Reprinted from

INTERNATIONAL JOURNAL OF

Radiation Oncology

BIOLOGY•PHYSICS

VOLUME 54, NUMBER 1 SEPTEMBER 1, 2002

ELSEVIER

Int. J. Radiation Oncology Biol. Phys., Vol. 54, No. 1, pp. 23–34, 2002

0360-3016/02/$–see front matter

PII S0360-3016(02)02898-5

CLINICAL INVESTIGATION **Head and Neck**

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.,† AND SANDRA J. FUNDER, R.N.‡

*Fermi National Accelerator Laboratory, Batavia, IL; †Provena Midwest Institute for Neutron Therapy at Fermilab, Batavia, IL; ‡S. J. Funder & Associates, Crown Point, IN

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, 26 patients who were experiencing late effects of radiotherapy were treated b.i.d. with impedance-controlled microcurrent therapy for 1 week. Objective range-of-motion measurements were made for cervical rotation, extension/flexion, and lateral flexion before therapy, at the end of each treatment day, and monthly for 3 months. In addition, each patient's subjective complaints were tabulated before treatment and reevaluated at the last follow-up visit. No additional 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 26 patients exhibited improved cervical rotation, 85% had improved cervical extension/flexion, and 81% had improved cervical lateral flexion. Twenty-two patients returned for the 3-month follow-up visit. Of these, 91% had maintained a cervical rotation range of motion greater than their pretherapy 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), the degree of improvement directly correlated with the severity. Thus, patients who had more severe initial symptoms experienced a higher percentage of improvement than did those with milder symptoms. For these patients, the cervical rotation range of motion changed from a baseline of 59° ± 12° to 83° ± 14° at 3 months; flexion/extension improved from 47° ± 10° to 73° ± 13°; and lateral flexion went from 31° ± 7° to 48° ± 9°. Some patients also reported symptom improvement for tongue mobility, facial asymmetry, xerostomia, cervical/facial muscle spasms, trismus, and soft tissue tenderness. No adverse effects were observed.

Reprint requests to: Arlene J. Lennox, Ph.D., Fermilab Neutron Therapy Facility, P.O. Box 500, Mail Stop 301, Batavia, IL 60510. Tel: (630) 840-3865; Fax: (630) 840-8766; E-mail: alennox@fnal.gov

Supported in part by Provena Saint Joseph Hospital Foundation and the U.S. Department of Energy under Contract DE-AC02-76HO3000.

Acknowledgments—Tom Kroc and Gordon Holmblad assisted in assembling the circular arcs and lasers used for measuring range of motion. The Electro-Myopulse 75F and the Electro-Acuscope 80L instruments were loaned to us by Advanced Biomedical Technologies.

Received Sep 28, 2000, and in revised form Apr 11, 2002. Accepted for publication Apr 18, 2002.

Conclusion: Impedance-controlled microcurrent therapy shows promise for remediation of range-of-motion limitations arising as late effects of radiotherapy for head-and-neck cancer. Additional 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. © **2002 Elsevier Science Inc.**

Microcurrent therapy, Neutrons, Radiation, Side effects, Head-and-neck cancer.

INTRODUCTION

As aggressive therapy with combination surgery, chemotherapy, and radiotherapy (RT) increases tumor control in head-and-neck neoplasms, posttreatment 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 the 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 at Fermilab. The patient experienced significantly milder erythema and mucositis than would historically be expected for radical RT in the neck area. This serendipitous observation led to a hypothesis that microcurrent therapy could be beneficial in managing the effects of RT. A literature search revealed several case studies (2–4) from the 1980s suggesting that microcurrent therapy was effective for treating RT sequelae, but these studies lacked adequate statistics and did not include follow-up information on the long-term effectiveness. The reports also lacked information on the specific treatment instruments and precise treatment protocols used. This pilot study was designed to determine whether the suggested efficacy would 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 RT and were experiencing tissue discomfort or limitations caused by fibrosis participated in the study. Because 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. The staff made objective range-of-motion measurements, and subjective complaints were solicited from the patients. The procedure and its possible lack of benefit were explained to the patients before they signed a document indicating informed consent. The Provena Saint Joseph Hospital Institutional Review Board approved the protocol.

Selection of study subjects

Eligible patients had finished either photon or neutron therapy at least 6 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 the availability for b.i.d. treatments daily for 1 week and the ability to return for scheduled follow-up visits. Exclusion criteria included the use of a pacemaker, use of calcium-channel blocker drugs, pregnancy, and a life expectancy of <6 months. Individuals who were unable to abstain from physical therapy to the affected area, routine use of antiinflammatory steroids, or nonsteroidal antiinflammatory drugs during the treatment and follow-up period were also excluded. Table 1 summarizes the baseline characteristics of the participants.

Choice of microcurrent technique and schedule

The use of electrical stimulation for pain relief is well established in physical therapy centers. Many commercial electrical stimulation devices are available, most of which are commonly referred to as transcutaneous electrical nerve stimulation units. Typical units emit electrical pulses with alternating positive and negative polarities in the 10–500-kHz range and currents in the milliampere range. Microcurrent units are often incorrectly referred to as transcutaneous electrical nerve stimulation 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 (Biomedical Design Instruments, Burbank, CA) 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-min 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 b.i.d. for 3 days. All agreed that lasting improvement tended to require several treatments per month for about 6 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 b.i.d. for 5 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.

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 points 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 ±0.25 cm, which is small compared with 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.

