Treatment of Hallux Rigidus with Synthetic Hemiarthroplasty versus Cheilectomy: A randomized controlled trial

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Project Summary:

Arthritis of the first metatarsophalangeal joint, otherwise known as hallux rigidus, is a common medical condition affecting approximately 2.5% of patients over the age of 50. [1] It is a progressive disorder that leads to pain, stiffness and altered gait mechanics. While non-operative management can be successful in some patients, many will undergo symptomatic worsening that can lead to the discussion of surgical intervention. While there are multiple surgical options available, Cheilectomy has become common practice for lower grade hallux rigidus, with arthrodesis (joint fusion) being common practice for higher grade hallux rigidus. There has been a push for additional options, however, to achieve adequate pain control, with maintenance of joint motion. Multiple joint replacement type procedures have been introduced with varying levels of success. The recent introduction of a polyvinyl alcohol implant called Cartiva, has been quite promising. Multiple studies have shown the safety and efficacy of this implant used in patients with moderate and high-grade hallux rigidus. Both 2 and 5 year follow up studies have shown continued improvement in pain relief and quality of life scores, with minimal negative side effects. [2,3] However, the primary outcome measures in studies up to this point have compared results between patients undergoing Cartiva implant vs. those undergoing arthrodesis. At the time of this writing, there has yet to be any investigation into patient results following cheilectomy versus Cartiva implant. While both procedures are indicated for patients with grade 2 hallux rigidus, there has not been a randomized clinical trial performed to compare these two procedures in a cohort of patients with grade 2 hallux rigidus. Furthermore, there is no data at this time as to patient characteristics that would make them a better candidate for one procedure or the other.

Background and Significance:

Hallux Rigidus is a common disorder that affects an estimated 1 in 40 people over the age of 50.[4] While debate remains about the primary cause of this disorder, it is likely multifactorial with contributing factors including previous trauma, malalignment and underlying genetic influences.[5] Regardless of the cause, the disorder can become progressive and significantly impact a patient's quality of life. Common symptoms include pain, swelling and limited range of motion. Patients often present with pain dorsally over the first metatarsophalangeal (MTP) joint secondary to osteophyte formation and swelling. This can restrict range of motion at this joint, as well as make daily activities, such as wearing closed-toed shoes, quite difficult.[6] Furthermore, continued pain can lead to gait abnormalities with more weight bearing through the lateral aspect of the foot and potential transfer metatarsalgia.[7]

Along with physical exam to identify first MTP range of motion, joint swelling, erythema and palpable osteophyte formation, radiographic evaluation is part of the standard of care in hallux rigidus evaluation. Coughlin and Shurnas proposed a grading system that has become widely used, based on the radiographic findings and range of motion at the MTP joint.[8] The grading system allowed clinicians to characterize patients from grade 0-4, helping guide treatment decisions.

Initial treatment is centered on pain relief with non-operative modalities. Modified shoe wear, custom orthotics with a Morton extension and activity modifications have all been shown to improve symptoms in some patients.[7] For patients that fail non-operative therapies, a wide array of surgical options exist. For patients with Grade 1 and 2 hallux rigidus, joint sparing procedures have

been primarily used, with the most common procedure being Cheilectomy. The Cheilectomy procedure involves removal of the dorsal osteophytes and 20-30% of the dorsal metatarsal head.[3] The benefits of this procedure include the ability to improve joint mobility, while still leaving the potential for future fusion. Success rates have been reported between 72% and 100% in patients with grade 1 and 2 hallux rigidus.[7]

Joint fusion has become common place in the treatment of advanced stage hallux rigidus, including grade 3 and 4. High fusion rates and patient satisfaction has been proven with fusion procedures in the first MTP joint.[7] However, the loss of motion at the first MTP joint associated with the fusion procedure can interfere with activities such as running and jumping, and can make shoe wear choices difficult[2]. These limitations led to the push for development of a joint replacement procedure, allowing for pain control and continued motion.

The use of silicone-based joint replacement has been met with mixed results, however concerns over the durability leading to implant fracture, osteolysis and difficulty of revision procedures has ultimately limited its use.[9] Ceramic implants were found to have good short-term results, however concerns remain regarding the large amount of subsidence seen in follow up, as well as potential osteolysis[10]. Furthermore, the amount of bone stock remaining following this procedure could make revision procedures quite challenging. Given these mixed results, there remained a significant drive to identify a joint replacement-type procedure with a device that could maintain adequate bone stock, preserve motion and withstand the daily stresses the first MTP joint faces.

