

History A 68-year-old white woman, was diagnosed with squamous cell carcinoma of the nasal cavity (nose, palate, maxillary sinus) in 11/95. Her medical history is significant for cervical cancer; she had undergone radiotherapy with cobalt (1963) and a complete response had been obtained. After the diagnosis of squamous cell carcinoma of the nasal cavity (nose, palate, maxillary sinus) approximately 30 years later, she underwent rhinotomy with radiotherapy (11/95, 7000 cGy). A complete response was obtained. She relapsed 9 months later and underwent extensive surgery (8/96, upper lip excision, rhinectomy, and bilateral maxillary sinus surgery; 2/97, left partial maxillectomy). However, a biopsy (4/24/97) demonstrated the presence of moderately to well differentiated squamous cell carcinoma. On 6/4/97, approximately 6 months after the original diagnosis, the patient was screened for study enrollment.

Baseline MTT The MTT (volume 3.23 cm³) was nasopharyngeal, located near the lower left orbit. The MTT had been previously radiated and recurred. The investigator's primary treatment goal was prevention of invasion of a vital structure and/or blood vessel. The patient selected a primary treatment goal of wound care.

Blinded Period The patient received 6 CDDP/epi gel treatments to the MTT over 43 days. The patient had a complete MTT response and benefited from treatment. The tumor response was first observed on Day 22, had a duration of 168 days, and was ongoing at last observation. The investigator's treatment goal, prevention of invasion of vital structure and/or blood vessel was achieved for 189 days. The patient's treatment goal, wound care, was assessed as unchanged. The physician's secondary treatment goal, prevention of a subcutaneous tumor from breaking through the skin, was also achieved for 189 days and attainment was ongoing at last observation. The patient discontinued the blinded period on Day 189.

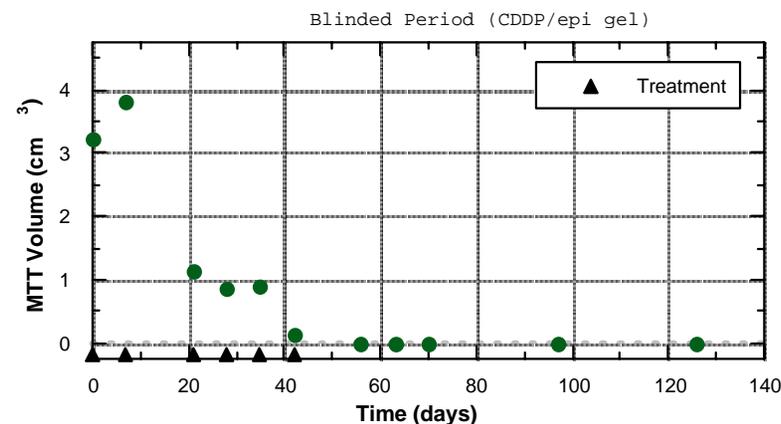
Extended Follow-Up Phase The patient did not enter this study phase.

Local Cytotoxic Effects The MTT showed no evidence of necrosis, ulceration, or eschar prior to treatment. After CDDP/epi gel treatment, necrosis and eschar peaked at "severe" from Days 29 to 43, after which there was no evidence of either condition from Day 71 to Day 189, the last assessment.

Serious Adverse Events The patient experienced no serious, treatment-related adverse events.

Other Significant Adverse Events There was 1 severe, treatment-related

TREATMENT GROUP		CDDP/epi gel
	1° Tx GOAL	BLINDED PERIOD OUTCOME
Investigator	Prevent invasion of vital structures	MET
Patient	Wound care	SAME
	TUMOR RESPONSE	PATIENT BENEFIT
During the Blinded Period		CR Yes
Any Time During the Study		CR Yes



Patient No. 5301 • Gender: Female • Age: 68 • Tumor Location: Nasopharyngeal • Study No. 414-94-2 • Stratum 1 • Investigator No. 0612

adverse event. This event was considered a local reaction at the treatment site: on Day 2, the patient experienced left eye swelling, which resolved on Day 3.

Other Disease/Intercurrent Illness The patient had a history of hypertension, cervical cancer, and gastrostomy tube placement.