

**Pilot Study of Impedance-controlled Microcurrent Therapy for  
Managing Radiation-induced Fibrosis in Head-and-Neck Cancer Patients**

Arlene J. Lennox, Ph.D.,\*+ Jeffrey P. Shafer, M.D.,+ Madeline  
Hatcher, R.N.,+ Janice Beil, R.N.,+ Sandra J. Funder, R.N.#

\*Fermi National Accelerator Laboratory, Batavia, Illinois

+Provena Midwest Institute for Neutron Therapy at Fermilab, Batavia, Illinois

#S. J. Funder & Associates, Crown Point, Indiana

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Address for reprints: Fermilab Neutron Therapy Facility,  
P.O. Box 500, Mail Stop 301,  
Batavia, Illinois 60510, USA

Corresponding Author: Arlene J. Lennox, Phone 630-840-3865,  
FAX 630-840-8766, email: [alennox@fnal.gov](mailto:alennox@fnal.gov)

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# Pilot Study of Impedance-controlled Microcurrent Therapy for Managing Radiation-Induced Fibrosis in Head-and-Neck Cancer Patients

## ABSTRACT

**Purpose:** To evaluate the effectiveness of impedance-controlled microcurrent therapy for managing treatment sequelae in head-and-neck cancer patients.

**Methods and Materials:** Between January 1998 and June 1999, twenty-six patients who were experiencing late effects of radiation therapy were treated *bid* with impedance-controlled microcurrent therapy for one week. Objective range-of-motion (ROM) measurements were made for cervical rotation, extension/flexion, and lateral flexion before therapy, at the end of each treatment day, and monthly for three months. In addition each patient's subjective complaints were tabulated before treatment and re-evaluated at the last follow-up. No further physical therapy or electrical stimulation was permitted during the follow-up period.

**Results:** At the end of the course of microcurrent therapy 92% of the twenty-six patients exhibited improved cervical rotation, 85% had improved cervical extension/flexion and 81% had improved cervical lateral flexion. Twenty-two patients returned for the three-month follow-up. Of these 91% maintained cervical rotation range of motion greater than their pre-therapy measurements. Eighty-two percent maintained improved cervical extension/flexion and 77% maintained improved lateral flexion. When the range-of-motion measurements were stratified by pretreatment severity (severe, moderate, mild, or asymptomatic) we observed that the degree of improvement was directly correlated with severity. That is, patients who had more severe initial symptoms experienced a higher percentage of improvement than those with milder symptoms. For these patients the cervical rotation ROM changed from a baseline of  $59 \pm 12$  degrees to  $83 \pm 14$  degrees at three months; flexion/extension improved from  $47 \pm 10$  to  $73 \pm 13$  degrees; and lateral flexion went from  $31 \pm 7$  to  $48 \pm 9$  degrees. Some patients also reported improvement in symptoms such as tongue mobility, facial asymmetry, xerostomia, cervical/facial muscle spasms, trismus, and soft-tissue tenderness. No adverse effects were observed.

**Conclusion:** Impedance-controlled microcurrent therapy shows promise for remediation of range-of-motion limitations arising as late effects of radiation therapy for head-and-neck cancer. Further studies are needed to validate these preliminary results and to optimize the microcurrent treatment protocol, particularly with respect to treatment schedules and combining microcurrent therapy with physical and/or drug therapy.

**Key Words:** Microcurrent Therapy, Neutrons, Radiation, Side effects, Head and Neck Cancer.

## **INTRODUCTION**

As aggressive therapy with combination surgery, chemotherapy and radiation therapy increases tumor control in head-and-neck neoplasms, post-treatment quality of life issues remain problematic (1). One area of concern is progressive fibrosis of soft tissue in the head, neck and supraclavicular area. For many patients, palpation of the treated areas reveals hard, unyielding tissue that limits range of motion and/or leads to pain associated with movement.

The concept of investigating microcurrent therapy to treat radiation-induced fibrosis arose from observation of a salivary-gland patient who was receiving microcurrent therapy for the surgical scar at a family physician's office while receiving neutron therapy treatments at Fermilab. The patient experienced significantly milder erythema and mucositis than would historically be expected for radical radiation therapy in the neck area. This serendipitous observation led to a hypothesis that microcurrent therapy could be beneficial in managing effects of radiation therapy. A literature search revealed several case studies (2-4) from the 1980's suggesting that microcurrent therapy was effective for treating radiation therapy sequelae but these studies lacked adequate statistics and did not include follow-up information on long term effectiveness. The reports also lacked information on the specific treatment instruments and the precise treatment protocols used. This pilot study was designed to determine whether the suggested efficacy would in fact be observed in a series of patients treated using a well-specified protocol.

## **METHODS AND MATERIALS**

Twenty-six head-and neck cancer patients who had completed radiation therapy and were experiencing tissue discomfort or limitations caused by fibrosis participated in the study. Since this was a pilot study to determine the efficacy of a new use of a standard therapeutic technique it was important that all participants have quantifiable symptoms with no expectation of resolution without intervention. Hence, patients experiencing documented progressive fibrosis were targeted. Objective range-of-motion measurements were made by the staff and subjective complaints were solicited from the patients. The procedure and its possible lack of benefit were explained to each patient before he or she signed a document indicating informed consent. The protocol was approved by the Provena Saint Joseph Hospital Institutional Review Board.

### *Selection of study subjects*

Eligible patients had finished either photon or neutron therapy at least six months before entering the study and had no evidence of disease. They had mental alertness sufficient to understand, evaluate and consent to the protocol, which included availability for *bid* treatments daily for one week and the ability to return for scheduled follow-up visits. Exclusion criteria included use of a pacemaker, use of calcium-channel blocker drugs, pregnancy, and life expectancy less than six months. Individuals who were unable to abstain from physical therapy to the affected area, routine use of anti-inflammatory steroids, or NSAID's during the treatment and follow-up period were also excluded. Table 1 summarizes the baseline characteristics of the participants.