This led to the use of the Cartiva implant, a polyvinyl alcohol hydrogel implant. Following extensive safety and wear testing, it was determined that this implant would be well suited for use in patients with hallux rigidus. Indicated for grade 2, 3 and 4 hallux rigidus, the initial study of Cartiva effectiveness compared outcomes of the implant versus arthrodesis. The prospective, randomized control trial evaluated 202 patients, with over 2/3 undergoing the Cartiva procedure.[2] Both short and midterm outcomes were very promising. 5-year revision rates were found to be 5% with no evidence of implant loosening or surrounding bone complication.[11] Additionally, the Cartiva implant was found to be equivalent to the gold standard, arthrodesis, when it came to post-operative patient outcome scores, range of motion and complications.[2]

With promising results from initial clinical trials, further evaluation into the efficacy and indications for Cartiva is necessary. To date, there is no published literature comparing Cheilectomy to Cartiva. Both procedures have shown to have beneficial results in patients with grade 2 hallux rigidus, yet these two procedures have not been directly compared in clinical trials since the invention of the Cartiva. With an estimated revision rate around 9% following Cheilectomy, it is possible that Cartiva could decrease the need for additional procedures.

Specific Aims/Study Objectives:

The major hypothesis of this study is that patient outcomes following Cartiva implantation will be non-inferior to those undergoing cheilectomy for patients with grade 2 hallux rigidus. Results will include the FAAM ADL and Sport Subscores, SF-36 scores, Visual analog pain scores and peak active dorsiflexion in the 2 patient populations. Additional results will include secondary

surgeries and adverse events. These will be evaluated pre-operatively and then post operatively at 2 weeks, 6 weeks, 3 months, 1 year and 2 year follow up. The 2 year follow up visit will be the primary end point of the study.

The primary objective of this study will be to evaluate the Cartiva procedure compared to the Cheilectomy with the above stated patient reported outcomes and physical exam measures. These two procedures are both indicated for the patient population selected in this study, however post-surgical results have never been compared to one another in current literature. The secondary objective will be to identify subsets of the study population which may be better suited for one of the two procedures. Through statistical analysis, we will attempt to identify patient variables that may impact the surgical response. This will allow surgeons to appropriately counsel their patients on which procedure they would benefit from.

Research Designs and Methods:

The study will include patients with grade 2 hallux rigidus using the grading system described by Coughlin and Shurnas.[8] Inclusion criteria will involve patients older than 18 and less than 88 years of age. These patients will have the ability to perform the questionnaires and will complete the informed consent process. Exclusion criteria will include patients with the diagnosis of gout or inflammatory arthropathy, those with inadequate bone stock of the 1st MTP joint (large bone cyst >1 cm, avascular necrosis), allergy to polyvinyl alcohol, anyone who is pregnant, anyone unable to commit to follow up appointments and patients with significant medical comorbidities that make them unsuitable for elective surgery. Subjects will be identified as having grade 2 hallux rigidus during a clinic visit with one of 3 fellowship trained foot and ankle orthopedic surgeons. After discussion of operative and non-operative interventions, patients will have the ability to decide to pursue surgery. If a patient decides to pursue surgical intervention, they will then be informed of the study. No additional subject recruitment will be performed.

Once a patient has agreed to take part in the study and has signed the informed consent, we will obtain baseline information from their medical records. This information will include gender, age, body mass index (BMI), smoking status, and prior 1st MTP joint procedures. At the patient's initial consultation visit (screening visit), their hallux rigidus grade will be defined by one of the 3 fellowship trained foot and ankle orthopedic surgeons based on the grading system from Coughlin and Shurnas.[8] Patients will then be block randomized, by Department of Orthopedics and Rehabilitation statistician, into either one of the two treatment groups. Blocks will be 4 or 6 subjects in size to ensure balance in the two treatment arms across the duration of the study. The standard of care surgical treatment options are either Cartiva hemiarthoplasty or cheilectomy, and are the same for this study. Typically, a surgeon would have an informed discussion with the patient, listing the risks and benefits of each procedure and allow the patient to determine which procedure they would like to pursue. However, for the purpose and specific aims of this study, patients will be randomized into one of the two treatment options. Brief descriptions of the procedures are provided below:

Cartiva hemiarthroplasty: The procedure starts with a small incision over the top of the 1st MTP joint. The joint is exposed. Bone spurs on the metatarsal and proximal phalanx are resected, leaving approximately 2 mm of surrounding bone on the metatarsal head. A guide pin is placed within the

metatarsal and a drill is then used to create a site for the implant. The implant is then placed using the implant introducer. The incision is then closed and a sterile dressing is placed.

Cheilectomy: A small incision is made over the top of the 1st MTP joint. The joint is exposed. Bone spurs on the metatarsal and proximal phalanx are resected. The top of the metatarsal head is then cut with a saggital saw. Additional bone spurs are resected. The incision is closed and a sterile dressing is placed.

