

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 The Springs at Boca Ciega Bay, in St. Petersburg, 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.

24 patients were treated with the Anodyne over the past year. 19 of the 24 patients reported significant or highly significant improvement in function that was attributable to the Anodyne application. Three of the 24 experienced some improvement; however, treatments were discontinued prematurely due to re-admittance to hospital due to unrelated medical complications. The remaining two candidates discontinued use for lack of perceived benefit.

The Anodyne proved most effective with individuals with peripheral neuropathy and orthopedic conditions such as knee, hip and shoulder fractures. Anodyne also helped to reduce pain with those with arthritis and fibromyalgia. Some success was noted in the treatment of those with joint contractures.

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 The Springs, 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 Joey Mingione, Administrator
The Springs at Boca Ciega Bay
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Anodyne Annual Report

The Springs at Boca Ciega Bay

June 2006

Key to Table below.

Patient: Numbers reported to respect identity.

Diagnosis: Condition for which therapy was provided.

Treatment Dates: Reporting occurred on weekly basis, based on treatments that were typically 3-5 times per week.

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	Polymyalgia Rheumatica (Lack of balance & sensation)	7/4/2005	NA	NA	1/2 of calf & foot loss of feeling	Balance poor	"I can't feel my feet."
		7/11/2005	NA	NA	1/3 calf & foot loss of feeling	Balance fair	"I can feel more of my feet."
		7/18/2005	NA	NA	Little loss of feeling in both legs	Balance fair	"This seems to be helping."
		7/25/2005	NA	NA	Experiencing tingling in both legs	Balance fair	"I actually feel my feet, they tingle."
		8/1/2005	NA	NA	Tell difference in textures	Balance good	"I can feel the carpet."
8/5/2005	NA	NA	Sensation remains good.	Balance good	"I can do the community outings again."		

Patient seen for 5 weeks, 3x/week for a total of 15 treatments. With the improvement in balance and sensation, patient was able to resume community involvement again.

2	Shoulder fracture	7/5/2005	7 out of 10	raise arm to 75 deg.	NA	unable to dress	"I love this, it helps with my pain."
		7/15/2005	5 out of 10	raise arm to 80 deg.	NA	needs 75% help	"It seems to be helping."
		7/22/2005	2 out of 10	raise arm to 130 deg.	NA	Needs 50% help	"I'm getting so much better."
		7/29/2005	0 out of 10	raise arm to 140 deg.	NA	can dress self	"I think it helps tremendously with movement."
8/5/2005	0 out of 10	able to dress self	NA	can dress self	"It has done wonders for me."		

Patient seen for 5 weeks, 15 treatments. Decrease in pain allowed for greater movement to dress self and rely on facility staff less, which increased her independence.

3	Arthritis in both knees	11/30/2005	9 out of 10	NA	NA	walk 2' w/help	"Please do something for my pain, I can't walk."
		12/7/2005	7 out of 10	NA	NA	walk 20' w/help	"I've already noticed my pain has decreased."
		12/14/2005	5 out of 10	NA	NA	walk 20' w/help	"I have half the pain I used to."
		12/21/2005	3 out of 10	NA	NA	walk 45' w/help	"Pain is much better and I can walk more."
12/27/2005	1-2 out of 10	NA	NA	walk 45' w/no help	"I can walk by myself now."		

Patient seen for 5 weeks, 15 treatments. Decreased pain allowed patient to return home with spouse.

4	Arthritis in Both hands	12/23/2005	10 out of 10	NA	NA	Grip strength Rt. 0, Lt. 10 lbs.	"I'm in so much pain, anything would help."
		12/30/2005	8 out of 10	NA	NA	Right 4 lbs., Left 12 lbs.	"My pain has gotten better, let's keep going."
		1/6/2006	8 out of 10	NA	NA	Right 4 lbs., Left 13 lbs.	"This is working pretty well."
		1/13/2006	7 out of 10	NA	NA	Right 6 lbs., Left 13 lbs.	"I'm doing things I haven't been able to do."
1/20/2006	4 out of 10	NA	NA	Right 9 lbs., Left 13 lbs.	"I'm not that much stronger, but my hands don't ache as much."		

Patient seen for 5 weeks, 15 treatments. Paraffin bath also used for pain management. Patient able to care for self in ALF.

Patient	Diagnosis	Treatment Dates	Pain	Flexibility	Sensation	Function	Patient Comments
5	Neuropathy in both Legs and bottoms of both feet	12/7/2005	5 out of 10	NA	Total numbness	walked 100' w/25% help	"I doubt this will work."
		12/14/2005	2 out of 10	NA	3/4 of feet sensation returned	walked 200' w/25% help	"My pain is better and I can feel my feet."
		12/21/2005	2 out of 10	NA	3/4 of feet sensation returned	walked 250' w/ittle help	"Not much difference this past week."
		12/28/2005	0 out of 10	NA	Sensation returned 100%	walked 300' Independ.	"My legs feel so much better. I am sleeping through the night."

