Proceedings

Light Activated Tissue Regeneration and Therapy

Engineering Conferences International *Year* 2004

The Use of Broadband Incoherent Infrared Radiation (SSIR System) for the Treatment of Non-Infectious Disorders

Floyd T. Neth
Gulf Tel Communications

Abstract

The Use of Broadband Incoherent Infrared Radiation (SSIR System) for the Treatment of Non-Infectious Disorders

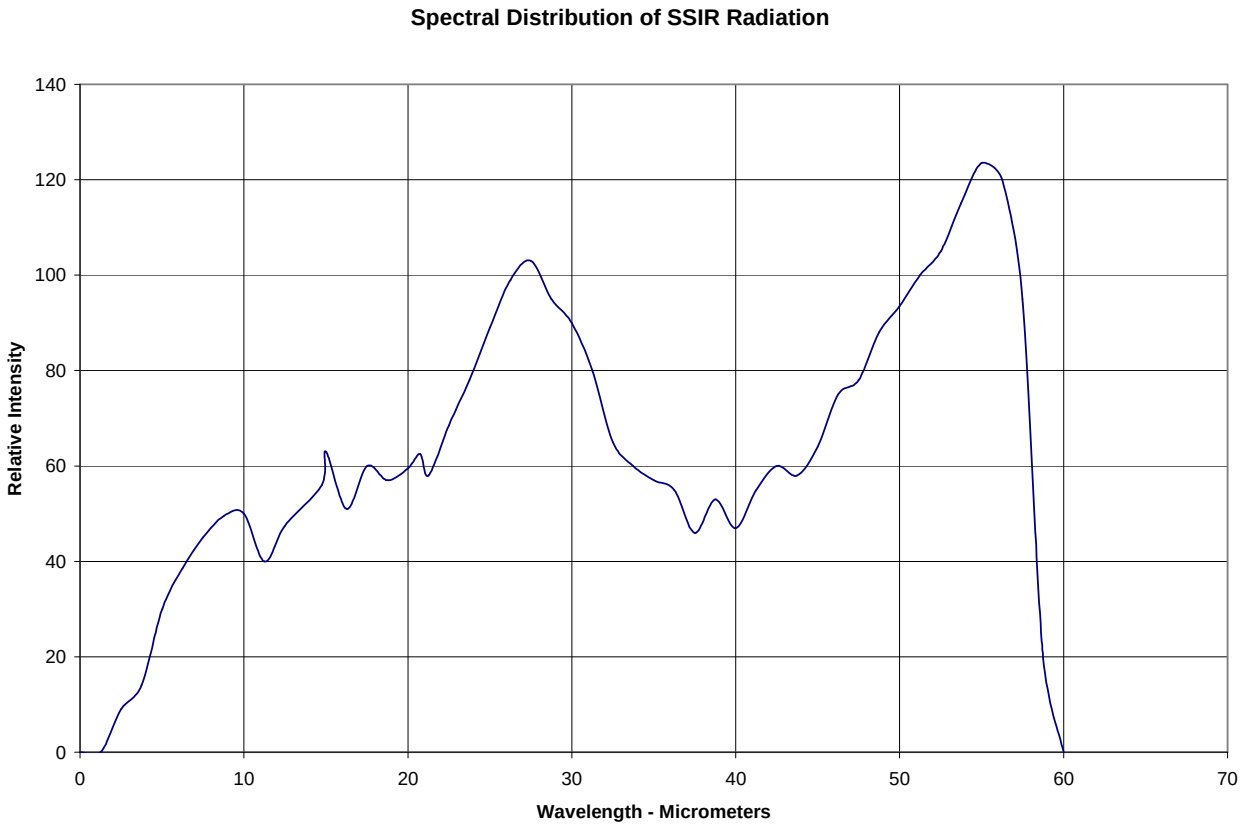
Research on the treatment of various chronic conditions with broad band infrared radiation was begun in the late 1980's at St. Petersburg, Russia, after successful development of special silicon diodes with relatively high output intensities. Diodes in current use have output throughout the range of 3,000 to 60,000 nanometers with total output power of 2 - 3 watts. About one-half of the output is below 25,000 nm and one-half above 25,000 nm with broad peaks between 22,000 and 32, 000 nm and between 45,000 and 57,000 nm. Conditions which have been successfully treated in clinical trials include Benign Prostate Hyperplasia, burns, Carpal Tunnel Syndrome, diabetes, osteoarthritis, periodontal disease, surgical wounds, and stomach and duodenal ulcers. Anecdotal incidents suggest that the radiation may be effective in the treatment of cancer chemotherapy side effects, drug withdrawal symptoms, gall bladder attacks, gout, muscle fatigue, pancreatitis, and warts. There is evidence that irradiation increases oxygen delivery to the tissues. Irradiation of the blood stream during open heart surgery stabilizes lactate and increases Heat Shock Protein 72.

Floyd T. Neth, PhD
23667 Patterson Rd
Robertsdale, AL 36567
USA
Tel/fax (251)960-1381
E-mail: nethrata@gulftel.com

The Use of Broadband Incoherent Infrared Radiation (SSIR System) for the Treatment of Non-Infectious Disorders

Introduction

The SSIR System uses broadband infrared radiation to treat a variety of non-infectious disorders. The spectral distribution of the radiation, produced by a special silicon diode, lies between 3,000 and 60,000 nanometers. (Figure 1) Typical input power is 2 - 4 watts. Input power is adjusted to produce a standard output radiation power, estimated at about 500 milli-watts. Normal aperture diameter is 30 mm, producing radiation intensity of 70 mW/cm^2 . A typical treatment session duration is 20 minutes, so energy applied to site is 84 $joules/cm^2$. A typical series of treatments is 20 minutes per day for 10 days.



