesion: 131 patients; 2-lesions: 36 patients; 3-lesions: 17 patients

140 tumours with 12-month follow-up

Fitzpatrick Type: **I** (23.3%); **II** (57.4%); **III** (17.6%), **IV** (1.1%), (0%), **VI** (0.6%).

12-Month Outcomes

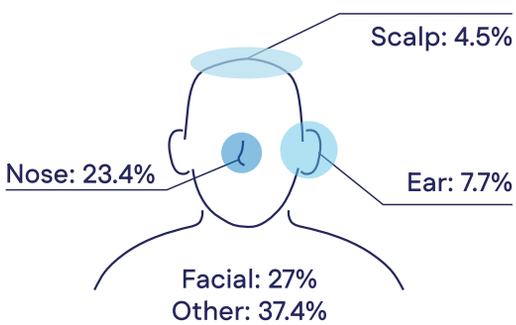
Efficacy:
97.3% overall response rate; 94.1% complete response rate

Cosmesis:
8.1 patient score, 7.7 clinician score, visual analogue scale (VAS)

QoL:
+9.23 improvement in Skin Cancer Index (SCI) score

Toxicity:
Grade 2 toxicity: 6.9%; No Grade 3 or 4 toxicities at 12-months

Lesion Locations



The EPIC-Skin study's 12-month interim 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 (QoL).

- **Efficacy:** The overall response rate was 97.3%, with a complete response rate of 94.1% (BCC: 93.9%, SCC: 94.2%).
  A complete response rate of 100% was reported for the Australian cohort.
- **QoL**: All average scores showed an increase in QoL from baseline.
- **Cosmesis:** Patients and clinicians reported favourable cosmesis outcomes.
- **Patient Comfort:** 100% reported no pain or discomfort during the session.

Average Improvement

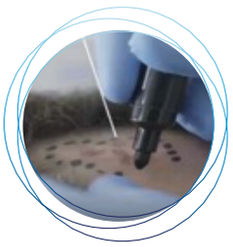
Emotion Subscale : **9.23 points**

Social Subscale : **7.41 points**

Appearance Subscale : **8.89 points**

Study Design

- Prospective, multicenter, single-arm, open-label, phase IV study conducted at 7 sites worldwide: Australia (3 sites), South Africa (1 site), and Europe (Germany, Austria, and U.K., 1 site each).
- Eligible patients were consented and enrolled with up to 3 punch biopsy-proven BCC and/or SCC lesions (≤ 3mm deep; ≤ 8cm2 area) for treatment. Lesions were treated in a single session with Rhenium-SCT at a dose of 50Gy targeted to the deepest point of the lesion.
- The primary objective is the assessment of Rhenium-SCT efficacy in the treatment of BCC / SCC lesions using modified RECIST criteria to standardise response rates.
- Patients enrolled in the study for regular follow-up time points out to 24-months post treatment.
- Secondary measurements were toxicity using CTCAE grading, cosmesis, treatment comfort and quality of life.



Patient preparation

Demarcation of lesion by skin specialist prior to treatment application.

Administration

The Rhenium-188 paste is applied in a thin layer onto an adhesive film affixed to the lesion for a predetermined period of time based on lesion depth and activity applied (20-180 minutes).

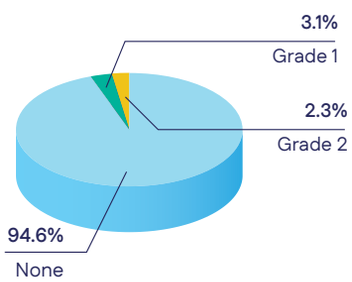
Treatment completion

After treatment time elapses, the film is removed, and the patient can return to regular activities immediately.

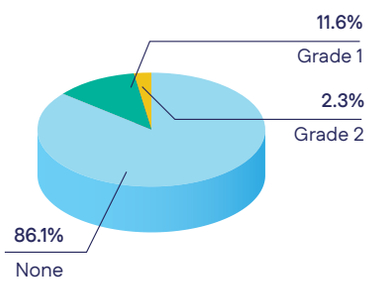
12-month toxicities

The adverse events observed were graded according to CTCAE criteria and in line with those reported for conventional radiotherapy. Most adverse events were mild and resolved quickly.

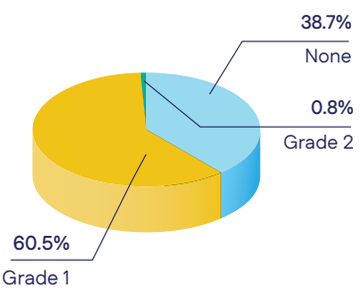
Ulceration



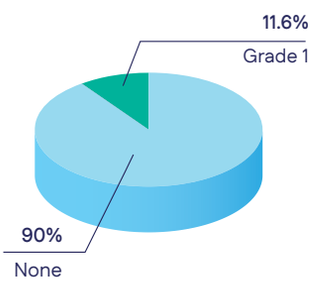
Induration



Hypopigmentation



Telangiectasia



Conclusion and Further Considerations

Rhenium-SCT is an effective non-invasive treatment option for NMSC in patients who are unsuitable for, or decline, surgery.

Cosmesis and Toxicity: Cosmesis scores were rated consistently high by both patients and clinicians, with a favourable toxicity profile that aligns with that of conventional fractionated radiation therapy outcomes.

Efficacy and safety: This analysis is part of a comprehensive protocol with follow-up extending to 24 months. Collectively, data from this study and others indicates that Rhenium-SCT is a durably effective and safe treatment for indicated NMSC lesions, particularly in patients with comorbidities, and those located in anatomic regions where there are concerns for the cosmetic or functional impacts of traditional surgical interventions.

Broad Utility: Rhenium-SCT was effective and well tolerated across all anatomical sites, which included scalp, nose, lips, ears, neck, trunk and limbs.

Learn more about patient suitability or find your nearest Rhenium-SCT treatment location

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241 Adeleide Street, Brisbane, QLD 4000.

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. J Dermatol Treat 2022;33:969–75. 4. Cipriani C et al. Int J Nucl Med 2017;114–22. 5. Carrozzo AM et al. Eur J Dermatol 2013;23:183–88. 6. Therasse P et al. J Natl Cancer Inst. 2000;92:205–216. 7. Rhee JS et al. Laryngoscope. 2007;117:399–405.

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