For each patient, the pretreatment data were used to classify each range of motion as asymptomatic or mildly, moderately, or severely limiting. If a patient's range was within 90% of the optimal range for a healthy young person, that patient was classified as asymptomatic for that measurement. Ranges between 70% and 90% of optimum were designated mildly limiting, and those of 50–70% were moderately limiting. Ranges <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 the three range-of-motion measurements, it was 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 ± 2.4. For 8 patients receiving only fast neutrons, it was 4.0 ± 2.7, and for 5 patients who were treated with neutrons after photon therapy, it was 2.4 ± 1.5. The 3 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 the treatment site, tumor pathologic features, stage, type of radiation, and doses.

Table 1. Baseline characteristics of 26 patients in the pilot study

	Fast neutrons	Photons	Neutrons and photons
Gender (*n*)			
Male	3	9	2
Female	5	4	3
Race (*n*)			
White	8	13	3
Black	0	0	2
Age (y)	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)
Time from RT to start of therapy (mo)	67 ± 61	30 ± 27	42 ± 38

Data presented as the average ± standard deviation, unless otherwise noted.

Abbreviations: RT = radiotherapy; n = neutrons; γ = photons.

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. The current was set as high as the patient could tolerate, typically at the maximal instrument setting of 600 μA. Good electrical conductivity was obtained using CEL-0071 Conductive Electrolyte.

During the first 20 min 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 (area 5 × 5 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 the scar tissue related to RT was treated in this manner. Thus, if a supraclavicular RT field had been given in addition to the primary treatment fields, the supraclavicular area was included in the microcurrent treatment area.

During the next 10 min, the current source was the Electro-Acuscope 80L in mode 1 with settings of 10 Hz and 600 μA. The single fixed electrode was replaced by two rectangular plates, each having an area of 10 × 27.2 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

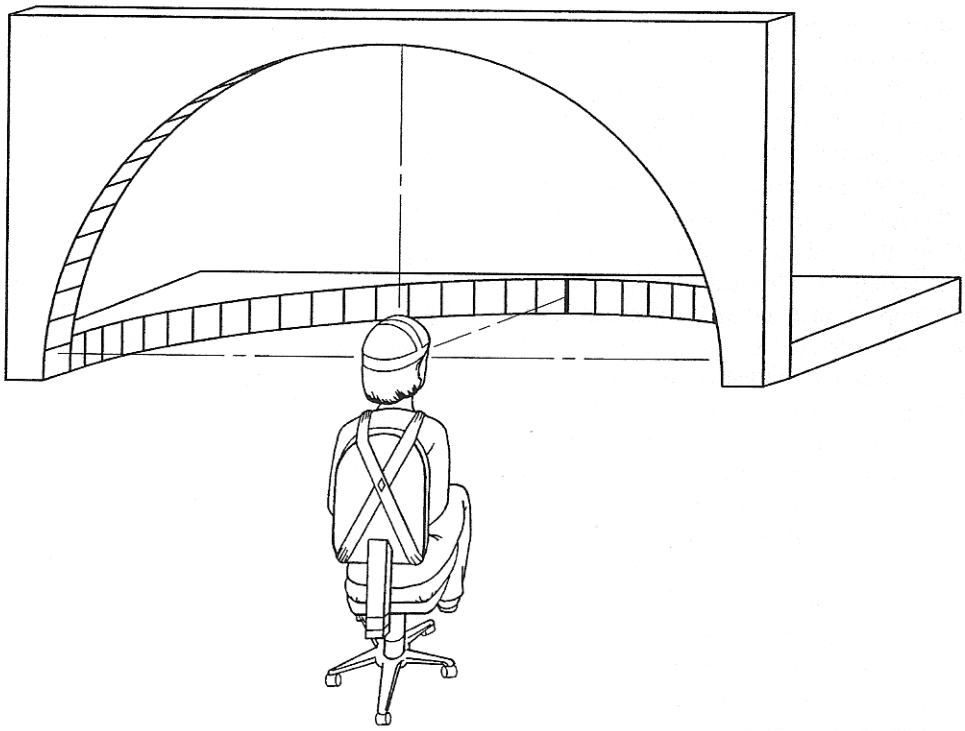

Fig. 1. Patient positioned at vertex of two mutually perpendicular protractors used to measure cervical range of motion.

area with the roller in the manner described above. Figure 5 shows the treatment technique. The session ended with a 1-min treatment using CRM-XR46 After Treatment Cream instead of the CEL-0071 Conductive Gel.

Patients were treated b.i.d., with a 4–5-h interval between treatment sessions. A total of 10 treatments was given during a 5-day period. Subjective symptoms were recorded and range-of-motion measurements made before the first treatment and at the end of each treatment day. Follow-up measurements and subjective assessments were made at 1-month intervals for a total of 3 months. No additional microcurrent or physical therapy was permitted until the end of the 3-month follow-up period.

RESULTS

Objective range-of-motion measurements

Tables 3 through 5 show the average pretreatment, post-treatment, and 3-month follow-up ranges for cervical rotation, extension/flexion, and lateral flexion measurements