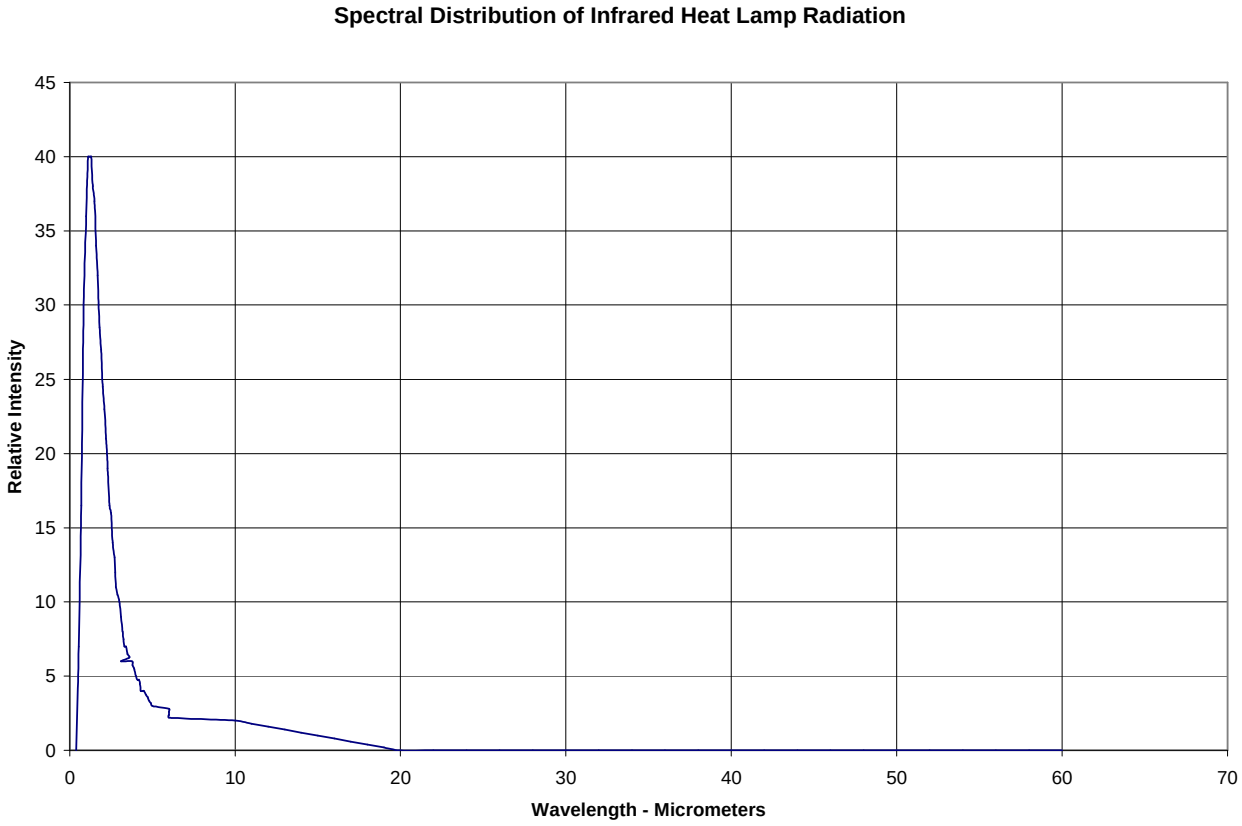


Figure 1.Comparison of Spectral Distributions of SSIR output with Infrared Heat Lamp Output

There are two adaptations of the SSIR System. In one the silicon diode is housed in a module similar to a wrist watch. The module is held in contact with the skin at the treatment site with a Velcro strap or adhesive tape. In the other the silicon diode is mounted in a conical reflector. Mounting hardware similar to a desk lamp is used to position the reflector over the treatment site. (Figure 2.).

Figure 2. Two Versions of SSIR System Devices

Disorders Successfully Treated

Proven by Clinical Trials.

- Osteoarthritis of:
  - Fingers
  - Knee
  - Elbow
  - Shoulder
  - Hip
- Carpal Tunnel Syndrome
- Early Parkinsonism
- Ehlers Danlos syndrome
- Elbow Crepitant Tendovaginitis
- Benign Prostate Hyperplasia
- Burn skin grafts
- Diabetes, Types I & II
- Facial surgical wounds
- Periodontal disease
- Stomach/duodenal ulcers

Anecdotal Indications.

- Osteoarthritis of:
  - Spine
  - Ankle
  - Toes
- Burns, direct treatment
- Cancer Chemotherapy Side Effects
- Gall Bladder Attacks
- Drug Withdrawal Symptoms
- Gout
- Muscle Fatigue
- Pancreatitis
- Postural hypotension
- Prostatitis, Acute and Chronic
- Warts
- Wounds, General

Carpal Tunnel Syndrome (CTS)

In three controlled clinical trials in St. Petersburg, Russia, all 52 carpal tunnel syndrome patients realized significant reduction in the severity of symptoms. Some received total relief of symptoms. In a trial at Robertsdale, Alabama, clinical trial data show a reduction or resolution in the severity of CTS symptoms in 8 of 9 participants and an improvement in functional status in 8 out of 9. (See Tables 1a., 1b. and 1c.)

Table 1a. Reduction in Severity of CTS Symptoms – St. Petersburg, Russia

CTS Severity Impairment Score							
Before Treatment		After Treatment					
Score		Patients	Patients Very Mild (20- 25)	Patients Mild (26- 35)	Patients Moderate (36 - 54)	Patients Severe (55 - 71)	Patients Very Severe (71 - 90)
Moderate	(36 - 54)	20	15	5	0	0	0
Severe	(55 - 71)	25	4	9	12	0	0
Very severe	(72 - 90)	7	3	2	2	0	0

Table 1b. – Reduction in Severity of CTS Symptoms – Robertsdale, AL

Patients CTS Severity Impairment Score							
Before Treatment		After Treatment					
Score		Patients	Patients None (11 - 22)	Patients Mild (23- 33)	Patients Moderate (34 - 44)	Patients Severe (45- 55)	Patients Very Severe (> 55)
Mild	(23 - 33)	2	1	1	0	0	0
Moderate	(34 - 44)	7	2	5	0	0	0

Table 1c. – Improvement in Functional Status.

CTS Functional Status Score						
Before Treatment		After Treatment				
Score	Patients	Patients No Difficulty (8 - 15)	Patients Mild Difficulty (16- 23)	Patients Moderate Difficulty (24- 31)	Patients Severe Difficulty (32 -39)	Patients Unable to Perform (40 - >)
Mild Difficulty (16 - 23)	7	6	1	0	0	0
Moderate Difficulty (24 - 31)	1	0	1	0	0	0
Severe Difficulty (32 - 39)	1	0	1	0	0	0

Osteoarthritis (OA) of Fingers, Hip, Knee, Elbow, and Shoulder.

