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INTRODUCTION:

This study is being done because post amputation pain (PAP) is common, yet very little is known about the causes of this pain. The purpose of this study is to see how PAP affects the body and brain by using sensory testing (such as pinprick testing), taking pictures of your brain (using a functional magnetic resonance imaging (fMRI) machine) and biomedical interventions (such as an injection of pain medicine). We hope that by learning the causes of PAP, we can help future amputees.

BODY:

Several new recruitment methods were enacted during this year. A plan was developed at the beginning of the year for the conception and development of the Amputee Registry was completed during this year. The registry allows us a tool in which to find through in that there is no criteria to be a part in it. We have used it to recruit at prosthetic clinics and start a collaboration with Schwab Rehabilitation Institute although nobody has been included for the study as of yet. to start reaching out and building collaborations with prosthetic clinics as well as clinicians that treat those with amputations. Attendance to the Amputee Coalition of Chicago (at the Rehabilitation Institute of Chicago) occurred to educate people about the study and recruit. During the meeting a presentation was made on the project and those interested gave their information. We worked with the marketing department to ensure that flyers were put up in all departments of the hospital. Marketing also gave some suggestions for details about how to grab people's attentions with design and how to target audience etc. Flyers and letters went out to clinics that were posted. Research assistants have been also attending clinics at RIC to recruit for subjects every week, twice a week. We have developed an inclusion/exclusion card for physicians to carry around so it is easier for them to recruit if study coordinators are not available. We have 7 completed and 10 enrolled. 3 did not make it through the entire study. We have screened 40 potential subjects. The goal for next year is to recruit more subjects and complete subjects. For the next quarter the goal is to have several more participants that have completed the study, and several more screened in order to reach our goal of 36 completers. The recruitment plan will also include continuing phone screens and visiting clinics to recruit participants

An efficient and systematic approach to the scheduling between Dr. Rho (injection in the neuroma), Dr. Hendrix (injection in the lower back), the fMRI scanners, Dr. Farmer, and participants has been put into place. Training was completed on 10/08 by Amy Kirsling on how to use the fMRI machines. Additional training will be acquired as well. On 12/5 modifications for the Northwestern IRB continuing review were required and on 12/9 the

continuing review was submitted. On 12/19 the approval letter was ready and sent to DOD on 12/28. Stipends for participants by Northwestern University were a logistical challenge at first as far as the timing of when to give them to participants and were worked out to be given to the participants in a timely and efficient manner. Invoices for the fMRI scans have had to be signed by the Principal Investigator to ensure that all time has been used efficiently with the scanners. The updating of clinicaltrials.gov along with all other necessary updates through Northwestern University such as eNOTIS has been completed. During this year the research team actively worked to ensure consistency with all forms and equipment necessary for the experiment and is consistently double checking them for consistency. A meeting was held to ensure the blind is secured and up to date, the blind is consistently checked to make sure it is secure and up to date. The blind is currently being kept in a safe and locked place by a neutral party. There is additional copy of it saved and locked in a different location as well. During this year the he data base was built and data were rechecked and cleaned, and will be rechecked and then sent off to John Burns to look over. The database was revised to portray one of the questionnaires more efficiently. An analysis of the fMRI data is currently being done. A meeting was held to talk about the interim analysis and a plan was put into place. An interim analysis will be planned after there are more completions of the study by participants.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research

- Analysis completed for fMRI images
- Recruitment techniques revisited and plan has been made to recruit more subjects to reach 36
- Coordination of all teams and equipment to refine experiment
- Recruited subjects
- 40 phone screenings completed
- 7 subjects have finished the whole protocol
- 10 enrolled subjects

REPORTABLE OUTCOMES: Analysis of fMRI images as well as a case series done on subjects who have had a lower back injection.

CONCLUSION: As soon as a few more subjects complete the study we will complete an interim analysis. Recruitment is the top priority for this year and completion of more subjects.

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APPENDICES:

CES-D 10

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

0= Rarely or none of the time (less than 1 day)

1= Some or a little of the time (1-2 days)

2= Occasionally or a moderate amount of time (3-4 days)

3= Most or all of the time (5-7 days)

1. I was bothered by things that usually don't bother me.	0	1	2	3
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2. I had trouble keeping my mind on what I was doing.	0	1	2	3
---	---	---	---	---

3. I felt depressed.	0	1	2	3
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4. I felt that everything I did was an effort.	0	1	2	3
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5. I felt hopeful about the future.	0	1	2	3
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6. I felt fearful.	0	1	2	3
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7. My sleep was restless.	0	1	2	3
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8. I was happy.	0	1	2	3
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9. I felt lonely.	0	1	2	3
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10. I could not get “going.”	0	1	2	3
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Time	Event Description	Phantom Limb Pain NRS Rating 0-10	Residual Limb Pain NRS Rating 0-10
	Pre-Injection		
	Injection Type: Neuroma or Symp Block	n/a	n/a
	15 min post-injection		
	1 hour post-injection		
	2 hours post-injection		
	3 hours post-injection		
	4 hours post-injection		
	5 hours post-injection		
	6 hours post-injection		
	7 hours post-injection		

PASS

Individuals who experience pain develop different ways to respond to that pain. We would like to know what you do and what you think about when in pain. Please use the rating scale below to indicate how often you engage in each of the following thoughts or activities. Circle any number from 0 (NEVER) to 5 (ALWAYS) for each item.