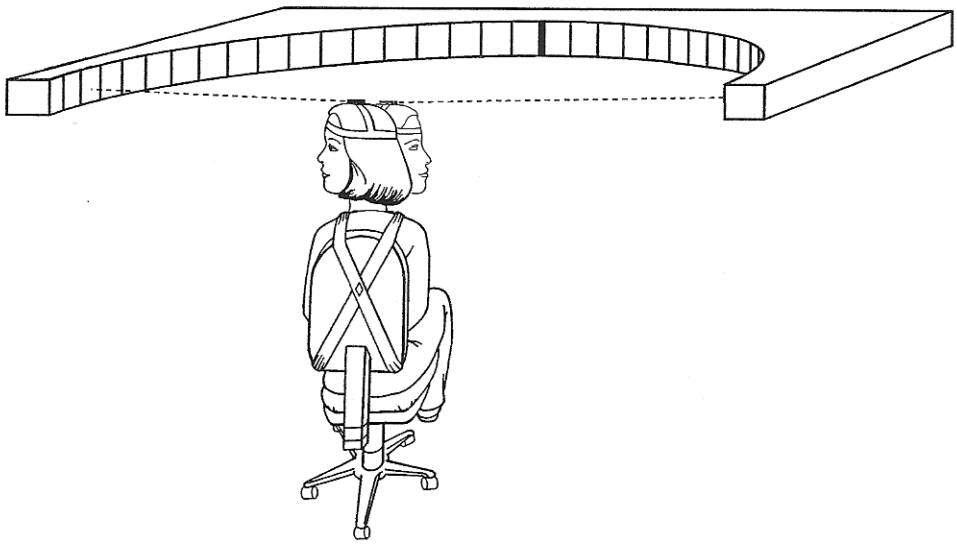

Fig. 2. Laser affixed to the patient's head measures left–right cervical rotation.

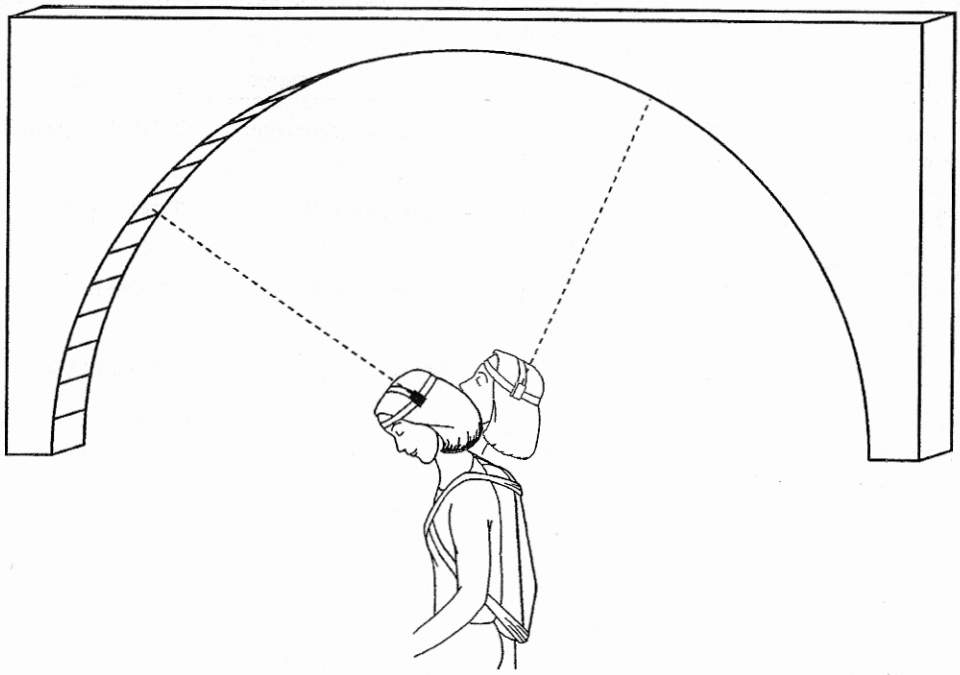

Fig. 3. Cervical extension/flexion measured using a laser affixed to the side of the head.

stratified by pretreatment severity and type of radiation given. For each type of motion, the degree of improvement was 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 3-month follow-up visit, most patients had better measurements at 3 months than they did before treatment. At the 3-month follow-up visit, the average severity score for the photon-only patients was 3.9 ± 2.3; for the neutron-only patients, it was 1.2 ± 1.2; and for the neutron-following-photon patients, it was 2.0 ± 1.0. No adverse side effects were observed. All the patients completed the treatments.

Cervical rotation

The range of right/left cervical rotation was compared with the nominal value of 170°, which is considered normal for a

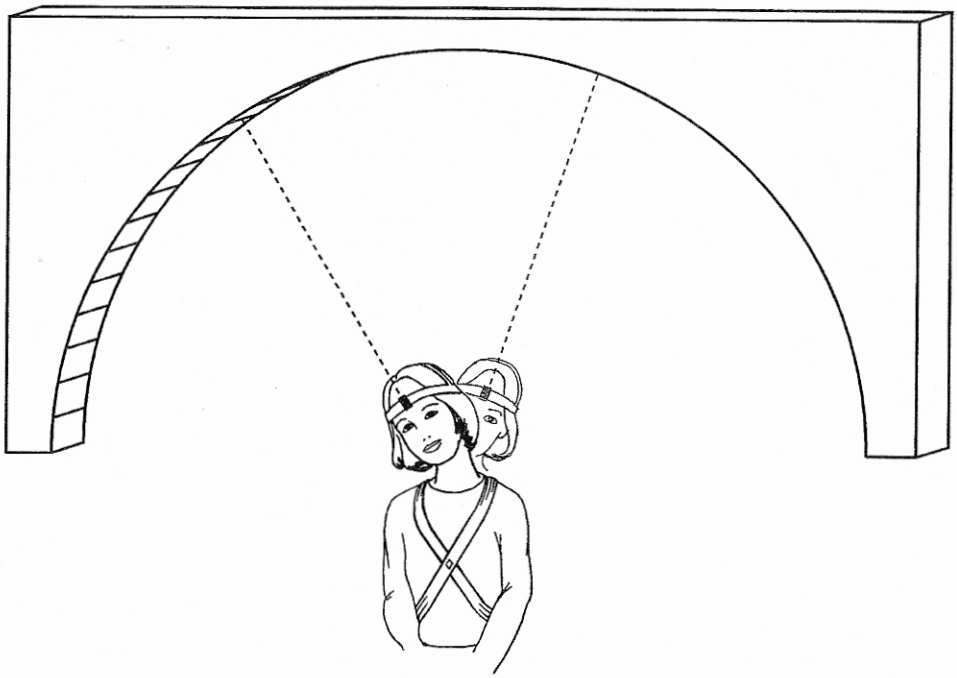

Fig. 4. Cervical lateral flexion measured using a laser affixed to the forehead.