Table 1. Baseline characteristics of 26 patients in the pilot study. Age, dose and time to start of therapy are averages, including the standard deviation.

	Fast Neutrons	Photons	Neutrons & Photons
Sex			
Male	3	9	2
Female	5	4	3
Race			
White	8	13	3
Black	0	0	2
Age (years)	52 ± 15	56 ± 9.3	63 ± 15
Radiation dose (Gy)	20.8 ± 0.8	64 ± 8.3	20.3 ± 0.1 (n) 36 ± 25 (γ)
Months from radiation to start of therapy	67 ± 61	30 ± 27	42 ± 38

### *Choice of microcurrent technique and schedule*

The use of electrical stimulation for pain relief is well established in physical therapy centers. There are many commercial electrical stimulation devices, most of which are commonly referred to as TENS (transcutaneous electrical nerve stimulation) units. Typical TENS units emit electrical pulses with alternating positive and negative polarities in the 10 to 500 kilohertz range and currents in the milliampere range. Microcurrent units are often incorrectly referred to as TENS units, but microcurrent units deliver lower currents (microampere range) and lower frequencies (0.5 to several hundred hertz). In general, units using higher current and frequencies are more effective at blocking

acute pain, but the pain relief is not lasting. Microcurrent therapy using lower frequencies requires longer treatment times to achieve pain relief, but the relief can endure for many hours after the treatment has terminated (5). Because the patients targeted for this study were experiencing chronic rather than acute symptoms, a microcurrent device was selected.

The costs of microcurrent devices range from several hundred to thousands of dollars. Some fraction of the cost is related to packaging, but most of it is associated with the degree of sophistication of the electronic circuits. It is well known that the body's impedance changes when electrical current passes through it. The more sophisticated devices contain circuitry that monitors impedance and adjusts the output current to compensate for changes. These devices also deliver fast-rise time pulses that can affect voltage-sensitive sodium and calcium ion channels (6). The Electro-Myopulse and Electro-Acuscope instruments chosen for this study deliver impedance-controlled, fast-rise time pulses. Their retail price is about \$8500 each. Electrotherapy treatments are reimbursable under established billing codes. Typical charges to a patient are \$40 - \$50 per 15-minute treatment. However, patients in this study were not charged for the therapy.

Physical therapists use microcurrent therapy in a variety of ways, often in combination with massage, heat and physical manipulation. Treatment schedules are not standardized, but are driven by insurance payment schedules and the patients' personal schedules. The treatment schedule for this study was established after informal discussions with a few physical therapists who had extensive experience using the Electro-Myopulse and Electro-Acuscope instruments for treating a variety of physical complaints. All agreed that noticeable improvement could be obtained most quickly if the patient were treated *bid* for three days. All agreed that lasting improvement tended to require several treatments per month for about six months and that some conditions could resolve completely if this long-term treatment schedule were followed, particularly if therapy started soon after the injury or symptom occurred. Given the advanced fibrosis of many of the study patients, it was decided to administer microcurrent treatments *bid* for five days and simply observe whether this therapy had any effect on severely fibrotic tissue. Any observed improvements were not expected to be lasting because no follow-up treatments at more spread-out intervals were scheduled. Until measurable evidence of the treatment's effectiveness was observed it did not seem reasonable to commit resources to a long-term treatment schedule.

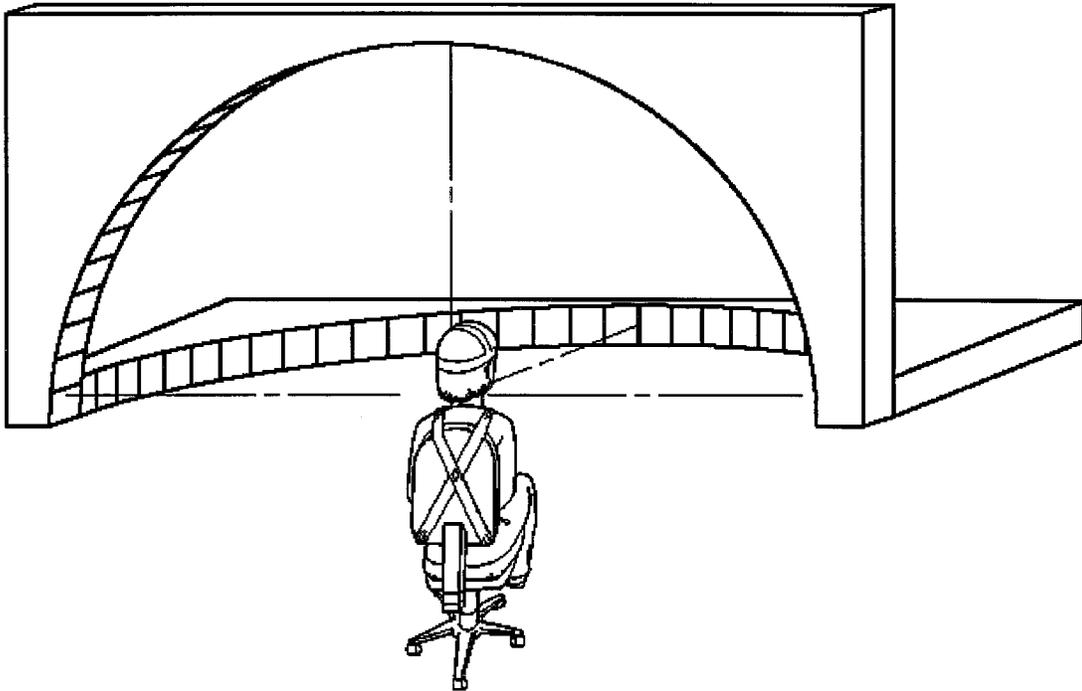


Fig.1. Patient positioned at vertex of two mutually perpendicular protractors used to measure cervical range of motion.