Clinical trial data collected on a total of 40 patients with erosive interphalangeal, scaphometacarpal, rheumatoid finger (remission stage), or post traumatic finger arthritis show average reduction in joint elastic stiffness of 53 % (range: 35 - 66, standard deviation: 7) and increase in relative joint range of motion of 49 % (range: 6 - 105, standard deviation: 28). Clinical trial data collected on a total of 60 knee patients with knee OA: medial, patellofemoral, and lateral compartments, rheumatoid (remission stage), or post traumatic show average reduction in joint elastic stiffness of 43 % (range: 30 - 55, standard deviation: 9); average improvement in relative joint range of motion of 12 % (range: -3 - +42, standard deviation: 9). Elastic stiffness and range of motion were measured with an electro-mechanical device. (See Table 2.)

Table 2. Improvement in Joint Elastic Stiffness and Range of Motion by Treatment of Osteoarthritis of the Fingers and Knees, Early Parkinsonism, and Ehlers-Danlos Syndrome with Incoherent Infrared Radiation (SSIR)

Diagnosis	Subjects	Per Cent Change					
		Elastic Stiffness			Relative Range of Motion		
		Average	Range	Standard Deviation	Average	Range	Standard Deviation
Finger-OA	**40**	**53**	**35 - 66**	**7**	**49**	**6 - 105**	**28**
EIA	10	59	54 - 62	2	75	50 - 95	12
S	10	58	50 - 66	6	47	30 - 62	12
RA(F)	10	47	37 - 57	8	12	6 - 18	4
PTA(F)	10	48	35 - 57	8	61	30 - 105	26
Knee-OA	**60**	**43**	**30 - 55**	**9**	**12**	**-3 - 42**	**9**
MC	8	57	47 - 68	6	16	8 - 34	10
LC	7	49	42 - 56	4	22	16 - 42	8
PC	7	41	31 - 49	6	24	16 - 42	9
RA(K)	8	37	33 - 43	4	13	8 - 24	6
PTA(K)	30	41	30 - 55	7	5	-3 - 18	4
Metabolic							
EP	10	39	2 - 52	10	21	10-42	11
ED*	10	47	19 - 95	23	9	-9 - 20	8

EIA - Erosive Interphalangeal Arthritis

S - Scaphometacarpal arthritis

RA(F) - Rheumatoid Finger Arthritis (remission stage)

PTA(F) - Post Traumatic Finger Arthritis

MC, LC, PC - Medial, Lateral, Pattelofemoral Compartment (knee)

RA(K) – Rheumatoid Knee Arthritis (remission stage)

PTA(K) – Post Traumatic Knee Arthritis

EP - Early Parkinsonism

ED* - Ehlers-Danlos Syndrome (negative values)

Clinical trial data collected on a total of 20 patients each with hip, elbow, or shoulder OA is shown in Table 3. Results were scored by the patient for joint pain, joint stiffness, physical function, and global assessment (general condition) using a standard questionnaire developed and validated for use in OA drug trials. A composite total score was obtained by adding scores for individual parameters. All patients showed improvement in one or more parameters and in global assessment, although the results varied widely among parameters and among patients. Total scores correlated well with the patient's global assessment.

Elbow Crepitant Tendovaginitis

Clinical data collected on a total of 20 patients with elbow crepitant tendovaginitis, also collected using a patient questionnaire, is shown in Table 3. All patients reported significant improvement in all categories, pain, stiffness, physical functions, and global assessment.

Table 3. Improvement in Symptoms of Osteoarthritis of Hip, Elbow, and Shoulder and Elbow Crepitant Tendovaginitis by Treatment with Incoherent Infrared Radiation (SSIR)

Diagnosis	Subjects	Per Cent Change														
		Pain			Stiffness			Physical Function			Global Assessment			Total		
		Avg	Range	SD	Avg	Range	SD	Avg	Range	SD	Avg	Range	SD	Avg	Range	SD
OA-Hip	20	58	14 - 86	24	81	8 - 83	21	39	12 - 75	20	52	11 - 87	25	31	13 - 17	20
OA-Elb	20	61	31 - 80	12	44	2 - 73	16	53	14 - 75	14	65	24 - 94	15	56	20 - 78	12
OA-Sh	20	61	19 - 94	18	46	19 - 81	15	56	9 - 85	19	54	6 - 97	27	58	20 - 89	18
ECTV	20	63	24 - 93	18	59	26 - 95	19	56	19 - 84	17	65	20 - 88	18	58	21 - 86	17

OA-Hip - Osteoarthritis of Hip **OA-Elb** - Osteoarthritis of Elbow **OA-Sh** - Osteoarthritis of Shoulder

ECTV - Elbow Crepitant Tendovaginitis **Avg** - Average **SD** - Standard Deviation

Table 4. Improvement in Joint Elastic Stiffness and Range of Motion by Treatment of Osteoarthritis of the Fingers and Knees, Ehlers-Danlos Syndrome, and Early Parkinsonism with Incoherent Infrared Radiation (SSIR) Retained after Six and Twelve Months

Diagnosis	Subjects	Per Cent Change												Capillary Oxygen Partial Pressure							
		Elastic Stiffness						Range of Motion						Before Treatment		Per Cent Change					
		Treatment		6 months		12 months		Treatment		6 months		12 months				Treatment		6 months		12 months	
		Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng	Avg	Rng
EIA	3	58	54-61	53	52-54	51	49-54	78	76-80	67	61-71	64	52-71	4	3-5	211	200-233	139	125-160	128	100-160
S	3	61	58-66	55	53-57	53	52-57	54	48-62	45	40-54	41	30-52	4	3-5	246	220-267	163	133-180	145	100-175
RA(F)*	3	47	45-49	43	39-46	42	42-43	12	8-17	9	6-14	9	5-13	3	2-4	261	200-350	172	150-200	125	100-150
PTA(F)	3	48	42-57	42	39-46	41	39-42	58	30-98	48	22-76	43	23-62	4	3-5	222	200-267	139	125-160	109	67-160
MC*	3	60	56-68	51	50-52	48	44-51	18	8-26	7	-1-18	8	4-12	2	2-3	339	267-400	189	150-250	183	167-200
LC	3	48	41-56	39	34-42	36	32-40	21	16-23	12	7-19	10	4-15	3	2-3	322	267-400	178	133-200	139	67-200
PC	3	40	36-43	33	25-38	32	23-37	27	16-42	18	10-31	13	6-23	2	2-3	394	333-450	256	200-300	194	150-233
RA(K)*	3	39	34-43	34	28-41	36	32-40	9	8-10	5	5-6	4	3-6	2	2-3	350	300-400	200	150-250	200	200-200
PTA(K)	3	42	36-46	35	32-39	33	29-38	4	3-5	1	0-3	1	0-3	2	2-3	417	400-450	294	250-333	278	250-333
EP	3	40	27-52	33	21-47	32	20-47	23	10-37	16	6-32	14	5-32	4	3-4	219	200-233	153	133-175	114	67-175
ED	3	43	25-56	35	20-47	29	16-38	6	-9-14	4	-7-10	4	-5-10	4	3-4	231	200-267	156	150-167	92	75-100

