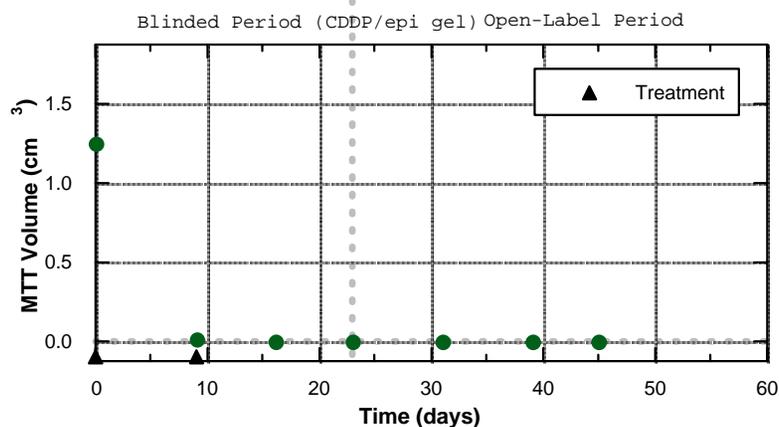


History A 61-year-old white man, was diagnosed with squamous cell carcinoma of the larynx in 1993. He underwent radiotherapy (4/7/93 to 5/26/93, 7000 cGy in 35 fractions). He relapsed several years later and underwent hemilaryngectomy and tracheotomy (10/9/96). Two years later, tracheotomy (10/30/98) and total laryngectomy and left modified neck dissection (11/5/98) were also performed. This was followed by radiotherapy (2/16/99 to 4/9/99, 11700 cGy in 115 fractions). However, 8 months later a biopsy (12/2/99) demonstrated the presence of moderately differentiated squamous cell carcinoma. On 12/7/99, 6 years after the original diagnosis, the patient was screened for study enrollment. Findings included 4 subdermal nodules in the submental area.

Baseline MTT The MTT (volume 1.25 cm³) was cervical, located under the chin (submental). The tumor had been previously radiated. The investigator’s primary treatment goal was prevention of a subcutaneous tumor from breaking through the skin. The patient’s primary treatment goal was pain control.

Blinded Period The patient received 2 CDDP/epi gel treatments to the MTT over 10 days. He had a complete MTT response and achieved benefit from CDDP/epi gel treatment. The tumor response was first observed on Day 10, lasted 37 days (continuing in extended follow-up), and was still responding at last observation. Although the investigator's primary treatment goal, prevention of a tumor from breaking through the skin, did not fail in the blinded period, the patient did not remain in the blinded period long enough for the goal to be evaluated for the 28 days required to classify it as "met". The patient’s treatment goal, pain control, was achieved. The score improved from "4" at baseline to alternating scores of "1" and "2" following treatment with CDDP/epi gel. The attainment of the patient's goal lasted 37 days (including extension into extended follow-up) and was ongoing at last observation. The patient’s prescribed narcotic pain control regimen remained unchanged throughout the study. The investigator’s secondary treatment goals of pain control, physical appearance, and wound care were achieved for 37 days and achievement was ongoing at last observation. The patient’s secondary treatment goals of physical appearance and wound care were achieved for 36 days and 37 days (continuing), respectively. Four other tumors were treated. Three were first treated at Day 10 and had complete responses. The fourth was a new tumor treated once on Day 17, and this tumor was assessed as having stable disease. The patient discontinued the blinded period on Day 24.

TREATMENT GROUP		CDDP/epi gel
	1° Tx GOAL	BLINDED PERIOD OUTCOME
Investigator	Prevent tumor from breaking through the skin	NE
Patient	Pain control	MET
	TUMOR RESPONSE	PATIENT BENEFIT
During the Blinded Period	CR	Yes
Any Time During the Study	CR	Yes



Extended Follow-Up Phase The patient continued to have a complete MTT response and to achieve benefit from CDDP/epi gel treatment. The patient's primary treatment goal, pain control, continued to be achieved, showing improvement from a baseline score of "4" to a score of "2" in the extended follow-up phase. Three other cervical tumors that were initially treated in the blinded period continued to have complete response. Two new tumors were initially treated with CDDP/epi gel on Day 32. These tumors were subsequently classified as progressive disease and not evaluable for response, respectively (the two tumors merged into one). The patient discontinued the study on Day 46.

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" on Day 32, with a preceding assessment of "moderate". Both necrosis and eschar were then assessed as "none" on Days 40 to 46, the last assessment.

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

Other Significant Adverse Events There were no severe, treatment-related adverse events.

Other Disease/Intercurrent Illness The patient had a history of coronary artery angioplasty with stent placement, thyrotoxicosis requiring radioactive iodine treatment (1993), anemia, percutaneous endoscopic gastrostomy tube placement, and depression.