### *Objective Measurement Techniques*

As shown in Fig. 1, cervical rotation, extension/flexion and lateral flexion were measured using two large protractors mounted in perpendicular planes. An elastic band with Velcro attachments was secured to the patient's head to permit the placement of a small laser that pointed to degree markings on circular scales used to measure range of motion in degrees. This laser was positioned relative to the point(s) about which the patient's head pivots during rotation, extension/flexion and lateral flexion. Stationary lasers were used to position the patient so that the movable laser was on a line that intersected the vertex of the large protractors. Figures 2 through 4 illustrate the setup for each angular measurement. Day to day patient positioning accuracy was  $\pm 0.25$  cm, which is small compared to the protractors' 112 cm radius. This choice of scale minimized the effect of day-to-day errors in positioning the patient's center of rotation at the vertex of the scale.

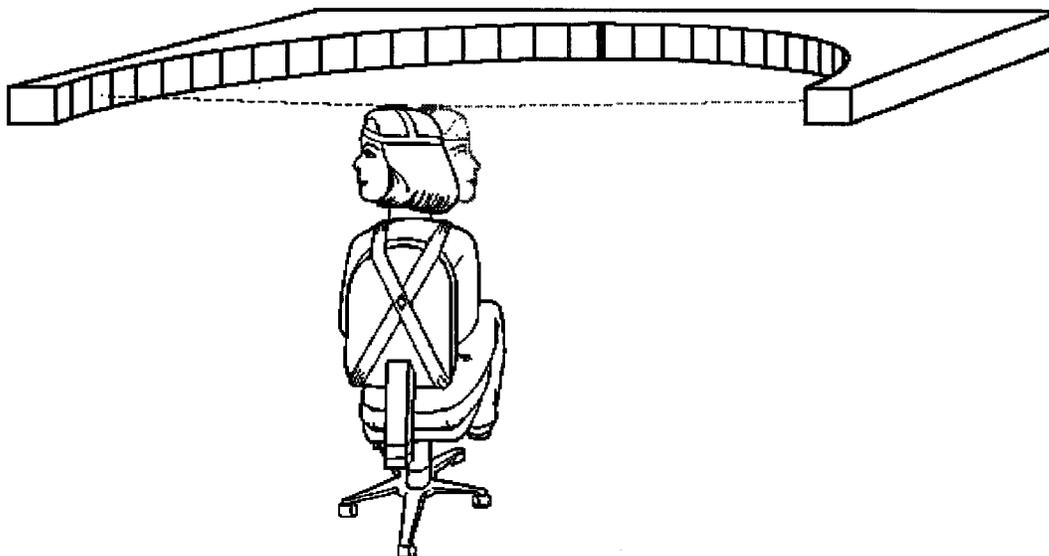


Fig.2. A laser affixed to the patient's head measures left-right cervical rotation.

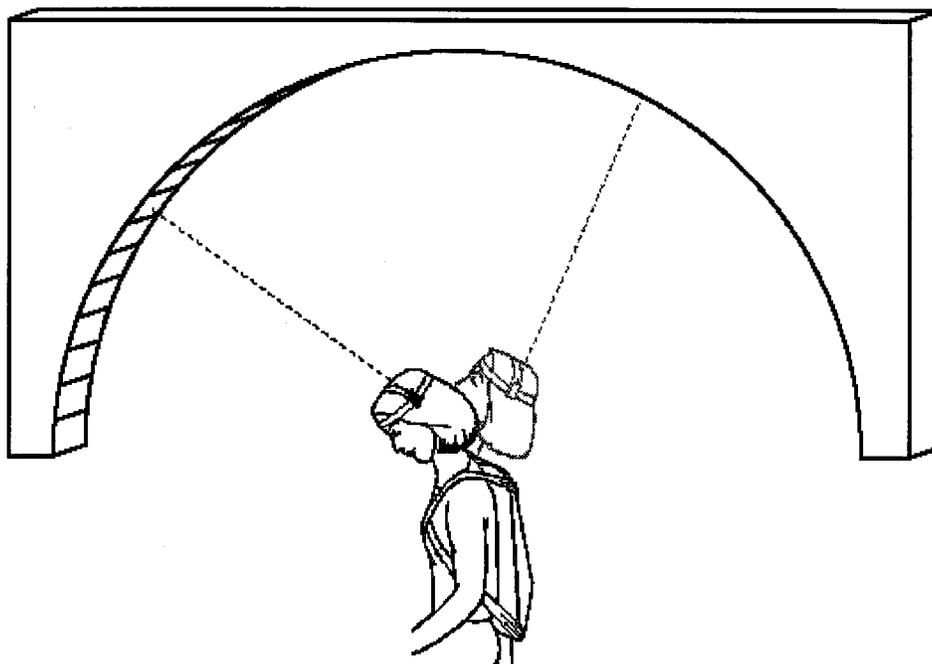


Fig.3. Cervical extension/flexion is measured using a laser affixed to the side of the head.