EIA - Erosive Interphalangeal Arthritis **MC, LC, PC** - Medial, Lateral, Pattelofemoral Compartment (knee)
RA(F) - Rheumatoid Finger Arthritis (remission stage) **S** - Scaphometacarpal arthritis

RA(K) - Rheumatoid Knee Arthritis (remission stage) **PTA(K)** - Post Traumatic Knee Arthritis

EP - Early Parkinsonism **ED** - Ehlers-Danlos Syndrome (negative values)

Avg – Average **Rng** - Range

*****One of three subjects effectively re-treated 9-11 months after initial treatment.

Benign Prostate Hyperplasia.

Clinical trial data on the treatment of benign prostate hyperplasia (BHP) with SSIR show some improvement in one or more parameters in nineteen of twenty subjects with improvements in various symptom parameters as shown in Table 5. Radiation is directed to the center of the perineum with the end of the reflector positioned against the skin.

Table 5. Improvement in Benign Prostate Hyperplasia (BPH) Symptom Parameters by Treatment with Incoherent Infrared Radiation (SSIR)

Parameter	Average % Improvement	Range of % Improvement	Standard Deviation
BPH Index	33	0 - 70	29
Urination Rate	20	0 - 67	16
Prostate Rel. Vol.	21	0 - 37	11
Doppler Flow	60	0 - 100	42
Leucocytes	43	2 - 69	20
Lecithin Grains	35	0 - 100	26
Prostatic Secretion pH	7	0 - 12	4

Burn Skin Grafts.

A total of 20 patients with facial or neck burns covering an area equal to 1-2 % of the body were treated with SSIR radiation, beginning the second day after the burn. Skin grafts after pre-treatment with SSIR were successful in all of the cases. The state of the blood circulation in the damaged area was measured by rheography with the results shown in Table 6. All indices were returned to normal or near normal by treatment with SSIR.

Table 6. Improvement in Blood Circulation Parameters by Treatment of Burns with SSIR Radiation

#	Diagnosis	Before treatment			After 1st session			After 10th session		
		RI	IVT	PR	RI	IVT	IPR	RI	IVT	IPR
1.	II degree burn on the left parotid area	0.05	21	90	0.06	20	86	0.08	17	77
2.	IIIA degree burn on left cheek and nose-lip fold	0.03	24	95	0.05	21	90	0.07	18	81
3.	II degree burn on the parietal area	0.04	22	91	0.06	20	85	0.09	16	76
4.	II degree burn on left auricle and side of neck	0.05	21	89	0.07	21	83	0.08	18	72
5.	II degree burn on the chin and lower lip	0.05	24	92	0.06	23	88	0.07	18	80
6.	II degree burn on the forehead	0.04	23	88	0.06	21	81	0.07	17	77
7.	IIIA degree burn on the right parotid area	0.04	26	96	0.06	24	91	0.08	19	79
8.	II degree burn on the chin	0.05	21	91	0.07	19	85	0.08	15	80
9.	II degree burn on the forehead and nose	0.04	24	89	0.06	22	80	0.07	18	73
10.	IIIA degree burn on right cheek and nose-lip fold	0.03	28	92	0.05	25	86	0.07	19	77
11.	IIIA degree burn on the chin and lower lip	0.03	25	93	0.06	22	88	0.07	17	79
12.	II degree burn on the left cheek and parotid area	0.06	21	87	0.07	18	80	0.09	15	75
13.	II degree burn on the chin	0.05	23	86	0.05	22	79	0.07	18	72
14.	IIIA degree burn on right auricle and side of neck	0.04	27	90	0.06	24	84	0.08	18	75
15.	II degree burn on the forehead	0.03	20	89	0.04	18	81	0.06	15	77
16.	II degree burn on the right cheek	0.05	23	92	0.06	19	88	0.07	16	80
17.	IIIA degree burn on the parietal area	0.04	26	97	0.06	22	91	0.08	17	82
18.	II degree burn on the parotid area	0.03	22	89	0.04	19	86	0.07	17	79
19.	II degree burn on the chin	0.04	24	91	0.06	21	85	0.09	18	79
20.	II degree burn on right cheek and nose-lip fold	0.05	21	90	0.07	19	84	0.10	16	78
	AVERAGES	0.042	23.3	90.85	0.0585	21.0	85.05	0.077	17.1	77.4
	STANDARD DEVIATIONS	±0.0087	±2.19	±2.76	±0.0085	±1.97	±3.54	±0.0095	±1.22	±2.8

Notes to tables: (1) **RI** = rheographic index (0.07 - 0.09 is normal); (2) **IVT** = index of tonic vascular tension (15 - 18 % is normal); (3) **IPR** = index of peripheral vascular resistance (70 - 80 % is normal).

Diabetes, Types I and II.

A large number of diabetes patients with both types I and II have been clinically treated successfully. In an initial study 100 patients suffering from types I and II diabetic angiopathy syndrome of the extremities received four consecutive daily treatments of 15 minutes each. Sessions were divided equally between the region of the lower back over the left and right kidneys. Increases in blood flow in the big toe occurred with temperature increases ranging from 0.9 to 1.5 degrees C. Significant reduction in pain and also a feeling of warmth was reported after the first treatment. Before treatment the rate of blood flow correlated positively with glucose and immunoreactive insulin. After treatment there was a positive correlation with concentration of MDA in the blood. (Table 7) Stabilization of blood pressure occurred in some patients with hypertension.