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

Severity	RT site	Dose (Gy)	Radiation	Pathologic features	Stage	Other therapy
9	Left thyroid	66	γ + e	Medullary carcinoma	T4N1bM0/Stage 3	Surgery
	Bilateral neck	66	γ + e			
	Supraclavicular nodes					
9	Oropharynx	63	γ + e	Squamous cell	T1N2bM0	Surgery
	Bilateral neck	50.4	γ + e			
	Supraclavicular nodes					
9	Left tonsil	74.4*	γ + e	Squamous cell	T3N2bM0	Surgery
	Bilateral neck	50.4				Chemotherapy
	Supraclavicular nodes					
8	Nasopharynx	22	n	Squamous cell	T2N2aM0/Stage 4	
	Supraclavicular nodes	14				
7	Maxillary sinus	20.4	n	Adenoid cystic	T4NxM0	Surgery
6	Supraglottic larynx	75*	γ + e	Squamous cell	T2N2bM0/Stage 4	Chemotherapy
	Supraclavicular nodes	51				
6	Nasopharynx	70	γ	Squamous cell	T2NbM0/Stage 4	Chemotherapy
	Bilateral neck	50				Surgery
	Supraclavicular nodes					
6	Right neck	58.7	γ	Colloidal carcinoma	Metastatic from breast	Chemotherapy
	Right supraclavicular nodes	45				
6	Nasopharynx and neck	45	γ	Malignant lymphoma	Recurrent/Stage 4	Chemotherapy
	Periaortic nodes					Surgery
6	Larynx	60.4	γ + e	Squamous cell	T4N0M0	Surgery
	Bilateral neck	50.4				
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	γ	Melanoma	Metastatic from cheek	Surgery
4	Left parotid	30	γ	Benign mixed	Recurrent	Surgery
		20.4	n			
3	Right nasal ala	59.5	γ + e	Squamous cell	Recurrent	Surgery
	Bilateral neck					
	Supraclavicular nodes	50.4	γ			
3	Tongue	60	γ	Keratinizing	T2N1Mx	Surgery
	Left neck	62.8	γ + e	Squamous cell		
3	Base of tongue	20	n	Adenoid cystic	T1N0M0	Surgery
3	Right submandibular	7.2	γ	Adenoid cystic	T1N0Mx/Stage 1	Surgery
		20.4	n			
	Right supraclavicular nodes	14.0	n			
3	Left parotid	19	γ	Mucoepidermoid	T1N2bM0	Surgery
		20.1	n			
	Supraclavicular nodes	14	n			
3	Right tonsil	74.4*	γ + e	Squamous cell	T3N1M0	Surgery
2	Left parotid	20.8	n	Acinic cell	Recurrent	Surgery
	Left supraclavicular nodes	14.3	n			
2	Right tonsil	61	γ + e	Squamous cell	T1N2bM0/Stage 4	Surgery
	Bilateral neck	64	γ + e			
	Supraclavicular nodes	46	γ			
2	Left parotid	60	γ	Adenoid cystic	Recurrent	Surgery
		20.4	n			
1	Base of tongue	20.4	n	Mucoepidermoid	T3NxM0	
1	Base of tongue	20.4	n	Adenoid cystic	T4N1M0	
0	Left parotid	65	γ	Adenoid cystic	Recurrent	Surgery
		20.4	n			

Abbreviations: RT = radiotherapy; γ = photons; e = electrons; n = neutrons.
* b.i.d. treatment.