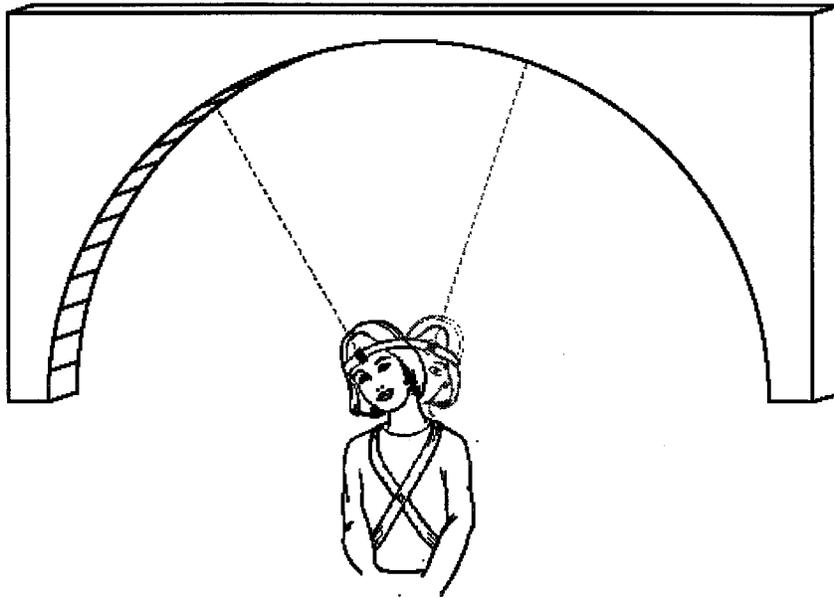


Fig.4. Cervical lateral flexion is measured using a laser affixed to the forehead.

For each patient the pretreatment data were used to classify each range of motion as asymptomatic, mildly, moderately or severely limiting. If a patient's range was within 90% of the optimal range for a healthy young person he or she was classified as asymptomatic for that measurement. Ranges between 70 and 90 % of optimum were designated mildly limiting, while 50-70% were moderately limiting. Ranges less than 50% of optimum were considered severely limiting. By assigning a value of 0 to asymptomatic, 1 to mild, 2 to moderate, and 3 to severe, for each of three range-of-motion measurements it is possible to assign a number between 0 and 9 to each patient, with 0 corresponding to no practical limitations and 9 corresponding to significant limitations in all three measurements. Using these designations, the average pretreatment severity for the 13 patients treated with photons only was  $5.6 \pm 2.4$ . For 8 patients receiving only fast neutrons it was  $4.0 \pm 2.7$  and for 5 patients who were treated with neutrons following photon therapy it was  $2.4 \pm 1.5$ . The three patients who had a severity of 9 had received electrons in addition to photons. Table 2 lists all 26 cases in order of severity along with information about treatment site, tumor pathology, stage, type of radiation, and dose.

Table 2. Patient characteristics listed in order of greatest to least severe radiation-induced range-of-motion limitations before impedance-controlled microcurrent therapy. \* indicates *bid* treatment.

Severity	Radiation Treatment Site	Dose (Gy)	Radiation	Pathology	Stage	Other Therapy
9	Left thyroid Bilateral neck Supraclav nodes	66 66	$\gamma + e$ $\gamma + e$	Medullary Carcinoma	T4N1bM0/Stage 3	Surgery
9	Oropharynx Bilateral neck Supraclav nodes	63 50.4	$\gamma + e$ $\gamma + e$	Squamous Cell	T1N2bM0	Surgery
9	Left tonsil Bilateral neck Supraclav nodes	74.4* 50.4	$\gamma + e$	Squamous Cell	T3N2bM0	Surgery Chemo
8	Nasopharynx Supraclav nodes	22 14	n	Squamous Cell	T2N2aM0/Stage 4	
7	Maxillary sinus	20.4	n	Adenoid Cystic	T4NxM0	Surgery
6	Supraglottic larynx Supraclav nodes	75* 51	$\gamma + e$	Squamous Cell	T2N2bM0/Stage 4	Chemo
6	Nasopharynx Bilateral Neck Supraclav nodes	70 50	$\gamma$	Squamous Cell	T2N2bM0/Stage 4	Chemo Surgery
6	Right Neck Right supraclav nodes	58.7 45	$\gamma$	Colloidal Carcinoma	Metastatic from breast	Chemo
6	Nasopharynx & neck Periaortic nodes	45	$\gamma$	Malignant lymphoma	Recurrent/Stage 4	Chemo Surgery
6	Larynx Bilateral neck	60.4 50.4	$\gamma + e$	Squamous Cell	T4N0M0	Surgery
5	Right submaxillary	20.4	n	Adenoid cystic	Stage 1	Surgery
5	Left Parotid	22	n	Adenoid cystic	T2N0M0/Stage 1	Surgery
4	Left Parotid	59.2	$\gamma$	Melanoma	Metastatic from cheek	Surgery
4	Left Parotid	30 20.4	$\gamma$ n	Benign mixed	Recurrent	Surgery
3	Right nasal ala Bilateral neck Supraclav nodes	59.5 50.4	$\gamma + e$ $\gamma$	Squamous Cell	Recurrent	Surgery
3	Tongue Left neck	60 62.8	$\gamma$ $\gamma + e$	Keratinizing Squamous Cell	T2N1Mx	Surgery
3	Base of tongue	20	n	Adenoid cystic	T1N0M0	Surgery
3	Right Submandibular Right supraclav nodes	7.2 20.4 14.0	$\gamma$ n n	Adenoid cystic	T1N0Mx/Stage 1	Surgery
3	Left parotid Supraclav nodes	19 20.1 14	$\gamma$ n n	Mucoepidermoid	T1N2bM0	Surgery
3	Right tonsil	74.4*	$\gamma + e$	Squamous Cell	T3N1M0	Surgery
2	Left parotid Left Supraclav nodes	20.8 14.3	n	Acinic Cell	Recurrent	Surgery
2	Right tonsil Bilateral neck Suprclav nodes	61 64 46	$\gamma + e$ $\gamma + e$ $\gamma$	Squamous Cell	T1N2bM0/Stage 4	Surgery
2	Left parotid	60 20.4	$\gamma$ n	Adenoid Cystic	Recurrent	Surgery
1	Base of tongue	20.4	n	Mucoepidermoid	T3NxM0	
1	Base of tongue	20.4	n	Adenoid Cystic	T4N1M0	
0	Left parotid	65 20.4	$\gamma$ n	Adenoid Cystic	Recurrent	Surgery

### *Treatment Protocol*

Alternating microampere current at frequencies ranging from 0.5 to 100 Hz was directed through the fibrotic area using one stationary and one moveable electrode. The current source was an Electro-Myopulse 75F instrument in mode 1 operated at the auto setting. Current was set as high as the patient could tolerate, typically at the maximum instrument setting of 600 microamps. Good electrical conductivity was obtained using CEL-0071 Conductive Electrolyte.