A controlled clinical trial involving 7 patients with diabetes and 5 with no disease conditions confirmed the original results. Table 8 shows the outcomes measured by a four-level sensory response questionnaire, local blood circulation and skin temperature of the feet. On average about 60 % of the increase in blood flow and temperature were retained one month later.

In another trial using 100 subjects relief of symptoms of angiopathy syndrome of the extremities was realized without recurrence within one year on 70 of the patients. The 30 patients with unsuccessful treatment had less than normal stomach acidity. Success of this group was increased by treatment with therapeutic iron and zinc compounds. In most cases SSIR radiation treatment of diabetes should be complemented with iron and zinc supplements.

TABLE 7. EFFECT OF INCOHERENT INFRARED RADIATION (SSIR) ON BLOOD FLOW AND RELATED PARAMETERS IN TREATMENT OF DIABETIC ANGIOPATHY OF THE EXTREMITIES.

	Before IR Treatment	**After IR Treatment**	**Correlation Coefficient with Blood Volume per Minute**	
			Before	**After**
Stroke volume	78.4 ± 2.3	93.3 ± 6.0		
Glucose	10.6 ± 2.5	8.7 ± 2.4	0.86	0.41
Insulin	8.6 ± 2.3	13.4 ± 3.1	0.74	0.37
MDA	4.2 ± 3.1	5.1 ± 2.1	0.33	0.74

Table 8. Improvement in Diabetes I and II by Treatment with Incoherent Infrared Radiation (SSIR)

#	Diagnosis	Existence of Pain in Muscles and Joints								Cold(-) or Warm(+) in Extremities				Bloodflow in Extremities (Conv. Units)				Skin Temp. Rad. Site Deg. C				Skin Temp. Feet Deg. C.			
		Without Movement				With Movement																			
		0s	1s	7s	1mo	0s	1s	7s	1mo	0s	1s	7s	1 mo	0s	1s	7s	1 mo	0s	1s	7s	1 mo	0s	1s	7s	1 mo
1	Diabetes I Intermed. Sev.	-	-	-	-	+++	+	-	-	---	+	+++	++	44	62	68	54	36.1	37.4	37.0	36.2	35.2	36.4	36.4	36.2
2	Diabetes I Intermed. Sev.	+	-	-	-	++++	++	±	-	---	+	++	++	36	51	58	49	35.9	37.4	37.6	36.1	35.4	36.1	36.7	36.0
3	Diabetes II Mild Sev.	-	-	-	-	++	-	-	-	---	+	++	+	41	74	67	59	35.8	37.7	37.5	36.3	35.3	37.1	36.4	36.2
4	Diabetes II Intermed. Sev.	++	+	-	+	+++	+	-	+	---	+	+++	+	37	67	74	61	35.6	36.8	37.1	36.2	35.1	36.4	36.3	35.9
5	Diabetes I Intermed. Sev.	+	-	-	-	++	-	-	-	---	-	++	++	51	84	81	76	36.5	36.9	37.1	36.2	35.2	35.9	36.1	35.4
6	Diabetes I Intermed.Sev.	-	-	--	-	++	-	--	--	---	+	+++	++	58	87	83	64	36.0	37.6	36.1	35.9	35.2	37.4	37.1	36.1
7	Diabetes II Intermed. Seve	+	--	--	--	+++	+	---	-	---	±	+	±	35	48	54	47	35.9	37.2	37.4	36.1	35.4	36.1	36.2	35.9
Averages for Group of Diabetic Patients														43	67	69	59	35.9	37.2	37.4	36.1	35.3	36.4	36.2	35.9
#	**Healthy Men Ages 17 – 21 Years**																								
1										+	++	+++	+	67	84	84	71	36.0	37.4	37.2	36.1	36.0	36.7	36.5	36.6
2										+	++	+++	+	68	93	95	69	36.1	37.5	37.1	36.2	35.8	36.5	36.6	36.1
3										+	+++	+++	+	71	91	92	74	36.4	37.6	37.5	35.9	36.2	36.4	36.3	36.3
4										+	++	+++	+	65	86	93	68	36.5	37.8	37.4	36.0	36.1	36.5	36.4	36.0
5										+	++	+++	+	74	89	94	73	36.0	37.6	37.3	35.8	36.2	36.4	36.4	36.2
Averages for Control Group														69	89	92	71	36.2	37.6	37.3	36.0	36.0	36.5	36.4	36.2

Notes to Tables:

(1) + means subject has symptom, number of +s is extent measured with a four-level questionnaire.
(2) – signifies absence of symptom or reduction in symptom, number of –s indicates extent of reduction.
(3) 0s is before treatment; 1s after 1 treatment; 7s after 7 treatments; 1 mo is 1 month after last treatment

A clinical trial involving 16 subjects with mild to moderate Type II diabetes, as indicated by initial levels of Random Plasma Glucose in the range of 11.1 to 22.2 mmol/L (200 - 400 mg/DL) and HbA1c in the range of 6.6 to 8.0 %, were treated with SSIR radiation for 10 minutes per day at each of two sites on either side of the lower back and 2 sites on either side of the middle abdomen Monday through Friday for 8 weeks. Table 9 shows the outcome measured by change in Random Plasma Glucose and change in HbA1c. All 16 patients showed improvement in both outcome measures. 8 of 16 reached the level of Random Plasma Glucose for non-diabetics. 14 of 16 reached American Diabetes Association HbA1c goal for diabetics of 7% or below. 9 of 16 reached American Association of Clinical Endocrinology goal of 6.5% or below. Results suggest that additional improvement may be realized with treatments extending beyond 8 weeks.

Table 9. Improvement in Random Plasma Glucose and HbA1c in Type II Diabetes Patients by Treatment with Incoherent Infrared Radiation (SSIR)

Patient	Before treatment		After 4 weeks		After 8 weeks	
	Glucose level mmol/L	HbA1c %	Glucose level mmol/L	HbA1 %	Glucose level mmol/L	HbA1c %
1	13.2	7.0	11.8	6.5	10.9	6.2
2	12.1	6.8	11.7	6.6	11.5	6.5
3	17.4	7.5	13.4	6.9	11.8	6.6
4	14.7	7.2	12.3	6.8	11.1	6.5
5	16.3	7.4	12.7	6.9	10.8	6.6
6	18.5	7.6	14.1	7.1	12.0	6.9
7	11.5	6.6	10.8	6.2	9.9	6.0
8	19.1	7.8	15.8	7.3	13.1	6.9
9	18.7	7.7	16.3	7.5	14.8	7.4
10	15.6	7.3	12.6	6.8	11.9	6.5
11	13.9	7.0	11.9	6.5	10.4	6.3
12	12.6	6.9	11.2	6.6	10.5	6.4
13	18.1	7.5	14.8	6.9	12.1	6.7
14	20.8	8.0	16.3	7.5	14.2	7.1
15	11.9	6.7	11.0	6.3	10.1	6.1
16	12.4	6.9	10.3	6.4	9.8	6.0

Note: Glucose level is Random Plasma Glucose

Facial Surgery Wounds.