Patient seen for 4 weeks, 12 treatments, was able to return to ALF and do everything himself.

6	Right shoulder fracture	1/22/2006	6 out of 10	Unable to assess	NA	needs 100% help to dress	"I've got to get this back."
		1/29/2006	4 out of 10	0-39 degrees	NA	needs 100% help to dress	"This thing makes my arm feel warm."
		2/4/2006	2 out of 10	0-47 degrees	NA	needs 75% help to dress	"I feel a littler better."
		2/13/2006	2 out of 10	0-61 degrees	NA	needs 25% help to dress	"My pain is less and I can move more."
		2/20/2006	1 out of 10	0-87 degrees	NA	able to put shirt on	"My arm hurts, but at least I can get this shirt on"

Patient seen for 5 weeks, 15 treatments. Decreased pain and increased movement allowed for return to ALF to take care of self independently.

7	Pelvic fracture	8/18/2005	10 out of 10	NA	NA	needed 100% help	"I can barely walk, my left leg hurts so bad."
		8/25/2005	6 out of 10	NA	NA	needed 25% help	"I'm taking less pain medication and I don't hurt as much as I did last week."

Patient seen 6 times per week for 2 weeks, 12 treatments. Decreased pain and improved function noted. Patient discontinued from Anodyne because of readmittance to hospital.

8	Neuropathy on bottom of both feet	8/2/2005	10 out of 10	NA	No sensation both feet	walk indoors 15'	"My feet are very painful and wake me at night."
		8/8/2005	5 out of 10	NA	No sensation both feet	walk indoors 150'	"I am sleeping better and noticed my pain is less."
		8/15/2005	3 out of 10	NA	Outside of feet sensation return	inside /outside 200'	"I can feel something on the bottom of my feet."
		8/22/2005	0 out of 10	NA	Outside of feet sensation return	inside /outside 300'	"I have no pain!"
		8/29/2005	0 out of 10	NA	3/4 of both feet return sensation	inside/outside 400'	"I am sleeping through the night."

Patient seen for 5 weeks, 15 treatments. Returned to independent living. Avoided placement in assisted living due to increased abilities.

9	Contractures of both knees	1/2/2006	8 out of 10	both knees bent 70 deg	NA	NA	"My legs hurt to straighten out."
		1/9/2006	6 out of 10	both knees bent 60 deg	NA	NA	"Leave my legs alone."
		1/13/2006	2 out of 10	both knees bent 45 deg	NA	NA	"My legs don't hurt as much."

Patient seen for 2 weeks, 10 treatments. Patient made significant progress with Anodyne and moist heat. Treatments were discontinued because of patient agitation due to moderate dementia.

10	peripheral neuropathy	3/10/2006	8 out of 10	NA	no sensation both feet	walks indoors 50'	"I hope this works I have had this for years"
		3/17/2006	7 out of 10	NA	still no sensation both feet	walks indoors 50-75'	"This is not helping"
		3/24/2006	6 out of 10	NA	Circulation noticed in heel area	walks indoors 75-100"	I am starting to feel something on my feet!
		3/31/2006	5/6 out of 10	NA	Feels warmth in both feet	balance improving	I feel my balance is better now that I can feel
		4/7/2006	4/5 out of 10	NA	Sensation noted on half of foot	walks outdoors some	I am walking outdoors and I am not afraid of falling
		4/14/2006	4 out of 10	NA	sensation noted except by toes	walks 300' in/outside	I don't have any pain and I feel so much better
		4/21/2006	0 out of 10	NA	sensation returns to entire ft foot	walks over 1,000 feet	"I would've thought this would have done so much for me"

"Thank you so much for showing me this machine!"

Patient seen for 7 weeks, 21 treatments. Pt made such good progress w/ ss with Anodyne therapy that she was able to regain all sensation in her right foot and reported no more pain in either foot. She is now able to go back out into the community for outings and fun with family and friends.

11	shoulder pain (severe)	4/3/2006	7 out of 10	raise arm 49 deg	NA	hurts too bad to use it	I don't use my arm for anything it is too painful.
		4/10/2006	7 out of 10	raise arm 61 deg	NA	not using it due to pain	"This is not helping at all...yet"
		4/17/2006	4 out of 10	raise arm 76 deg	NA	able to propel w/c	"This feels a lot better."
		4/24/2006	1 out of 10	raise arm 78 deg	NA	able to put shirt on	"This is the best I can remember feeling!"
		5/1/2006	1 out of 10	raise arm 78 deg	NA	able to dress entire body	"I am not sure this can get any better"

Pt seen for 5 weeks 15 treatments. Pt made remarkable progress in this short time period and was able to return home from ALF to family up north where she didn't need as much help.