During the first twenty minutes of each treatment session the fixed electrode was taped to the shoulder blade closest to the affected tissue. This electrode was a flat, square conducting plate of area  $5 \times 5 \text{ cm}^2$ . The movable electrode was a cylindrical roller, 7.6 cm in diameter and 7.6 cm long. The roller was repeatedly moved slowly from a region of healthy tissue just outside the fibrotic area into and across the region of scar tissue. For each patient all of the scar tissue related to radiation therapy was treated in this manner. Thus, if a supraclavicular radiation therapy field had been given in addition to the primary treatment fields, the supraclavicular area was included in the microcurrent treatment area.

During the next ten minutes the current source was the Electro-Acuscope 80L in mode 1 with settings of 10 Hz and 600 microamps. The single fixed electrode was replaced by two rectangular plates, each having an area of  $10 \times 27.2 \text{ cm}^2$ , and connected to the current source through a preamplifier. The patient held one hand on each plate while the therapist treated the fibrotic area with the roller in the manner described above. Figure 5 shows the treatment technique. The session ended with a one-minute treatment using CRM-XR46 After Treatment Cream instead of the CEL-0071 Conductive Gel.

Patients were treated twice per day, with a four to five hour interval between treatment sessions. A total of ten treatments was given over a period of five days. Subjective symptoms were recorded and range-of-motion measurements were made before the first treatment and at the end of each treatment day. Follow-up measurements and subjective assessments were made at one-month intervals for a total of three months. No additional microcurrent or physical therapy was permitted until the end of the three-month follow-up period.



Fig. 5. Electrotherapy treatment technique. Patients' hands rest on large metal plates while impedance-controlled microcurrent therapy is delivered using a metal roller.

## RESULTS

### *Objective Range-of-Motion Measurements*

Tables 3-5 show the average pretreatment, post-treatment and 3-month follow-up ranges for cervical rotation, extension/flexion, and lateral flexion measurements stratified by pretreatment severity and type of radiation given. For each type of motion the degree of improvement is directly proportional to the pretreatment severity. Despite our expectations that any improvement observed at the end of the treatment week would be lost at the three-month follow-up visit, most patients had

Table 3. Average cervical rotation  $\pm$  standard deviation, stratified by severity of limitation, before microcurrent treatment, at the end of treatment, and three months later with no additional treatment. Optimal range-of-motion for a healthy young person is 170 degrees. The first three columns show the type of radiation received by the 26 patients who started the study, followed by the 22 patients who returned for the 3-month follow-up. Nn indicates number of patients who had only neutrons, Np is the number who received only photons. Np+n is the number of patients who were treated with neutrons after photon therapy. The total number in each category is given by N.

Nn	Np	Np+n	Pre-treatment Rating	Pre-treatment Range (degrees)	Post-treatment Range (degrees)	% Change from pretreatment range	3-month Follow-up Range(degrees)	% Change from pretreatment range
1,0	3,3	-	Severe	59 $\pm$ 19 N = 4	97 $\pm$ 30 N = 4	64%	83 $\pm$ 14 N = 3	41%
2,2	6,5	2,1	Moderate	101 $\pm$ 10 N = 10	131 $\pm$ 15 N = 10	30%	119 $\pm$ 9 N = 8	18%
4,4	4,4	2,1	Mild	131 $\pm$ 8 N = 10	153 $\pm$ 16 N = 10	17%	140 $\pm$ 13 N = 9	7%
1,1	-	1,1	Asymptomatic	164 $\pm$ 1 N = 2	165 $\pm$ 9 N = 2	1%	154 $\pm$ 22 N = 2	-6%

Table 4. Average cervical extension/flexion  $\pm$  standard deviation, stratified by severity of limitation, before microcurrent treatment, at the end of treatment, and three months later with no additional treatment. Optimal range-of-motion for a healthy young person is 120 degrees. The first three columns show the type of radiation received by the 26 patients who started the study, followed by the 22 patients who returned for the 3-month follow-up. Nn indicates number of patients who had only neutrons, Np is the number who received only photons. Np+n is the number of patients who were treated with neutrons for a recurrence after photon therapy. The total number in each category is given by N.

Nn	Np	Np+n	Pre-treatment Rating	Pre-treatment Range (degrees)	Post-treatment Range (degrees)	% Change from pretreatment range	3-month Follow-up Range(degrees)	% Change from pretreatment range
-	3,3	-	Severe	47 $\pm$ 10 N = 3	70 $\pm$ 12 N = 3	49%	73 $\pm$ 13 N = 3	55%
2,1	3,3	-	Moderate	73 $\pm$ 9 N = 5	106 $\pm$ 9 N = 5	45%	107 $\pm$ 20 N = 4	47%
4,4	5,4	2,1	Mild	96 $\pm$ 7 N = 11	114 $\pm$ 15 N = 11	19%	110 $\pm$ 9 N = 9	15%
2,2	2,2	3,2	Asymptomatic	117 $\pm$ 6 N = 7	126 $\pm$ 15 N = 7	8%	117 $\pm$ 14 N = 6	0%

Table 5. Average cervical lateral flexion  $\pm$  standard deviation, stratified by severity of limitation, before microcurrent treatment, at the end of treatment, and three months later with no additional treatment. Optimal range-of-motion for a healthy young person is 90 degrees. The first three columns show the type of radiation received by the 26 patients who started the study, followed by the 22 patients who returned for the 3-month follow-up. Nn indicates number of patients who had only neutrons, Np is the number who received only photons. Np+n is the number of patients who were treated with neutrons after photon therapy. The total number in each category is given by N.