A total of 30 patients undergoing various facial surgeries were treated with SSIR radiation of the wound and facial artery in consecutive daily sessions of 10 minutes each. Results were evaluated by observing edema and measuring vascular parameters by rheovasography. Reduction of pain and disappearance of edema were noted after the first session. The appearance of the scar is less pronounced than expected in the normal case. This should be of particular interest to cosmetic plastic surgeons. All parameters had become normal after six sessions. (See Table 10.)

TABLE 10. Improvement in Healing of Facial Surgery Wounds by Treatment with Incoherent Infrared Radiation (SSIR)

		After surgery				After 1st session				After 6th session			
#	Diagnosis	ed	PB	VWR	IVT	ed	PB	VWR	IVT	ed	PB	VWR	IVT
1.	Deformation scar on the upper lip after cleft corrective surgery	+	100	79	91	-	118	88	82	-	127	93	71
2.	Deformation of the nose tip after nasal split corrective surgery	+	100	80	88	-	115	91	80	-	128	96	69
3.	Deformation scar after the trauma of parotid area	+	100	82	87	-	122	92	79	-	135	97	68
4.	Deformation scar on the upper lip after cleft corrective surgery	+	100	78	90	-	117	87	79	-	126	92	69
5.	Deformation scar on the forehead after trauma	+	100	77	92	-	125	87	81	-	131	93	72
6.	Contracting scar on the upper lip	+	100	81	89	-	121	90	78	-	130	94	67
7.	Deformation scar on the chin area after the burn	+	100	83	92	-	118	92	80	-	131	96	71
8.	Deformation of the nose tip after the nasal split corrective surgery	+	100	81	91	-	123	92	77	-	128	95	68
9.	Deformation of the nose tip after nasal split corrective surgery	+	100	79	90	-	114	90	79	-	125	94	72
10.	Deformation scar on the upper lip after cleft corrective surgery	+	100	80	92	-	126	89	81	-	134	94	73
11.	Deformation scar on the forehead area after trauma	+	100	78	89	-	119	89	80	-	130	93	70
12.	Contracting scar on the upper lip	+	100	77	88	-	120	88	77	-	131	93	66
13.	Deformation scar on the upper lip after cleft corrective surgery	+	100	82	86	-	117	91	75	-	126	96	65
14.	Deformation scar on the upper lip after cleft corrective surgery	+	100	79	89	-	122	92	78	-	129	97	70
15.	Deformation of the nose tip after nasal split corrective surgery	+	100	83	89	-	121	93	81	-	130	98	74
16.	Deformation scar on the forehead area after trauma	+	100	81	90	-	116	90	79	-	127	95	68
17.	Deformation scar on the chin after trauma	+	100	80	87	-	120	91	76	-	129	95	67
18.	Contracting scar on the upper lip	+	100	82	89	-	123	90	78	-	133	96	68
19.	Deformation of the nose tip after nasal split corrective surgery	+	100	78	92	-	118	89	81	-	132	94	70
20.	Deformation scar on the upper lip after cleft corrective surgery	+	100	77	90	-	124	88	81	-	135	94	71
21.	Deformation scar on the upper lip after cleft corrective surgery	+	100	81	91	-	121	92	79	-	129	98	68
22.	Deformation scar on the parotid area after trauma	+	100	79	87	-	122	90	78	-	131	95	69
23.	Contracting scar on the upper lip	+	100	78	90	-	118	89	79	-	126	94	68
24.	Deformation scar on the right cheek after trauma	+	100	83	92	-	119	93	81	-	125	98	71
25.	Contracting scar on the upper lip	+	100	80	89	-	123	91	80	-	132	95	70
26.	Deformation of the nose tip after nasal split corrective surgery	+	100	81	87	-	119	90	79	-	130	96	69
27.	Deformation of the nose tip after nasal split corrective surgery	+	100	79	86	-	120	91	75	-	131	95	65
28.	Deformation scar on the upper lip after cleft corrective surgery	+	100	78	88	-	124	89	77	-	135	94	67
29.	Deformation scar on the nose and cheek after trauma	+	100	82	91	-	121	90	82	-	129	95	70
30.	Deformation of the nose tip after nasal split corrective surgery	+	100	79	92	-	117	91	83	-	130	96	71
	AVERAGES	+	100	79.9	89.47	-	120.1	90.17	79.17	-	129.83	95.03	69.23
	STANDARD DEVIATION			±1.8	±1.87		±2.9	±1.62	±1.98		±2.83	±1.56	±2.17

Notes to table: (1) ed = edema; (2) PB = Pulse blood filling (results obtained after surgery taken as 100); (3) VWR = reduction in vascular walls resistance (normal is 95 or greater); (4) IVT = index of tonic vascular tension (normal is lower than 70)

Peridontal Disease.

SSIR radiation has been used clinically at the Stomatological Clinic of the First St. Petersburg Medical Institute (Russia) for treating paradontosis and paradontitis. Results of treatment of 14 patients in a clinical trial are shown in Table 11. Bleeding, edema, and hyperesthesia were eliminated with 5 consecutive daily sessions of ten minutes each. Peripheral resistance and muscle tone as determined by rheodontographic analysis were returned to near normal in all cases. Change in amplitude and smoothing of the peaks and valleys of the rheodontographs indicate increase in flexibility of the walls of the blood vessels after treatment. (Figure 3.)

SSIR is also used to reduce pain and hasten healing after shred surgery for severe cases. Pain disappears after the first session. Healing proceeds without complications and the time required is reduced by 1-2 days.

In patients with alveolitis and pain in the gum cavity following tooth extraction, pain is reduced after 2-3 sessions; disappears after 5 sessions.