		<u>NEVER</u>					<u>ALWAYS</u>				
1.	I think that if my pain gets too severe, it will never decrease	0	1	2	3	4	5				
2.	When I feel pain I am afraid that something terrible will happen.....	0	1	2	3	4	5				
3.	I go immediately to bed when I feel severe pain	0	1	2	3	4	5				
4.	I begin trembling when engaged in activity that increases pain.....	0	1	2	3	4	5				
5.	I can't think straight when I am in pain	0	1	2	3	4	5				
6.	I will stop any activity as soon as I sense pain coming on	0	1	2	3	4	5				
7.	Pain seems to cause my heart to pound or race.....	0	1	2	3	4	5				
8.	As soon as pain comes on I take medication to reduce it.....	0	1	2	3	4	5				
9.	When I feel pain I think that I may be seriously ill.....	0	1	2	3	4	5				
10.	During painful episodes it is difficult for me to think of anything else besides the pain.....	0	1	2	3	4	5				
11.	I avoid important activities when I hurt.....	0	1	2	3	4	5				
12.	When I sense pain I feel dizzy or faint	0	1	2	3	4	5				
13.	Pain sensations are terrifying	0	1	2	3	4	5				
14.	When I hurt I think about the pain constantly.....	0	1	2	3	4	5				
15.	Pain makes me nauseous (feel sick)	0	1	2	3	4	5				
16.	When pain comes on strong I think I might become paralyzed or more disabled	0	1	2	3	4	5				
17.	I find it hard to concentrate when I hurt.....	0	1	2	3	4	5				
18.	I find it difficult to calm my body down after periods of pain.....	0	1	2	3	4	5				

19.	I worry when I am in pain.....	0	1	2	3	4	5
20.	I try to avoid activities that cause pain.....	0	1	2	3	4	5

CES-D 10

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

0= Rarely or none of the time (less than 1 day)

1= Some or a little of the time (1-2 days)

2= Occasionally or a moderate amount of time (3-4 days)

3= Most or all of the time (5-7 days)

1. I was bothered by things that usually don't bother me.	0	1	2	3
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2. I had trouble keeping my mind on what I was doing.	0	1	2	3
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3. I felt depressed.	0	1	2	3
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4. I felt that everything I did was an effort.	0	1	2	3
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5. I felt hopeful about the future.	0	1	2	3
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6. I felt fearful.	0	1	2	3
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7. My sleep was restless.	0	1	2	3
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8. I was happy.	0	1	2	3
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9. I felt lonely.	0	1	2	3
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10. I could not get “going.”

0 1 2 3

NRS Data Collection Form

Time	Event Description	Phantom Limb Pain NRS Rating 0-10	Residual Limb Pain NRS Rating 0-10
	Pre-Injection		
	Injection Type: Neuroma or Symp Block	n/a	n/a
	15 min post-injection		

	1 hour post-injection		
	2 hours post-injection		
	3 hours post-injection		
	4 hours post-injection		
	5 hours post-injection		
	6 hours post-injection		
	7 hours post-injection		

PASS

Individuals who experience pain develop different ways to respond to that pain. We would like to know what you do and what you think about when in pain. Please use the rating scale below to indicate how often you engage in each of the following thoughts or activities. Circle any number from 0 (NEVER) to 5 (ALWAYS) for each item.

NEVER

ALWAYS

21.	I think that if my pain gets too severe, it will never decrease	0	1	2	3	4	5
22.	When I feel pain I am afraid that something terrible will happen.....	0	1	2	3	4	5
23.	I go immediately to bed when I feel severe pain	0	1	2	3	4	5
24.	I begin trembling when engaged in activity that increases pain.....	0	1	2	3	4	5
25.	I can't think straight when I am in pain	0	1	2	3	4	5
26.	I will stop any activity as soon as I sense pain coming on	0	1	2	3	4	5
27.	Pain seems to cause my heart to pound or race.....	0	1	2	3	4	5
28.	As soon as pain comes on I take medication to reduce it.....	0	1	2	3	4	5
29.	When I feel pain I think that I may be seriously ill.....	0	1	2	3	4	5
30.	During painful episodes it is difficult for me to think of anything else besides the pain	0	1	2	3	4	5
31.	I avoid important activities when I hurt.....	0	1	2	3	4	5
32.	When I sense pain I feel dizzy or faint	0	1	2	3	4	5
33.	Pain sensations are terrifying	0	1	2	3	4	5
34.	When I hurt I think about the pain constantly.....	0	1	2	3	4	5
35.	Pain makes me nauseous (feel sick)	0	1	2	3	4	5
36.	When pain comes on strong I think I might become paralyzed or more disabled	0	1	2	3	4	5
37.	I find it hard to concentrate when I hurt.....	0	1	2	3	4	5
38.	I find it difficult to calm my body down after periods of pain.....	0	1	2	3	4	5
39.	I worry when I am in pain.....	0	1	2	3	4	5
40.	I try to avoid activities that cause pain.....	0	1	2	3	4	5

SUPPORTING DATA: N/A (it is too early in the protocol to begin an interim analysis but this will be a future goal).