Patient	Diagnosis	Treatment Dates	Pain	Flexibility	Sensation	Function	Patient Comments
12	knee pain after surgery	7/4/2005	8 out of 10	bend knee 110 deg	no sensation 4" around kneecap	NA	"My knee hurts more than I thought it would"
		7/11/2005	5 out of 10	bend knee 111 deg	sensation returned around knee	NA	"I didn't need pain pills this morning!"
		7/18/2005	3/4 out of 10	bend knee 114 deg	sensation 100% still remains	NA	"The pain is almost gone- this is great!"
		7/25/2006	1 out of 10	bend knee 120 deg	0% sensation	NA	"I don't need my pain pills anymore!"

Pt seen for 4 weeks 12 treatments. Pt was having difficulty with her pain following knee surgery in which it was hindering her progress in therapy. Anodyne treatments allowed for her to be able to tolerate the much needed aggressive knee therapy to return to her hobbies of golf and dancing.

13	shoulder arthritis	7/18/2005	6 out of 10	NA	NA	needing help to dress	"I have hired someone to help me get dressed"
		7/25/2005	4 out of 10	NA	NA	still needing help to dress	"When is this supposed to help?"
		8/1/2005	2/3 out of 10	NA	NA	able to buttons shirt	"I don't need the help and I can do other things"
		8/8/2005	(at most) 2/10	NA	NA	Independent in dressing	"I don't have any pain and I can open my door"

Pt seen for 4 weeks 12 treatments. Pt was receiving ultrasound and electrical stimulation for 5 weeks prior to using Anodyne treatment. Within 12 treatments pt's progress was significantly improved with minimal to no pain and no longer needed the assistance of a private duty aide to assist her in dressing and other daily activities pt was limited in doing.

14	compression fractures	3/2/2006	10 out of 10	NA	NA	unable to walk 15'+	"I am in so much pain, I cant do anything"
		3/9/2006	8 out of 10	NA	NA	able to walk 30'	"My back does not hurt like it used to."
		3/16/2006	6 out of 10	NA	NA	gets out of bed herself	"I cant believe I can do some things again"
		3/23/2006	4 out of 10	NA	NA	able to walk 75'+ indep	"I am able to walk and do the little things I used to"

Pt seen for 4 weeks 12 treatments. Pt is a nursing facility resident and was needing more assistance and was not able to walk to the dining room for all meals like she used to. Her pain really limited her quality of life. within her living environment.

15	pubic fracture	8/7/05	8 out of 10	NA	NA	walks with assistance	"I hurt so bad I don't want to move at all"
		8/15/2005	6 out of 10	NA	NA	walks slow about 15'	"I hope this helps me some more"
		8/22/2005	4 out of 10	NA	NA	tolerating more activity	"I still hurt but not as bad as I did a few weeks ago"

Pt seen for 3 weeks 9 treatments. Pt was making progress with decreased complaints of pain and was gaining more movement. Patient was sent to hospital for other unrelated diagnosis.

16	frozen shoulder	7/1/2005	8 out of 10	arm out to side 70 deg	NA	unable to comb hair	"I am not able to get myself ready in the morning"
		7/8/2005	8 out of 10	arm out to side 75 deg	NA	no change	"I am not feeling any different does this thing work?"
		7/15/2005	5 out of 10	arm out to side 78 deg	NA	able to put shirt on	"I am combing my hair and my pain is less!"
		7/22/2005	1to 2 out of 10	arm out to side 80 deg	NA	gets ready be herself	"I cant believe this I feel so much better"
		7/28/2005	0 to 2 out of 10	arm out to side 90deg	NA	combs entire head of hair	"I don't remember the name of this thing but it is great!"

Pt seen for 5 weeks 15 treatments. Pt went from being unable to perform such tasks as combing her hair and getting dressed due to her pain and stiffness in her shoulder to being move her arm freely with minimal to no pain at all.

17	peripheral neuropathy	1/30/06	6 out of 10	NA	no sensation in forefoot/bigtoes	walks 75' loss of balance	"I don't feel anything on the bottom of my feet & the pain is so great I cannot sleep at night."
		2/6/2006	4 out of 10	NA	no sensation in forefoot/bigtoes	walks 100' loss of balance	"My pain feels less and I can walk more, but I still cannot sleep through the night."
		2/13/2006	3 out of 10	NA	sensation noted in forefoot	walks 200' fair balance	"I can feel my feet, but not my big toes and I am sleeping better through the night."
		2/20/2006	2 out of 10	NA	sensation noted in big toes too	walks 300' good balance	"I am sleeping through the night and do not want to feel like that again."
		2/27/2006	0 out of 10	NA	all sensation regained in both feet	walks over 500'	"I haven't felt like this in at least 10 years"

Pt seen for 5 weeks 15 treatments. Pt's return of sensation and decreased complaints of pain was significant. Pt was able to sleep through the night and improved his balance with walking with return of sensation."