Nn	Np	Np+n	Pre-treatment Rating	Pre-treatment Range (degrees)	Post-treatment Range (degrees)	% Change from pretreatment range	3-month Follow-up Range(degrees)	% Change from pretreatment range
1,0	5,4	-	Severe	31 $\pm$ 7 N = 6	51 $\pm$ 20 N = 6	65%	48 $\pm$ 9 N = 4	55%
2,2	4,4	1,1	Moderate	53 $\pm$ 5 N = 7	76 $\pm$ 10 N = 7	43%	79 $\pm$ 16 N = 7	49%
3,3	4,4	1,1	Mild	69 $\pm$ 5 N = 8	82 $\pm$ 17 N = 8	19%	75 $\pm$ 12 N = 8	9%
2,2	-	3,1	Asymptomatic	92 $\pm$ 22 N = 5	102 $\pm$ 25 N = 5	11%	103 $\pm$ 30 N = 3	12%

better measurements at three months than before treatment. At the three-month follow-up the average severity score for the photon-only patients was  $3.9 \pm 2.3$ ; for the neutron-only patients it was  $1.2 \pm 1.2$ ; and for the neutron-following-photon patients it was  $2.0 \pm 1.0$ . No adverse side effects were observed. All of the patients completed the treatments.

### *Cervical Rotation*

Range of right/left cervical rotation was compared to the nominal value of 170 degrees, which is considered normal for a healthy young individual (7). Ninety-two percent (24/26) of the patients exhibited improved cervical rotation at the end of microcurrent therapy. Of the twenty-two who returned for the three-month follow-up visit, three experienced continued improvement, while seventeen lost some of their range-of-motion, though their average mobility was somewhat better than it had been before microcurrent therapy. One patient in the mildly limited category experienced no improvement and one asymptomatic patient had measurements in the mildly limited category at. Figure 6 illustrates improvements for the three patients who started with severe limitations and completed all three follow-up visits on schedule.

## Cervical Rotation

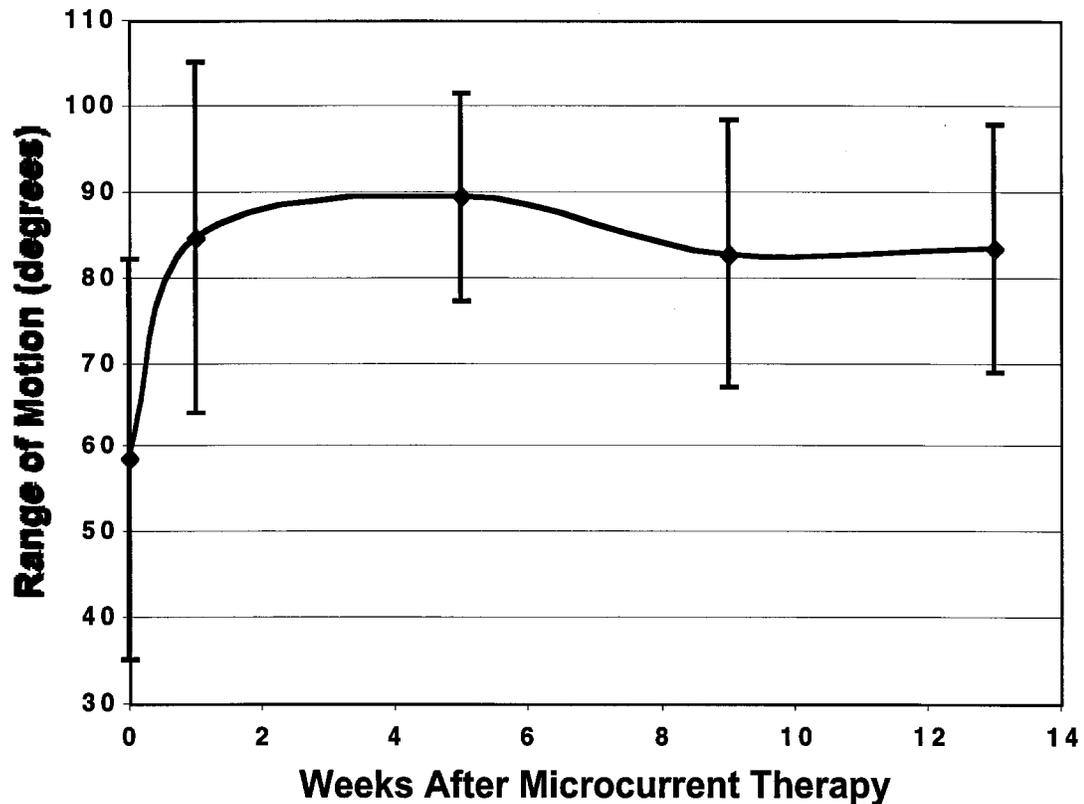


Fig.6. Range of cervical rotation for three patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.the three-month follow-up

### *Cervical Extension/Flexion*

Range of cervical extension/flexion was compared to the nominal value of 120 degrees, which is considered normal for a healthy young individual (7). Eighty-five percent (22/26) of the patients exhibited improved extension/flexion at the end of microcurrent therapy. Of the twenty-two who returned for the three-month follow-up visit, eight maintained or improved their end-of-treatment status. Ten of the twenty-two patients lost some range of motion but their mobility was still better than it had been before microcurrent therapy. The four patients who experienced no long-term improvement were already functioning within 80-90% of normal range. Figure 7 illustrates improvements for the three patients initially classified as most severely limited in extension/flexion.