Table 11. Results of the Treatment of Paradontosis and Paradontitis with SSIR

#	Diagnosis	Before Treatment							After Treatment						
		Bl.	Ed.	Hyp.	IH	RI	IPR (%)	IVT (%)	Bl.	Ed.	Hyp.	HI	RI	IPR (%)	IVT (%)
1	General Paradontitis Intermediate Severity	+	+	+	1.3	.11	90	30.5	-	-	-	1.1	.1	70	15
2	"	+	+	+	1.4	.21	65	12.5	-	-	-	1.0	.1	70	15
3	"	+	+	-	1.3	.07	40	40	-	-	-	1.0	.09	75	16
4	General Paradontosis Initial Stage	+	+	-	1.2	.11	29	10	-	-	-	1.0	.1	70	15
5	General Paradontosis Developing Stage Intermediate Severity	+	+	+	1.4	.22	93	20	-	-	-	1.1	.09	90	14
6	"	+	+	±	1.2	.12	92	31	-	-	-	1.0	.08	75	16
7	Paradontitis	-	-	+	1.1	.20	93	17	-	-	-	1.1	.09	85	15
8	"	-	-	+	1.2	.11	94	16	-	-	-	1.0	.08	84	14
9	General Paradontitis Initial Stage	+	±	-	1.3	.12	65	12	-	-	-	1.1	.09	75	13
10	"	+	±	-	1.3	.11	93	17	-	-	-	1.0	.08	85	14
11	"	+	-	-	1.4	.12	65	13.5	-	-	-	1.0	.09	72	13
12	General Paradontitis Developing Stage Intermediate Severity	+	+	+	1.3	.13	92	28	-	-	-	1.0	.1	70	15
13	General Paradontitis Initial Stage	+	-	-	1.4	.10	68	12.5	-	-	-	1.0	.1	74	14
14	General Paradontitis Developing Stage Mild Severity	+	-	-	1.3	.07	70	12	-	-	-	1.0	.08	75	13
Average for Patients No 1,5,6,7,8,10,12					**1.26**	**.143**	**92.4**	**22.8**				**1.04**	**.09**	**79.9**	**14.7**
Average for Patients No 2,4,9,11,13					**1.34**	**.133**	**58.4**	**12.1**				**1.02**	**.096**	**72.2**	**14.0**

Notes to Table: (1) General paradontitis - peridontose with inflammation stretching over all the teeth. (2) Hyperesthesia - excessive sensitivity of naked tooth neck and root.

(3) Index of Dental Hygiene - (**IH**) - according to the method of Fedrov & Volodkina (in healthy persons 1.0) (larger the number, the poorer the hygiene)

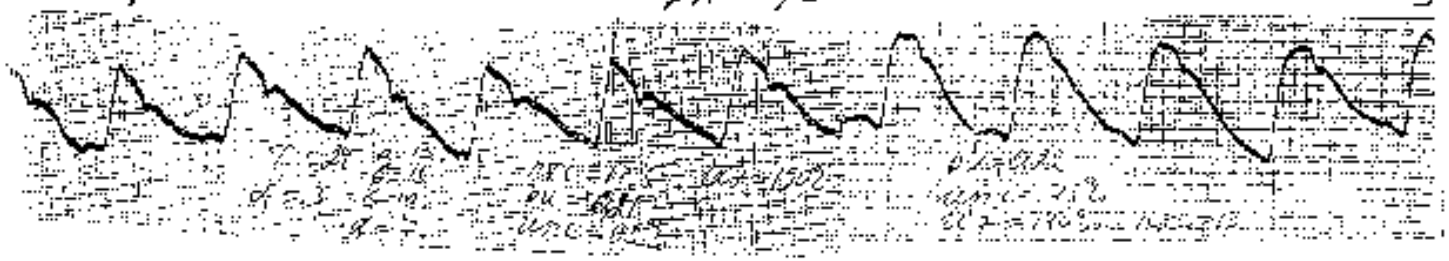
(4) Indices calculated from rheoparadontographic data. (**RI**), rheographic index (0.07 - 0.09 is normal). (**IPR**), index of peripheral resistance (70 - 90 % is normal); if IPR is more than 90%, patient has constriction and spasm of blood vessels, e.g. in arteriosclerosis, if IPR is less than 70% there is dilatation of blood vessels. (IVT), index of muscle tone (13 - l5% is normal).

(5) + indicates presence or increase; - indicates absence or decrease. **BL** = bleeding **ED** = edema **HYP** = hyperesthesia

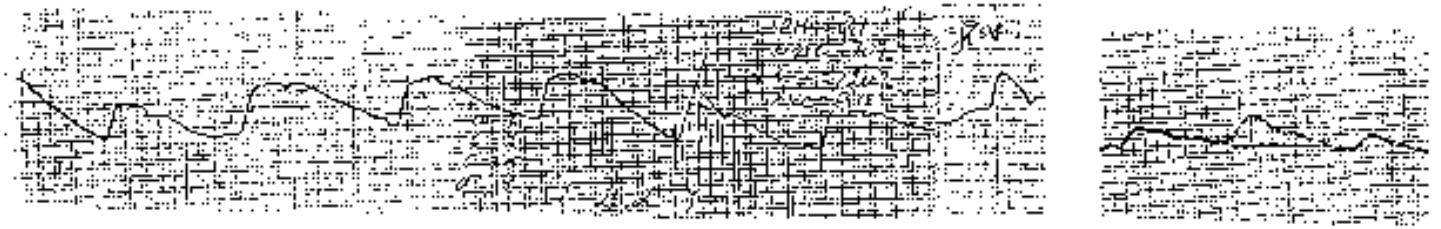
Exhibit D

Rheoparadontographs

Before SSIR Treatment



After SSIR Treatment



Smoothing of pulse peaks shows reduction in peripheral resistance of walls of blood vessels.

Figure 3. Rheodontographs Before and After Treatment with SSIR Radiation

Stomach /Duodenal Ulcers.

A total of 340 patients with uncomplicated and chronic gastric or duodenal ulcers have been treated in clinical trials with SSIR radiation. The ulcer was located with an endoscope and the radiation directed over the site, using 20-minute sessions at one or two day intervals. Pain was eliminated in 1-4 sessions, with cure, determined endoscopically, realized in 2 - 9 sessions. There were no recurrences within one year after treatment.

Anecdotal Indications.

Osteoarthritis:

Ankle.