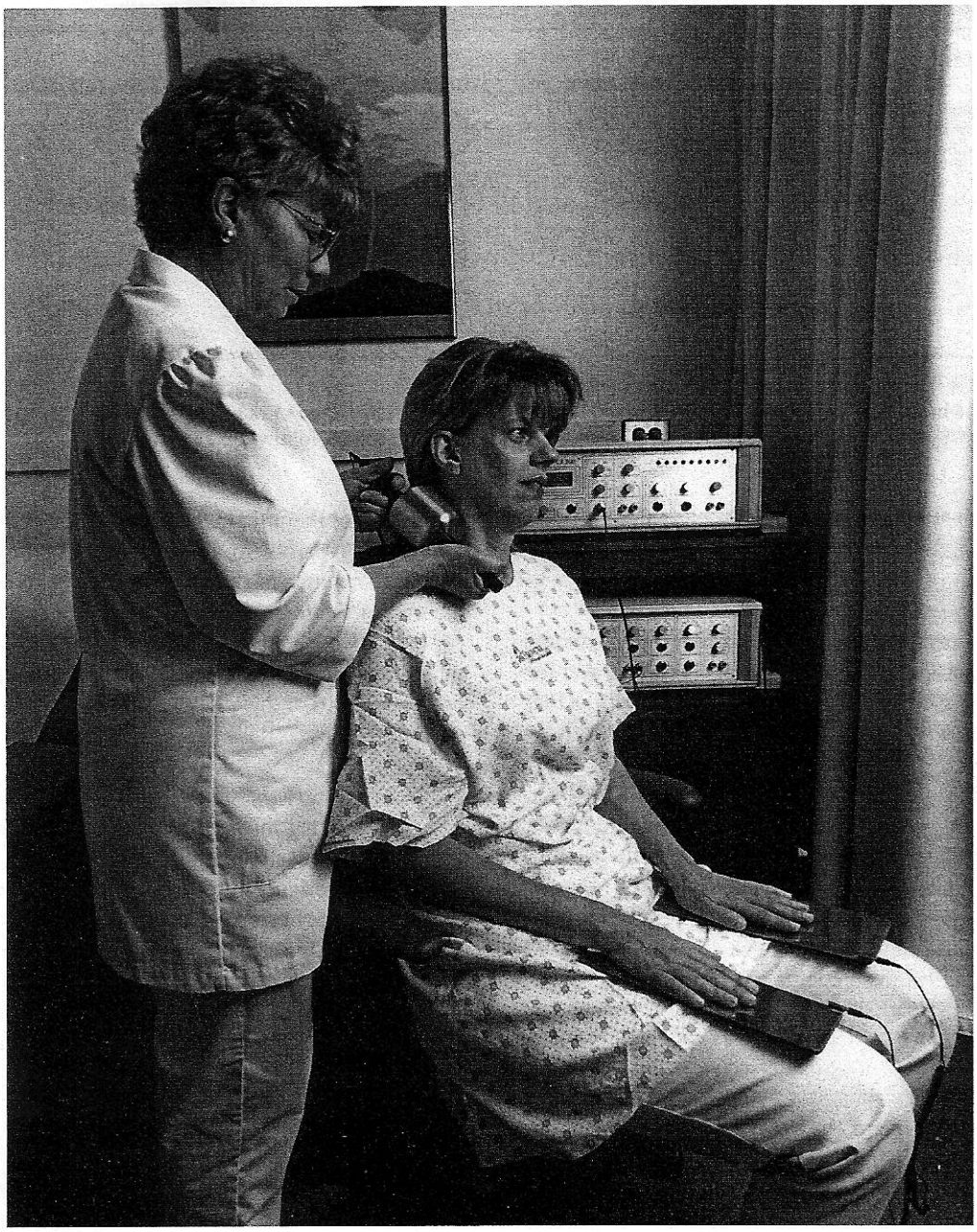

Fig. 5. Electrotherapy treatment technique. Patient's hands rest on large metal plates while impedance-controlled microcurrent therapy is delivered using a metal roller.

healthy, young individual (7). Of the 26 patients, 24 (92%) exhibited improved cervical rotation at the end of microcurrent therapy. Of the 22 who returned for the 3-month follow-up visit, 3 experienced continued improvement, and 17 had lost some of their range of motion, although 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 the 3-month follow-up examination. Figure 6 illustrates the improvement for the 3 patients who started with severe limitations and completed all three follow-up visits on schedule.

Cervical extension/flexion

The range of cervical extension/flexion was compared with the nominal value of 120°, considered normal for a healthy, young individual (7). Of the 26 patients, 22 (85%) exhibited improved extension/flexion at the end of microcurrent therapy. Of the 22 who returned for the 3-month follow-up visit, 8 maintained or improved their end-of-treatment status. Ten of the 22 patients lost some range of motion but their mobility was still better than it had been before microcurrent therapy. The 4 patients who experienced no long-term improvement were already functioning within 80–90% of the normal range. Figure 7 illustrates the

Table 3. Cervical rotation, stratified by severity of limitation, before, at the end, and 3 months after treatment

Patients (*n*)			Pretreatment rating	Pretreatment range (°)	Posttreatment range (°)	Change from pretreatment range (%)	3-mo follow-up range (°)	Change from pretreatment range (%)
Neutrons	Photons	Both						
1, 0	3, 3	—	Severe	59 ± 19 (n = 4)	97 ± 30 (n = 4)	64	83 ± 14 (n = 3)	41
2, 2	6, 5	2, 1	Moderate	101 ± 10 (n = 10)	131 ± 15 (n = 10)	30	119 ± 9 (n = 8)	18
4, 4	4, 4	2, 1	Mild	131 ± 8 (n = 10)	153 ± 16 (n = 10)	17	140 ± 13 (n = 9)	7
1, 1	—	1, 1	Asymptomatic	164 ± 1 (n = 2)	165 ± 9 (n = 2)	1	154 ± 22 (n = 2)	−6

Data presented as the average ± standard deviation, unless otherwise noted.

Optimal range-of-motion for a healthy young person is 170°. First 3 columns show type of radiation received by 26 patients who started the study, followed by the number of patients (total 22) who returned for the 3-month follow-up.

improvements for the 3 patients initially classified as most severely limited in extension/flexion.

Cervical lateral flexion

The range of cervical right/left lateral flexion was compared with the nominal value of 90°, considered normal for a healthy, young individual (7). Of the 26 patients, 21 (81%) exhibited improved range of lateral flexion at the end of microcurrent therapy. Of the 22 patients who returned for the 3-month follow-up visit, 8 had continued to improve their range of motion without any additional therapy. Nine patients experienced a decrease compared with their range of motion 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 4 patients who started with severe limitations and completed all three follow-up visits on schedule.

Oral opening

Oral opening was measured using a Therabite scale (Fig. 9). The measurement was made for all 26 patients, even if trismus was not a complaint. Of the 26 patients, 21 (81%) exhibited improved oral opening after impedance-controlled microcurrent therapy. Only 16 of the 26 patients stated that trismus was a problem. Four of the 16 had 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 3 months. For the 7 patients who maintained improvement in oral opening, the average increase was 4.6 ± 2.2 mm 3 months after the end of microcurrent therapy.

Subjective observations

Before starting microcurrent therapy, patients were asked to fill out a questionnaire regarding any symptoms they might be experiencing as a result of RT. During the treatment week, they turned in daily written observations of any changes 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.

