

June 1, 2006

Ms. Barbara Dombrowski
AHCA
2727 Mahan Drive, MS #51
Tallahassee, Florida 32308

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**BUREAU OF
LONG TERM CARE SERVICES**

Dear Ms. Dombrowski,

The purpose of this letter is to furnish a final report of the Anodyne experience over the past year at Santa Rosa Health & Rehabilitation Center in Milton, Florida. Thank you Ms. Dombrowski for your support and guidance throughout this process and thanks to AHCA for this grant program as the results speak for themselves. The Anodyne near infrared machine has proved to be a valuable treatment tool to reduce pain, reduce swelling, increase sensation and improve function for a variety of patients.

The format for this report reviews the operational overview, clinical outcomes in terms of qualitative and quantitative datum, alternative treatment options and some general observations. The attached Table 1 describes individual patient treatment outcomes and patient comments.

Operational Overview

Orientation to the machine involved an initial three hour training conducted by a variety of highly skilled Anodyne representatives. Use of the machine proved relatively simple. (A) Apply a protective barrier (saran wrap) on the skin over the chosen sight, (B) place the pads that emit light on the chosen sight over the barrier, (C) turn the machine on and adjust the intensity according to desired use, and (D) leave on for 20-30 minutes each treatment. The training suggested that measurable results would take a minimum of 12 treatments.

The mechanism at work is basically twofold. The light emitted acts to dilate blood vessels and provide gentle warmth. These two features result in increased circulation, decreased pain, and increased sensation which in turn, produce better functional capabilities.

Patients were seen either three times per week or five times per week depending on the individual plan of care. There are only two conditions for which the Anodyne may not be used, pregnancy and active cancer.

Clinical Outcomes

The attached Table 1 describes the relevant outcomes and patient comments. The key defines the column headings, however a review is appropriate. **Patients:** are numbered to maintain confidentiality. **Diagnosis:** reflects the reason why therapy was involved. **Treatment dates:** reflect the weekly documentation required for those being treated by Anodyne. Candidates were

treated either three or five times per week. **Pain Scale:** defines pain on a scale of one to 10. One is very minor pain, 10 is the worst pain imaginable. Naturally, the lower the pain, the better. **Flexibility** measures how much a joint can move, measured in degrees. 90 degrees is a right angle. For example, to put on a shirt a person needs about 130 degrees of shoulder movement. **Sensation:** again the more, the better. **Function:** therapy intervenes based on the inability of a patient to perform some kind of functional activity. Whether it be walking to the bathroom or getting dressed, the goal of therapy is to help people do as well as possible in daily life. **Patient Comments:** are the quotes supplied to the therapist throughout each treatment week.

One feature of the Anodyne treatments that is not reported is the reduction in pain medications required for comfort. While Table 1 describes pain level reported by the patients, reporting the reduced need of pain medications was an oversight that is not included. Patient interviews performed intermittently reflected a highly significant decrease in pain medication use. Common was a person that "had to have" 3 or 4 percocets per day to manage pain. Following a week or two of Anodyne, this would drop to 1 or 2 per day and in most cases, down to zero need for percocet following a month long regimen of Anodyne.

15 patients were treated with the Anodyne over the past year. 14 of the 15 patients reported significant or highly significant improvement in function that was attributable to the Anodyne application. The remaining candidate discontinued use for lack of perceived benefit.

The Anodyne proved most effective with individuals with peripheral neuropathy and wounds.

Rather than requiring 12 treatments to elicit measurable progress as the training indicated, many candidates experienced positive side effects after only a week or two worth of treatment. Other indications were that it felt soothing and warm.

With respect to other treatment interventions attempted, in the case of the two premature discharges, massage and gentle range of motion was attempted with equally fair results. The Anodyne machine represents a different approach to treatment. Modalities such as electrical stimulation and ultrasound have different applications and as such, were not appropriate in these situations. Other modalities such as diathermy were not available for comparison. Typical plan of cares for these candidates included gait training, activities of daily living, therapeutic exercises, therapeutic activities and neuromuscular re-education.

The apparent ability of the Anodyne to help restore circulation and sensation sets it apart from other applications.

The overwhelming sentiment of patient feedback was positive and in most cases, came as a surprise to the patient that anything could help reduce their pain or improve sensation, as many had just learned to live with the pain or numbness.