Patient	Diagnosis	Treatment Dates	Pain	Flexibility	Sensation	Function	Patient Comments
18	both shoulders arthritic	7/5/2005 7/13/2005 7/22/2005 7/29/2005 8/5/2005	7 out of 10 5 out of 10 2 out of 10 1to2 out of 10 0 out of 10	raise arm 75 deg raise arm 80 deg raise arm 130 deg raise arm 140 deg raise arm 150 deg	NA NA NA NA NA	unable to dress self assisting with dressing dresses self propels wheelchair independent status	" I hope this does something for my pain" " It is helping me already" "My pain is just melting away" " I didn't think my pain could be helped like this" No more pain and doing things all by myself"

Pt seen for 5 weeks 15 treatments. Pt was suffering from pain which resulted in lack of movement in both shoulders. Pt made great progress and regained her independence.

19	fractured humerus	2/20/2006 2/28/2006	7to10 out of 10 2to3 out of 10	arm in immobilizer arm movement started	NA NA	Unable to move arm gentle movements	" What will this do for me?" " I cannot believe the pain has gone way down so quick"
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Pt seen for 2 weeks 6 treatments. Pt was making noticeable improvements with decreased complaints of pain in her shoulder. Pt moved up north with her family where she is contacting the nearest anodyne treatment facility.

20	peripheral neuropathy	4/3/2006 4/10/2006	NA NA	NA NA	no sensation in heels and toes heel sensation returns	walks 100' w/walker walks 200' w/cane	" I use this walker because I tend to lose my balance because I can't feel my toes or heel." " I would never think I could use a cane and feel something in my heels."
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Pt seen for 2 weeks 6 treatments. Pt was making excelerated progress, and was discharged to her home with a home health company who also uses anodyne therapy treatments to continue her remarkable progress. Pts. Goal to be able to walk without the use of a cane.

21	fibromyalgia	6/27/2005 7/1/2005 7/8/2005 7/15/2005 7/20/2005	6 out of 10 4 out of 10 2 out of 10 1 out of 10 0 out of 10	NA NA NA NA NA	NA NA NA NA NA	walks 30' w/pain walks 50' w/dec.pain walks 100'w/lesspain walks 100'+ lesspain walks w/no pain	"I have to have all my meals sent to my room" "I still cant go to the dining room for meals" "I went to the dining room today!" "I am doing better everyday" " I have no pain anymore and I am sleeping better" "THANK YOU!"
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Pt seen for 5 weeks 15 treatments. Pt made significant progress and pain no longer exists at all. Patient walks to the dining room and is sleeping better at night with anodyne treatments.

22	neuropathy of both lower legs	8/1/2005 8/8/2005 8/15/2005 8/22/2005 8/29/2005	10 out of 10 8 out of 10 6 out of 10 4out of 10 0 out of 10	NA NA NA NA NA	lack of sensation feet/calves some sensation noted in calves some sensation noted in feet more sensation noted sensation restored feet/calves	walks 20' balance probs walks 50'less pain walks 75' less pain walks 200'less pain walks 400'+no pain	"I don't have good feeling in my feet." "I seem to feel something in my calves now" "I am starting to feel my feet" "This is truly amazing" "I am able to feel my feet and calves and I am able to walk anywhere I want to without losing my balance and no pain!"
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Pt seen for 5 weeks 15 treatments. Pt fully regained all sensation in calves and both feet. Able to walk out in community again and is totally pain free.

23	arthritic knee pain	1/30/2006 2/7/2006	6 out of 10 3 out of 10	NA NA	NA NA	10w/pain 15w/ less pain	"I hurt" "It is better but I am still sore"
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Pt seen for 2 weeks 6 treatments. Pt was showing signs of decreased pain in the knee and was slowly able to walk further, then was discharged to the hospital for unrelated conditions.

24	pain/stiffness both shoulders	2/6/2006 2/13/2006 2/20/2006 2/27/2006	7 out of 10 7 out of 10 5 out of 10 5 out of 10	NA NA NA NA	NA NA NA NA	pain limits abilities pain limiting abilities still pain limits abilities pain still limits abilities	"I have hurt for years" " I don't feel any better" " I only feel some relief" " I don't feel much better and I don't want this anymore"
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pt seen for 4 weeks 12 treatments. Pt was showing signs of decrease of pain his shoulders, but opted not to continue coming to therapy for further anodyne treatments.