DISCUSSION

In head-and-neck cancer patients, radiation-induced fibrosis can lead to many different complaints, depending on

Table 4. Cervical extension/flexion, stratified by severity of limitation, before, at the end, and 3 months after treatment

Patients (*n*)			Pretreatment rating	Pretreatment range (°)	Posttreatment range (°)	Change from pretreatment range (%)	3-mo follow-up range (°)	Change from pretreatment range (%)
Neutrons	Photons	Both						
—	3, 3	—	Severe	47 ± 10 (n = 3)	70 ± 12 (n = 3)	49	73 ± 13 (n = 3)	55
2, 1	3, 3	—	Moderate	73 ± 9 (n = 5)	106 ± 9 (n = 5)	45	107 ± 20 (n = 4)	47
4, 4	5, 4	2, 1	Mild	96 ± 7 (n = 11)	114 ± 15 (n = 11)	19	110 ± 9 (n = 9)	15
2, 2	2, 2	3, 2	Asymptomatic	117 ± 6 (n = 7)	126 ± 15 (n = 7)	8	117 ± 14 (n = 6)	0

Data presented as the average ± standard deviation, unless otherwise noted.

Optimal range-of-motion for a healthy young person is 120°. First 3 columns show type of radiation received by the 26 patients who started the study, followed by the number of patients (total 22) who returned for the 3-month follow-up.

Table 5. Cervical lateral flexion, stratified by severity of limitation, before, at the end, and 3 months after treatment.

Patients (*n*)			Pretreatment rating	Pretreatment range (°)	Posttreatment range (°)	Change from pretreatment range (%)	3-mo follow-up range (°)	Change from pretreatment range (%)
Neutrons	Photons	Both						
1, 0	5, 4	—	Severe	31 ± 7 (n = 6)	51 ± 20 (n = 6)	65	48 ± 9 (n = 4)	55
2, 2	4, 4	1, 1	Moderate	53 ± 5 (n = 7)	76 ± 10 (n = 7)	43	79 ± 16 (n = 7)	49
3, 3	4, 4	1, 1	Mild	69 ± 5 (n = 8)	82 ± 17 (n = 8)	19	75 ± 12 (n = 8)	9
2, 2	—	3, 1	Asymptomatic	92 ± 22 (n = 5)	102 ± 25 (n = 5)	11	103 ± 30 (n = 5)	12

Data presented as the average ± standard deviation, unless otherwise noted.

Optimal range of motion for a healthy young person is 90°. First three columns show type of radiation received by the 26 patients who started the study, followed by the number of patients (total 22) who returned for the 3-month follow-up.

the size and placement of the treatment fields, the total dose, and whether the patient also underwent 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 the 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. Most of the patients in the mildly and moderately limited groups had learned to compensate for the limitations and were surprised when the measurements showed how much capability they had lost. The patients who were most severely limited received the greatest degree of benefit.

Patients also received relief from a number of complaints 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 additional studies on the role of microcurrent therapy in treating trismus are warranted. Our xerostomia

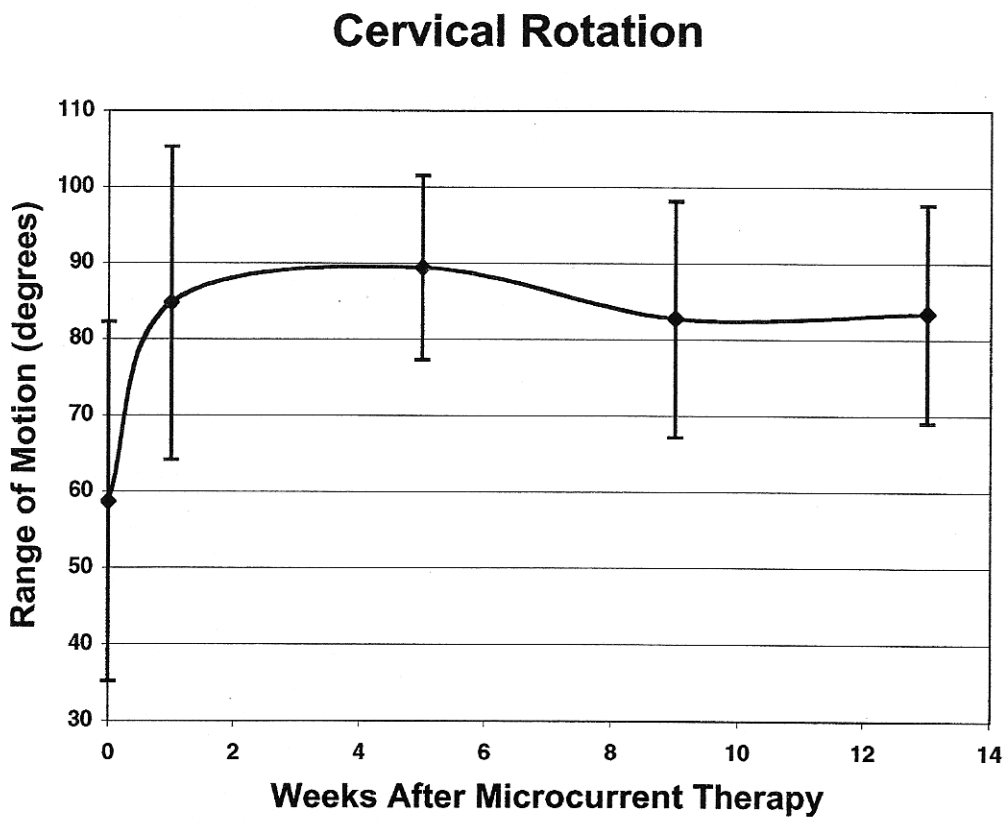

Fig. 6. Range of cervical rotation for 3 patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.