General Observations

Initially, therapist acceptance of the Anodyne was fair. Much skepticism accompanied questions during the training sessions. The tide turned, however, after therapist started using the Anodyne and patients began reporting good results. Therapist began trying it on themselves and found positive results.

Following the success at Santa Rosa, the parent company purchased an Anodyne unit for each of the remaining buildings. The Anodyne have proven to be a valuable treatment tool to help people heal and feel better. While it is not a panacea, the Anodyne does have a very positive impact on most people and is a worthwhile addition to any therapy program.

Again we thank AHCA and yourself for the opportunity to participate in this grant process and we look forward to future collaborations in an effort to improve the lives of the people we serve.

Best Regards,



Ken Leeman

On behalf of Renita Enfinger, Administrator
Santa Rosa Health & Rehabilitation Center
5386 Broad Street
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Anodyne Annual Report

Santa Rosa Health & Rehab

June 2006

Key to Table Below.

Patient: Numbers reported to respect identity.

Diagnosis: Condition for which therapy was provided.

Treatment Dates: Weekly time frame when Anodyne was used.

Pain Scale: (-1-10 out of 10) Pain of 1/10 is little pain reported, pain of 10/10 is the worst pain imaginable.

Flexibility: Measured in degrees. 0 is neutral for a given joint, the second number reflects the most movement performed actively by patient. For example:

Elbow: 0 is straight (extended), 90 degrees would be bent to form a right angle.

Knee: 0 is straight (extended), 90 degrees would be typical of a seated position, right angle as well.

Sensation: Describes how much a person can feel in a given body part. For instance:

Left Foot: 3/5 sensation would indicate sensation in 3 out of 5 places in the foot. 1/5 sensation would indicate less sensation than 3/5 sensation.

Function: For a given activity of daily living, how much of the activity can a patient do on their own expressed in percentages. For example:

Upper Body Dressing: Putting a shirt or bra on is one example, the ability to perform 50% of this activity would be better than being able to do 25%.

Patient Comments: Relative to the Anodyne treatments, this area reports patient feedback, typically on a weekly basis.

Patient	Diagnosis	Treatment Dates	Pain	Flexibility	Sensation	Function	Patient Comments
1	Neuropathy: Old Stroke	2/8/2006	None reported	NA	Absent below knees	Balance poor	"I can't feel my feet "
		2/16/2006	None reported	NA	No change	Balance poor	"I can feel my shins. "
		2/22/2006	None reported	NA	Dull sensation in toes	Balance fair	"I can feel my foot. "

Patient seen for 3 weeks, 5x/week for a total of 15 treatments. Improvement in sensation allowed the patient to feel her feet and improve her ability to stand.

2	Neuropathy: Renal Failure	1/11/2006	10 out of 10	Ankles Restricted	Absent in both feet	Unable to walk	"I would like to get stronger. "
		1/18/2006	8 out of 10	same	same	Unable to walk	"It's about the same. "
		1/25/2006	7 out of 10	some increase range	same	Can stand w/ assistance	"I'm getting better. "
		2/1/2006	6 out of 10	same	Decreased pain	Increased standing ability	"It's good to stand again. "
		2/8/2006	5 out of 10	same	Increased sensation	Same	"It doesn't hurt as much. "
		2/14/2006	5 out of 10	Improved ankle range	Increased sensation	Walks with severe pain.	"I want to keep walking. "
		2/21/2006	5 out of 10	Improved ankle range	R: 2/5, L: 2/5	Walks with walker.	"It's nice to walk again. "
		Patient seen for 7 weeks, 35 treatments. Decreased pain allowed for greater movement to dress self and rely on facility staff less, which increased her independence.					

3	Leg ulcers: Pain & decreased sensation in both legs	1/9/2006	10 out of 10	NA	80% Slough, 20% mixed granulation	Major risk for infection	"Will this work?"
		1/14/2006	7 out of 10	NA	65% Slough, 35% mixed granulation	same	"It doesn't hurt. "
		1/23/2006	5 out of 10	NA	50% Slough, 50% mixed granulation	Some risk reduction	"My wound is getting smaller. "
		1/30/2006	4 out of 10	NA	35% Slough, 65% mixed granulation	Risk continues to ↓	"The pain is almost gone. "
		2/6/2006	3-4 out of 10	NA	30% Slough, 70% mixed granulation	same	"I'm doing much better. "
		2/13/2006	3 out of 10	NA	20% Slough, 80% mixed granulation	same	"Can I go home soon?"
		2/20/2006	same	NA	same	same	"I'm leaving soon. "
		2/27/2006	same	NA	10% Slough, 90% granulation (near healed)	same	"Thank you very much. "
Patient seen for 7 weeks, 35 treatments. Decreased wound size allowed patient to return home.							