Osteoarthritis (OA) of the ankle along with that of other joints has been treated routinely at an arthritis clinic in St. Petersburg, Russia, with success equal to that shown in clinical trials on other joints.

Toes.

A patient in the United States who was treating OA of the First CMC joint and who also had OA in her toes realized relief in the feet while irradiating the thumb before relief at the treatment site.

Spine.

Two patients in the United States with acute and chronic OA of the spine have received complete relief of symptoms. One with a severe acute case centered at the eighth vertebra was given a series of 10 treatments with nearly complete elimination of symptoms. After waiting one week he received another series of 10 treatments, with total relief after the fifth treatment. He completed the second 10 treatment series in May, 1998. By October, 2001 no symptoms had reappeared.

It is to be expected that osteoarthritis of any joint in the human body may respond to SSIR treatment. The poorest candidate seems to be the hip. Response is not universal but it appears that failures are generally concentrated in those joints in which all or nearly all of the cartilage has degenerated.

Burns, Direct Treatment.

People in the United States who have had access to an instrument have been prone to treat a variety of conditions which occur. One person received immediate relief of pain and diminishing of blood vessel proliferation, and ultimate healing of a burn on the hand which was becoming steadily worse. He also received immediate relief of sunburn pain without normal blistering. Two patients received relief of pain on fingers which touched a hot object within 4 minutes after beginning the treatment session. Expected blistering failed to occur and pain did not return after treatment.

Postural Hypotension.

A one hundred year old woman was trying the radiation on a line of tumors formed along the incision line of an earlier breast excision. She had been suffering spells of hypotension when arising at night to use the bathroom. After a few treatments with SSIR near her heart she noticed the postural hypotension incidents no longer occurred. It was later determined that she had a partially blocked aorta.

Pancreatitis.

Heavy drinking of alcohol is endemic in Russia, leading to many incidents of pancreatitis. Immediate relief of pain and subsequent elimination of inflammation has been achieved with SSIR irradiation.

Gall Bladder Attacks.

One woman who is subject to frequent gall bladder attacks gets immediate relief of pain without recurrence during that attack after irradiating with SSIR. Radiation has reduced the frequency of attacks.

Acute and Chronic Prostatitis.

A 71 year old patient whose prostate biopsy indicated minor acute and chronic prostatitis was advised to have Prostate Specific Antigen complex test at 6 month intervals. He has had a series of SSIR prostate radiation treatments between each test interval. No increase in Benign Prostate Hyperplasia symptoms have occurred after one year and the PSA level has remained constant, suggesting the prostatitis has been arrested.

Cancer Chemotherapy Side Effects.

One middle aged woman undergoing chemotherapy in 1999 treated herself with SSIR radiation to the lower back. The side effects of the chemotherapy were not as intense as expected.

General Wound Healing.

Many wounds have been treated with SSIR radiation but without controlled studies. More rapid healing than expected is generally reported. Some wounds which had been particularly resistant to healing have undergone normal healing after treatment.

Muscle Fatigue.

Persons who are subject to several episodes of muscle cramp during the night after strenuous exercise and loss of electrolyte have reported that SSIR irradiation of the normally affected muscle along with oral electrolyte replacement eliminates or reduces the number and severity of the episodes. Competitive bicyclists have reported rapid recovery of muscles after treating with SSIR radiation.

Gout.

One person has successfully treated gout by irradiation of the affected foot.

Drug Withdrawal Symptoms

Russian physicians have reported relief of drug withdrawal symptoms by treatment with SSIR radiation during drug rehabilitation.

Open Heart Surgery

The external bloodstream was irradiated with SSIR radiation during open heart surgery in a series of operations. Recovery time was reduced and success rate increased. Lactic acid was stabilized and there was an increase in Heat Shock Protein 72.

Mechanism Hypothesis

In the studies with outcomes reported in Table 4 above, the partial pressure of capillary oxygen (PPO) was measured before treatment, after treatment, after 6 months and after one year with a very precise transcutaneous oximeter. For purposes of analysis a related study determined PPO for healthy persons in a range of ages with results shown in Table 12. As expected normal levels of transcutaneous oxygen decreased slightly with age. When this data is compared with the same data for osteoarthitic joints before treatment, immediately after a treatment series, six months later, and one year later it is clear that there is a severe oxygen deficiency at osteoarthritic joints (average healthy 13; arthritic 3) .This is largely eliminated by SSIR treatment (average healthy 13; treated 12). It is evident that the treatment with SSIR has restored oxygen to oxygen deficient tissue. This allows tissue regeneration where that process has been curtailed. The tissue regeneration also occurs in walls of blood vessels, restoring flexibility and providing increased blood delivery of nutrients. Evidence for this was shown in the studies of treatment of periodontal diseases with changes in the amplitude and smoothing of peaks and valleys of the rheodontographs. It was shown in the treatment of facial surgical wounds with index of peripheral resistance returning to normal. It was shown in the treatment of diabetes with measured increases in blood flow in the feet bringing about increases in skin temperature. For every condition that has been treated effectively it can be reasonably concluded that the results are realized by improvement in localized metabolism All results of treatment of every condition are consistent with improved tissue regeneration associated with increased oxygenation and the corresponding improvement in local metabolism. In some cases, for example increases in insulin after irradiating the pancreas, this may be regeneration of organ tissue and restored function of the organ. In osteoarthritis improvement in joint stiffness and range of motion may occur through cartilage regeneration. Reduction in inflammation and a corresponding diminishment of pain may be related to increases in the rate of healing brought about with increase in oxygen and blood nutrients delivery.

Table 12. Age Related Transcutaneous Oxygen Partial Pressure (PPO) in Healthy Joints Compared with PPO of Osteoarthritic Joints Before Treatment, After Treatment, Six Months After Treatment and One Year After Treatment.

Age Group	PPO	Average	Standard Deviation
31-40	15	14.6	0.58
	15		
	14		
	15		
	14		
41-50	13	13.6	0.55
	14		
	14		
	14		
	13		
51-60	13	12.6	0.55
	12		
	13		
	12		
	13		
61-70	12	11.6	0.55
	11		
	11		
	12		
	12		
Healthy (31-70) 20		13.1	1.25
Before Treatment 33		3.1	1.0
After Treatment 33		11.6	1.9
6 Month After 33		8.7	2.7
1 Year After 30		8.0	2.7