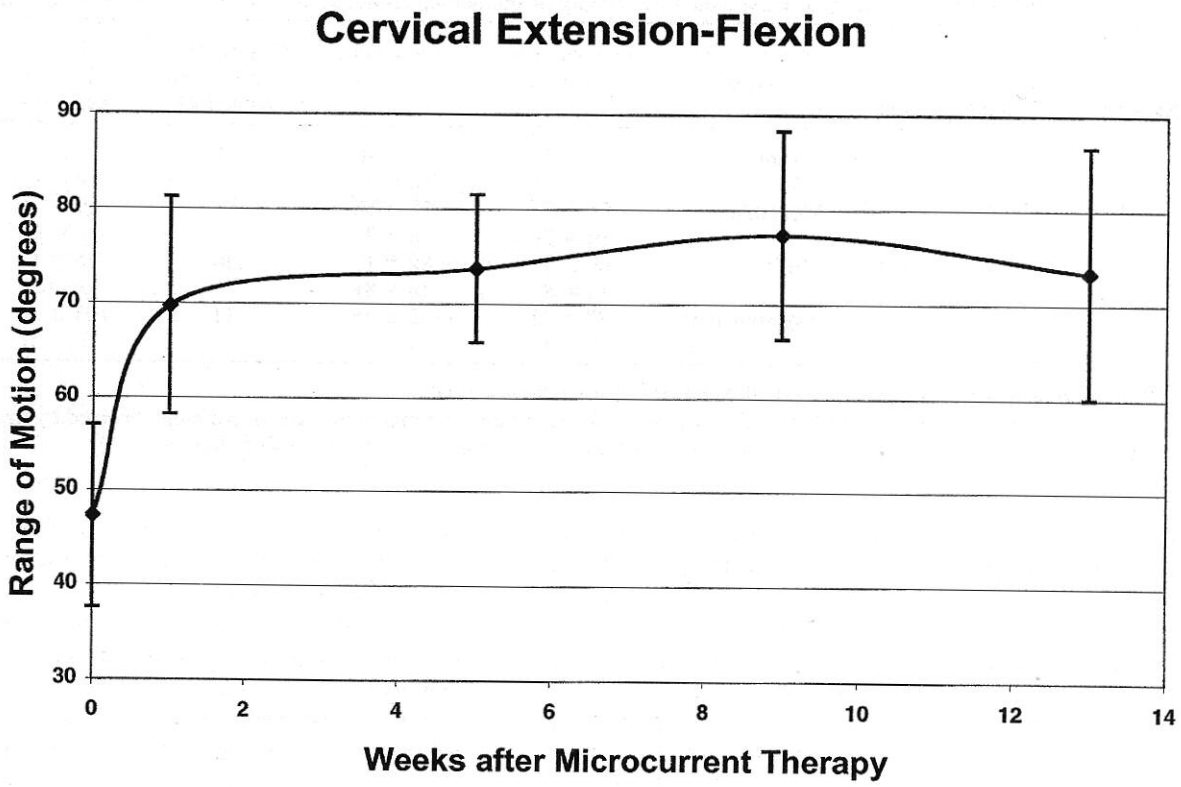

Fig. 7. Range of cervical extension/flexion for 3 patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.

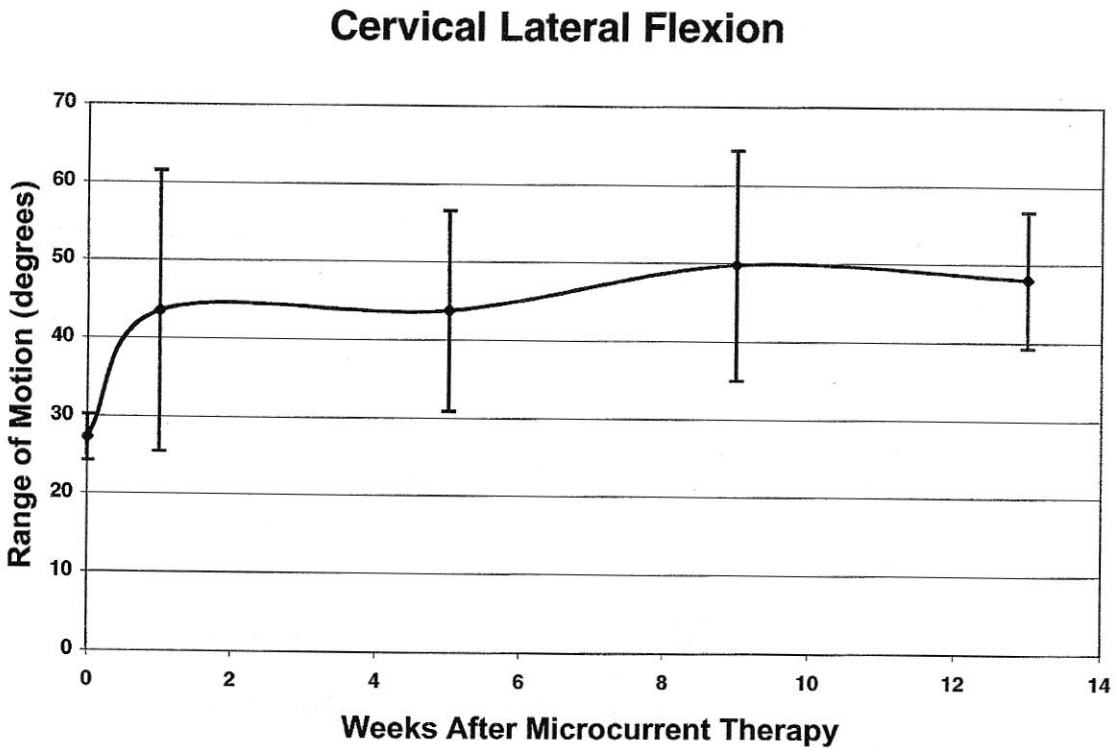

Fig. 8. Range of cervical lateral flexion for 4 patients initially experiencing severe range-of-motion limitation. No microcurrent therapy was given after the first week of treatment.