Patient	Diagnosis	Treatment Dates	Pain	Flexibility	Sensation	Function	Patient Comments
4	Diabetes Neuropathy	8/16/2006	5 out of 10	NA	Absent - both feet: 0/5	Not able to walk at evaluation	"I would like to go back home."
		8/23/2006	3 out of 10	NA	R: 1/5, L: 0/5	Not able to walk.	"I can not feel much difference."
		9/13/2006	4 out of 10	NA	R: 2/5, L: 0/5	Less pain, better sensation	"My feet feel better."
		9/20/2006	3 out of 10	NA	R: 3/5, L: 1/5	Walks short distances w/ help	"It feels good to walk."
	Poor leg sensation	9/27/2006	1 out of 10	NA	R: 3/5, L: 1/5	Walks longer w/ help.	"I haven't walked this far in a long time."
		10/5/2006	0 out of 10	NA	Good on R: 4/5; fair on L: 2/5.	No pain	"I haven't walked this far in a long time."
Patient seen for 8 weeks, 40 treatments. No complaints of pain at d/c.							

5	Degenerative Joint Disease (TMJ pain)	5/12/2005	6 out of 10	NA	NA	Significant jaw pain w/ eating	"I would like to eat with out pain."
		5/19/2005	5 out of 10	NA	NA	same	"There's a little difference."
		5/26/2005	4 out of 10	NA	NA	some pain reduction	"I can move my jaw better."
		6/2/2005	3 out of 10	NA	NA	same	"It's getting better."
		6/9/2005	3 out of 10	NA	NA	1/2 the pain compared to start	"My jaw feels much better than it did."
		Patient seen for 4 weeks, 12 treatments. Complaint of pain reduced from 6 out of 10 at eval to 3 out of 10 at d/c.					

6	Diabetes Pain	7/21/2005	8 out of 10	NA	NA	Pain interferes w/ sleep	"I can not sleep at night."
		7/28/2005	5 out of 10	NA	NA	same	"My pain is much better."
		8/4/2005	3 out of 10	NA	NA	better sleep	"I can sleep at night again."
		8/11/2005	3 out of 10	NA	NA	Restful sleep	"I'm much better."
		Patient seen for 4 weeks, 20 treatments. Complaint of pain reduced from 8 out of 10 at eval to 3 out of 10 at d/c.					

7	Diabetes (Neuropathy)	8/16/2005	5 out of 10	NA	NA	Can not stand.	"I can not stand up because my feet hurt."
		8/23/2005	3 out of 10	NA	NA	Can stand w/ decreased pain	"I can stand up without it hurting so much."
Patient seen for 2 weeks, 10 treatments. Complaint of pain reduced from 5 out of 10 at eval to 3 out of 10 at d/c.							

8	DM & Renal failure (Wound)	8/9/2005	8 out of 10	NA	No tactile sensation.	2 x 2 cm wound	"I can see it healing."
		8/16/2005	5 out of 10	NA	same	Healed	"My doctor thinks I'm doing great."
		d/c to hospital					"I would like to restart when I get back."
		Patient seen for 3 weeks, 15 treatments. Sensation increased from none at eval to 4/5.					

9	Diabetes (wounds)	6/9/2006	8 out of 10	NA	No protective sensation below knees	Can not walk.	"My feet hurt if I stand."
		6/16/2006	6 out of 10	NA	Same	Walks 3 feet.	"My pain is much better."
		6/23/2006	5 out of 10	NA	Same	Walks 15 feet w/ walker.	"The pain is going down. I sleep better."
		6/28/2006			Non-compliant w/ treatment plan. D/C'd from active therapy.		
Patient seen for 3 weeks, 15 treatments. Complaint of pain reduced from 8 out of 10 at eval to 5 out of 10 at d/c.							