## Cervical Extension-Flexion

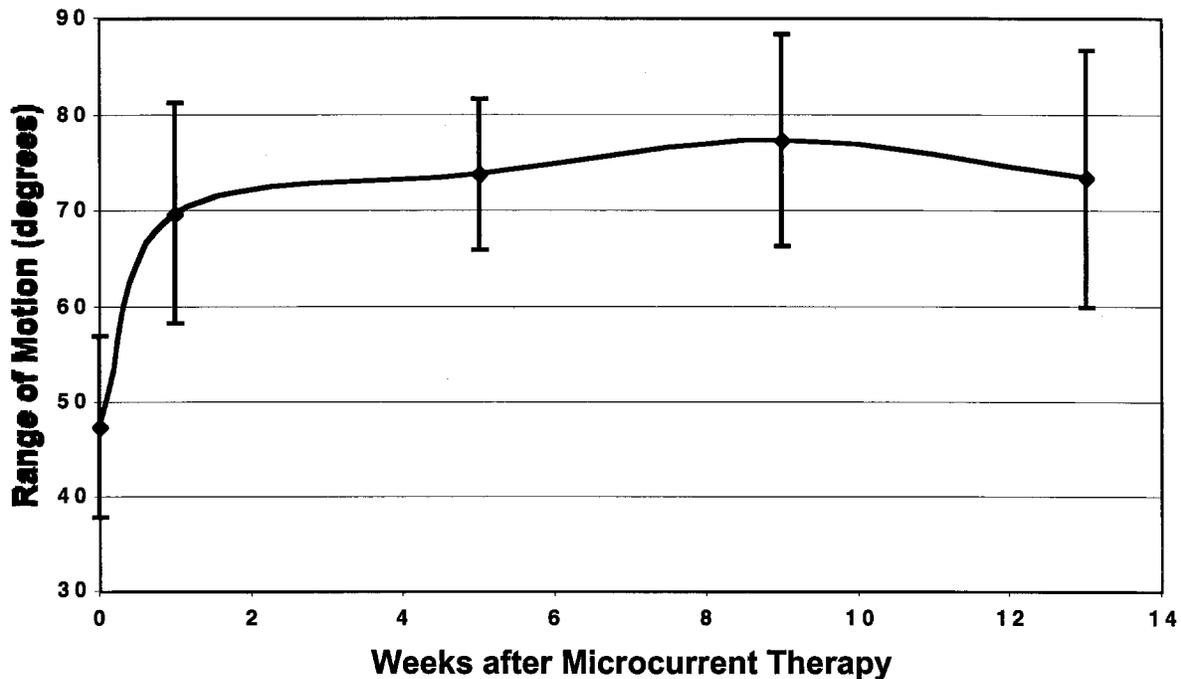


Fig.7. Range of cervical extension/flexion for three patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.

### *Cervical Lateral Flexion*

Range of cervical right/left lateral flexion was compared to the nominal value of 90 degrees, which is considered normal for a healthy young individual (7). Eighty-one percent (21/26) of the patients exhibited improved range of lateral flexion at the end of microcurrent therapy. Of the twenty-two patients who returned for the three-month follow-up visit eight had continued to improve their range of motion without any additional therapy. Nine patients experienced a decrease compared to their ranges at the end of therapy but their mobility was still better than their measurements before therapy. Five patients experienced no long-term improvement. Figure 8 illustrates the improvements for the four patients who started with severe limitations and completed all three follow-up visits on schedule.

## Cervical Lateral Flexion

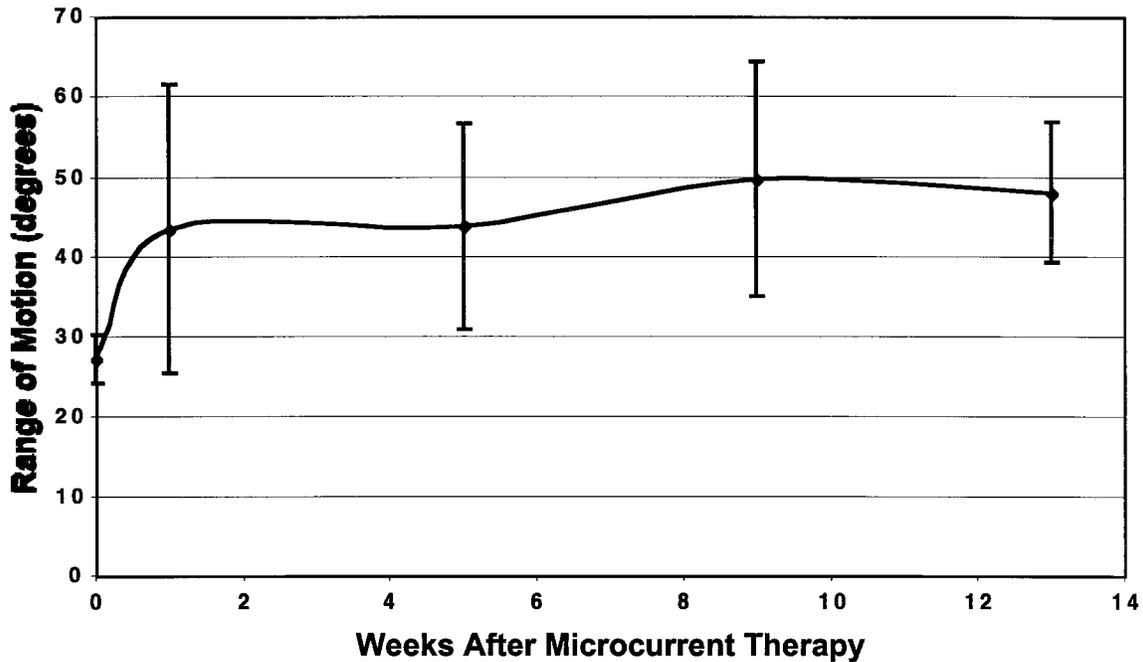


Fig.8. Range of cervical lateral flexion for four patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.