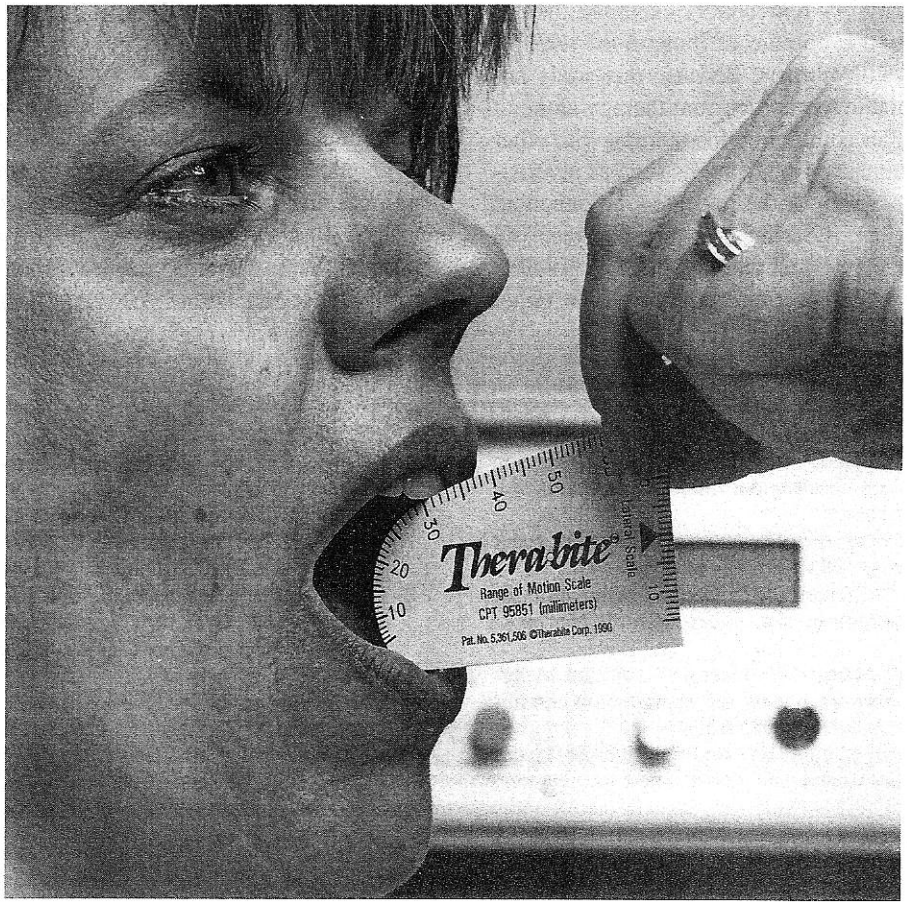

Fig. 9. Therabite scale used to measure oral opening.

data are currently being analyzed and will be published separately.

Perhaps the most encouraging outcome of this study was that many of the benefits observed at the end of the treatment week were sustained. In some cases, continued improvement occurred during the 3-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). The 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. 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 with fibrosis.

Table 6. Patients with improvement in subjective complaints

Symptom	Patients 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)

At the onset of the study, it was expected that any improvement in symptoms would be transient, because no follow-up treatment was offered. The data indicate that this assumption was incorrect. Although the group size was small, the data shown in Figs. 6 through 8 suggest that improvement continued during the first and second months 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 maximal achievable benefit. For patients who are just beginning RT, it is possible that an optimal treatment schedule would include administering impedance-controlled microcurrent treatment concurrent with RT.

In designing the study, we deliberately excluded the use of any agent or activity that could contribute to the relief of symptoms associated with fibrosis. Because 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 modality alone.

CONCLUSION

Impedance-controlled microcurrent therapy shows promise in improving the 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 the quality of life for RT patients.

REFERENCES

1. Cooper JS, Fu K, Marks J, *et al.* Late effects of radiation therapy in the head and neck region. *Int J Radiat Oncol Biol Phys* 1995;31:1141–1164.
2. Bauer W. Electrical treatment of severe head and neck cancer pain. *Arch Otolaryngol* 1983;109:382–383.
3. Boswell NS, Bauer W. Noninvasive electrical stimulation for the treatment of radiotherapy side-effects. *Am J Electromed* 1985;1(3):5–6.
4. King GE, Jacob RF, Martin JW. Electrotherapy and hyperbaric oxygen: Promising treatments for postradiation complications. *J Prosthetic Dentistry* 1989;62:331–334.
5. Omura Y. Electro-acupuncture: Its electrophysiological basis and criteria for effectiveness and safety—Part 1. *Acupunct Electrother Res* 1975;1:157–181.
6. Biedebach M. Accelerated healing of skin ulcers by electrical stimulation and the intracellular physiological mechanisms involved. *Acupunct Electrother Res Int J* 1989;14: 43–60.
7. Oslance J, Liebenson C. Outcomes assessment in the small private practice. In: Liebenson C, editor. Rehabilitation of the spine. Media, PA: Williams & Wilkins; 1996. p. 79.
8. Polk C. Electric and magnetic fields for bone and soft tissue repair. In: Polk C, Postow E, editors. Handbook of biological effects of electromagnetic fields. 2nd ed. Boca Raton: CRC Press; 1996. p. 231–246.
9. Cheng N, Van Hoof H, Bockx E, *et al.* The effects of electric currents on ATP generation, protein synthesis, and membrane transport in rat skin. *Clin Orthop* 1982;171:264–272.
10. Delanian S, Balla-Mekias S, Lefaix J. Striking regression of chronic radiotherapy damage in a clinical trial of combined pentoxifylline and tocopherol. *J Clin Oncol* 1999;17:3283–3290.