10	Alcoholic Neuropathy	3/2/2006	Hands are numb	Some mass flexion of	No tactile sensation in hands.	Can not dress himself.	"I can't use my hands."
		3/9/2006	same	wrists/ trace thumb	same	Needs help on toilet.	"I need help with just about everything."
		3/16/2006	same	some improvement	same	Can not push wheelchair.	"I'm ready for therapy."
		3/23/2006	same	some improvement	same	Can hold glass w/ 2 hands.	"I'm always first in therapy in the mornings."
		3/30/2006	same	some improvement	some deep pressure sensation	Beginning to push wheelchair	"Welcome to work."
		4/7/2006	same	some improvement	same	Holds glass w/ one hand.	"I can use my hands again."
		4/14/2006	same	Near full range	3/5 tactile in both hands	Can hold hair brush.	"I do better each week."
		4/21/2006	same	Full range in hands	4/5 tactile in both hands	Can play cards.	"I'm doing pretty good."
		4/28/2006	same	Complete functional use of hands at d/c.	Some weakness remains.		On restorative nursing program.
		Patient seen for 9 weeks, 45 treatments. Had no use of hands at eval to complete use of hands at d/c.					

Patient	Diagnosis	Treatment Dates	Pain	Flexibility	Sensation	Function	Patient Comments
11	Diabetes Neuropathy	5/1/2006	N/A	Trace movement	Little sensation Right hand	Drops things	"I can't hold on to anything with my right hand."
		5/7/2006	N/A	1/2 available range	same	Needs help buttoning clothes	"It's getting better."
		5/14/2006	N/A	Full range	same	Better grip	"I can close my hand now."
		5/19/2006	N/A	Full range	same	Can hold glass w/ 2 hands.	"It's much better."

Patient seen for 3 weeks. 15 treatments. Treatments included Anodyne and paraffin bath. Full use of hand at d/c.

12	Leg wounds PVD	6/20/2006	10/10 leg pain	NA	Wound: 5.4x2.5x.5cms	Could not walk at eval	".... pain is overwhelming."
		6/27/2006	9/10	NA	NA	Can stand	"It's not as bad."
		7/5/2006	8/10	NA	NA	Walks	"I'm doing better."
		7/11/2006	7/10	NA	NA	Walks short distances	"No new complaints."
		7/18/2006	7/10	NA	NA	Distance improving	"It's much better."
		7/25/2006	4/10	NA	NA	Distance improving	"My legs don't hurt near as bad."
		8/1/2006	3/10	NA	NA	Walks with walker at will	"I'm ready to go home."
		8/8/2006	0/10	NA	Wound: 3.4x2.2x.2cms	Back to driving car	"I'm going home."

Patient seen for 8 weeks. 40 treatments. Significant reduction of wound size and pain. Discharged home.

13	Diabetes Neuropathy	8/1/2006	Numb	NA	No sensation below knees	Could not walk at eval	".... pain is overwhelming."
		8/8/2006	same	NA	same	Can stand	"It's not as bad."
		8/15/2006	same	NA	same	Walks	"I'm doing better."
		8/22/2006	same	NA	same	Walks short distances	"No new complaints."
		8/29/2006	same	NA	same	Distance improving	"It's much better."
		9/5/2006	same	NA	Can feel light touch	Distance improving	"My legs don't hurt near as bad."
		9/12/2006	same	NA	same	Distance improving	"I'm ready to go home."
		9/19/2006	same	NA	Can feel tactile sensation	Walks 300', on uneven terrain	"Thank you."

Patient seen for 7 weeks. 35 treatments. Could not walk at eval, and could walk at will at d/c.

14	Alzheimer's Disease Both legs Contracted	8/1/2006	Non-verbal	Hips/knees fetal position	Unable to determine	Treatment initiated to reduce caregiver burden. With both legs contracted in the fetal position, daily hygiene was difficult to accomplish. Anodyne was used in conjunction with soft splints and manual therapy techniques to increase this patients' range of motion.
		8/8/2006	same	same	same	
		8/15/2006	same	slight improvement	same	
		8/22/2006	same	slight improvement	same	
		8/29/2006	same	slight improvement	same	At the end of the course of treatment, caregivers were more easily able to care for this resident. And the resident experienced less discomfort during daily activities of daily living and repositioning
		9/5/2006	same	slight improvement	same	
		9/12/2006	same	slight improvement	same	
		9/19/2006	same	Hipps/ knees 80 deg	same	in bed.

Patient seen for 6 weeks. 18 treatments. Knees and hips in full flexion at eval, able open half way at d/c.

15	Falls at home Diabetes	8/9/2005	No pain	Within functional limits	No sensation in both feet.	Multiple falls	"My doctor wanted me to have Anodyne."
		8/16/2005	same	same	same		"I don't want to use a cane."

This Out-Patient did not return to participate in plan of care after the second week. D/C therapy.