Primary study data will be collected both pre-operatively at the patient's initial consultation visit and then again at post-operative visits at 2 weeks, 6 weeks, 3 months, 1 year and 2 years. This study data will include the following: Active peak dorsiflexion of the first MTP joint, SF-36 score, Visual analog pain score (VAS) and FAAM. This will be recorded on the attached Data Collection Form at each visit. The VAS will be performed by providing patient's with a 10 cm line and having them mark on the line where they would rate their daily pain in their 1st MTP joint.[12] That distance from the beginning of the line will then be measured in millimeters to identify the patient's VAS score. The patient's active peak dorsiflexion will be measured in clinic with a goniometer with the patient standing and weight bearing on their operative foot. The Medical Outcomes study Short form (SF-36) has been validated and thoroughly tested for a wide range of medical conditions, including ankle arthritis, to monitor patient symptoms and responses to treatment.[13] The questionnaire focuses on both the mental and physical aspects of a certain condition to generate composite score. The score provides the opportunity to compare patient outcomes prior to and following their surgical intervention, as well as track their progress throughout the recovery process. Finally, the Foot and Ankle Ability Measures (FAAM) questionnaire will be collected at the above stated time points. This measure has been validated for subjects with foot and ankle musculoskeletal disorders. It has also been shown to be more responsive to changes in physical functioning than the SF-36 score.[13] At each follow up visit, the patient will be evaluated for any adverse events. If an adverse event is identified, an adverse event form (attached) will be completed. All of the above will apply to the 2 week visit, except for the administration of questionnaires/surveys. Additionally, subjects will have incision check, suture removal, and a physical completed during this visit.

Following completion by the patient at each clinical visit, the Data Collection Form will be stored in the physician's secured office in a specified folder. Dr. Andrew Brooks will collect the hard copy Data Collection Forms and questionnaires and enter them into the Department of Orthopedics and Rehabilitation's REDCap Database. After data entry, the Data Collection Forms will then be stored in a secure location through the Department of Orthopedic Surgery research division, where it will be held for 7 years.

When it comes to study timeline, a patient will be given the opportunity to enroll in the study at their initial consultation visit with one of the three board certified foot and ankle surgeons. If a patient has been diagnosed with Grade 2 hallux rigidus and is a surgical candidate, they will be given the opportunity to enroll in the study. If the patient desires to participate in the study, data will be collected from them at their initial consultation visit as described in the Data Collection Form. They will then undergo surgical intervention based on their randomization. Following surgery, they will follow up in clinic at 2 weeks, 6 weeks, 3 months and 1 year following surgery. These follow up visits are standard of care and would occur regardless of patient participation in

the study. At each visit, standard of care radiographs will be taken to evaluate the first MTP joint and the VAS, SF-36 and FAAM-ADL and Sports questionnaires will be completed specifically for research. The final study visit will be at 2 years post-surgery with final radiographs and questionnaires.

	Screening	Surgery	Week 2	Week 6	Month 3	Year 1	Year 2
Informed Consent	X						
Demographics and Medical/Surgical History	X						
Data Collection Form			X	X	X	X	X
Review of Imaging			X	X	X	X	X
Physical Exam			X	X	X	X	X

Data Safety and Monitoring Plan:

As seen in previous literature, both the Cheilectomy and Cartiva hemiarthroplasty procedures are relatively low risk. Furthermore, both procedures are indicated for patients with Grade 2 Hallux Rigidus. In the study done by Baumhauer et al, 9% of patients in the Cartiva group required implant removal and revision to a MTP joint fusion.[2] All cases were due to persistent pain following Cartiva implant, with no evidence of significant bone loss or implant wear. Additionally, all cases of revision were successfully revised to an arthrodesis without complication.[2] Additionally, there is an estimated 8-10% revision rate following Cheilectomy, with revision to arthrodesis being the common procedure.[14] For this study, the primary surgeons will use their clinical judgement to determine if a patient will require a revision procedure if they have persistent pain following their initial surgery.

Andrew Brooks, surgical resident in the Department of Orthopedic Surgery will be responsible for the monitoring of this data, under supervision from the PI, Dr. Kurt Rongstad. We plan to assess our data and do a primary study evaluation when our enrollment has reached 25% of our stated enrollment goal. Unanticipated problems, adverse events, protocol deviations and violations will be reported to the IRB within 14 days following.

If, at the point of initial evaluation (25% of targeted enrollment), there is a higher than expected complication rate in either treatment arm, the study will be postponed at that time for further evaluation and possible discontinuation.

In the case that our initial evaluation shows negative results and occurs prior to a continuing review, we will contact the IRB with the information and seek to reevaluate or possible discontinue the study. All study team members have completed relevant training materials, are well versed in maintaining clinical integrity and data validity, and will be formally instructed in the

proper application of this protocol. Data/images will be evaluated by the PI, Dr. Kurt Rongstad, as well as Dr. Ronald Guiao and Dr. Kathryn Williams, study team members. This data will be passed to Dr. Andrew Brooks, whereupon it will be stored securely as outlined in the Data and Record Keeping section of our protocol."