### *Oral Opening*

Oral opening was measured using a THERABITE scale as shown in Figure 9. The measurement was made for all 26 patients, even if trismus was not a complaint. Eighty-one percent (21/26) of the patients exhibited improved oral opening after impedance-controlled microcurrent therapy. It should be noted that only 16 of the 26 patients stated that trismus was a problem. Four of the sixteen showed no improvement during the course of the study. One had no improvement at the end of the treatment week but had gained 3 mm in oral opening at the end of three months. For the seven patients who maintained improvement in oral opening the average increase was  $4.6 \pm 2.2$  mm three months after the end of microcurrent therapy.



Fig.9. Therabite scale is used to measure oral opening.

### *Subjective Observations*

Before starting microcurrent therapy patients were asked to fill out questionnaires regarding any symptoms they might be experiencing as a result of radiation therapy. During the treatment week they turned in daily written observations of any change in symptoms. Subjective observations were also recorded at the time of each follow-up visit. Table 6 lists the number of patients reporting various symptoms along with the percentage of patients who said that the therapy had provided noticeable relief of the symptoms.

Table 6. List of subjective complaints. Denominator indicates number of patients reporting a symptom. Numerator is the number who reported an improvement in the symptom after impedance-controlled microcurrent therapy.

Symptom	Percentage reporting improvement.
Tongue immobility	3/8 = 37%
Impaired speech	3/6 = 50%
Stiffness discomfort	24/26 = 92%
Facial asymmetry	6/7 = 86%
Soft tissue edema	11/17 = 65%
Trismus	10/16 = 62%
Dry mouth	15/20 = 75%
Difficulty swallowing	4/10 = 40%
Cervical/facial spasms	10/12 = 83%
Fibrosis	12/20 = 60%
Inability to purse lips	5/5 = 100%
Difficulty breathing	3/3 = 100%
Tenderness	10/15 = 67%
Pain	9/13 = 69%
Numbness	6/8 = 75%

## DISCUSSION

In head-and-neck cancer patients, radiation-induced fibrosis can lead to many different complaints, depending on the size and placement of treatment fields, the total dose, and whether the patient also had surgery. Limitations in neck range-of-motion are common and are quantifiable. Because this study was looking for objectively measured changes associated with microcurrent therapy, the protocol was designed to achieve improvement in range of motion. Measurements were made on all patients in the study regardless of whether the patient considered range-of-motion limitations to be a problem. In fact, most of the patients in the mildly and moderately limited groups had learned to compensate for the limitations and were surprised when measurements showed how much capability they had lost. As could be expected, the patients who were most severely limited received the greatest degree of benefit.

Patients also received relief from a number of complaints that were not directly targeted in the treatment protocol, the most significant of which were trismus and xerostomia. When the study was

completed some case studies were done using a different microcurrent protocol along with physical therapy for the relief of trismus. The results were encouraging, and suggest that further studies on the role of microcurrent therapy in treating trismus are warranted. Our xerostomia data are currently being analyzed and will be published separately.

Perhaps the most encouraging outcome of this study is the fact that many of the benefits observed at the end of the treatment week were sustained. In some cases there was continued improvement during the three month follow-up period suggesting that the treatment had initiated tissue repair. The beneficial effects of electric current for soft tissue repair have been described by Polk (8). Exact mechanisms for tissue repair are not completely understood, but one theory indicates that microcurrent stimulation influences the migration of extracellular calcium ions to penetrate the cell membrane. The higher level of intracellular calcium encourages increased synthesis of adenosine triphosphate (ATP). Protein synthesis is encouraged by affecting mechanisms that control DNA, thus encouraging cellular repair and replication (9). It is also believed that microvoltage may affect the cascade of reactions involved in a variety of inflammatory responses. Our data support the view that microcurrent therapy can initiate long-term benefit for patients suffering from fibrosis.

At the onset of the study it was expected that any improvement in symptoms would have been transient because no follow-up treatment was offered. The data indicate that this assumption was incorrect. Though the group size is small, data shown in Figures 6-8 suggest that improvement continued during the first and second month after microcurrent therapy. The treatment schedule needs to be optimized, perhaps delivering fewer treatments the first week followed by weekly and then monthly treatments to determine the maximum achievable benefit. For patients who are just beginning radiation therapy, it is possible that an optimum treatment schedule would include administering impedance-controlled microcurrent treatment concurrent with radiation therapy.

In designing the study we deliberately excluded the use of any agent or activity that could contribute to relief of symptoms associated with fibrosis. Since this study has shown benefits attributable to microcurrent therapy alone, it is appropriate to consider combining this therapy with other physical therapy techniques or medications such as pentoxifylline/Vitamin E (10). Seven of the patients who benefited from microcurrent therapy indicated that they had received no benefit from previous physical therapy, but it is possible that the combination might be more effective than either single modality.

## **CONCLUSIONS**

Impedance-controlled microcurrent therapy shows promise in improving range-of-motion and alleviating other symptoms associated with radiation-induced fibrosis. Studies should be done to validate our preliminary results and to optimize the treatment schedule to achieve longer lasting benefit. Protocols combining microcurrent therapy with physical therapy and/or promising medications could prove to be very beneficial in improving quality-of-life for radiation therapy patients.

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