Statistical Considerations:

The primary hypothesis of the study is to show that long term (2 year) functional outcomes for those undergoing Cartiva are no worse than the long term functional outcomes for those undergoing Cheilectomy. The primary outcome is the FAAM – ADL subscore from baseline to 2 years post-surgery. The MCID of FAAM-ADL is 8 units and we assume the SD of the difference in FAAM – ADL from baseline to 2 years post-surgery is near 17 units. To have 80% power in a non-inferiority test under these assumptions, we would need to recruit 57 subjects per group. For those subjects that are lost-to-follow-up or have a subsequent surgery we will impute the missing 2 year follow-up value in two ways: 1) by LOCF (last observation carried forward) and 2) by mean 2 year follow-up value for those in the same surgical group. We will then examine results from both method as a sensitivity analysis of our imputation method. To further, assist in ensuring enough patients in each group we will inflate our sample size to 60 per group for a total of 120 patients.

Primary analyses will follow the ITT principle and be based on changes in outcomes from baseline to 2 years follow-up between the two randomized groups. Statistical testing for primary analyses will consist of non-inferiority t-tests between the two groups for each numerical outcome. Secondary analyses will consist of similar non-inferiority t-tests between the two groups but at differing follow-up time points (i.e. 3 months, 6 months, and 12 months). Rates of secondary surgeries will be estimated for each group and 95% Cis will be calculated. Exploratory comparison analyses, including RM-ANOVA and log-rank survival analysis, will be examined as well to see if there were statistical differences in the various outcomes between groups. These analyses methods will be applied similarly to the secondary outcomes as well. For each patient reported outcome measure, we will use the Minimal clinically important difference (MCID) for each measure. As described above, the MCID for the FAAM-ADL subscore is 8 units. The MCID for the FAAM-Sports subscore is 9 units. The MCID for the SF-36 Physical component is estimated at 2 units for patients with lower extremity osteoarthritis conditions. The MCID for the VAS was found to be -8 mm when evaluating patients with foot pain.[15] Using these values, we will evaluate non-inferiority by comparing the changes from pre-operative results to the results at the described time points. Non-inferiority will be defined as differences that are less than the MCID between the Cartiva and Cheilectomy groups. Furthermore,we will assess whether patient characteristics affected the functional results between the two surgical groups by including a patient characteristic by group interaction into the statistical models.

Data and Record Keeping:

The hard copies of the Data Collection Form and questionnaires will be collected in the respective clinics of the three fellowship-trained orthopedic surgeons participating in the study. Data will be recorded on an SF-36 questionnaire form, an FAAM questionnaire form and a visual

analog scale. These questionnaires will be completed by the patient during their clinical visits. The questionnaire forms will be stored in their locked offices and collected by Dr. Andrew Brooks every month. The data from the questionnaire will then be entered into a secure database. The questionnaire forms will be stored in the University of Wisconsin Department of Orthopedic Surgery research division offices. It will be held there for 7 years. The Data Collection Form attached to this document is an example of the form that the physician will complete at both the preoperative and postoperative patient visits.

Any future research wishing to utilize data from this study will need an IRB approved protocol, before they can access the data.

References

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Data Collection Form

Study ID: _____

Pre-operative Or Post-Operative Visit (How many weeks post op?): _____

Hallux Rigidus Grade: _____

FAAM-Sports Score: _____

FAAM-ADL Score:_____

VAS Score: _____

SF-36 Score: _____

1st MTP Peak Active Dorsiflexion: _____

Pre-Operative Use Only

Gender: _____

BMI: _____

# of Previous 1st MTP Procedures: _____

Current Smoker (Y/N): _____

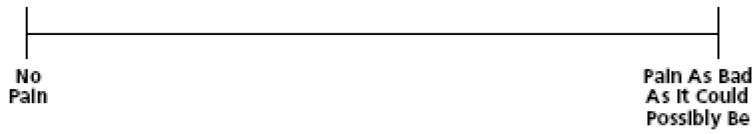
Post-Operative Use Only

Evidence of Radiographic Implant Loosening (Y/N): _____

Evidence of Radiographic Osteolysis (Y/N): _____

Indication for Revision Procedure (Y/N): _____

Visual Analog Scale (VAS)†



Adverse Event Form:

Study ID: _____

Date of AE: _____

Title of AE:

Summary of AE:

Current Status of AE (Resolved, ongoing):

Action Taken Regarding AE:

FAAM Questionnaire

Please Answer **every question** with **one response** that most closely describes your condition within the past week.
If the activity in question is limited by something other than your foot or ankle mark "Not Applicable" (N/A).

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Standing	Δ	Δ	Δ	Δ	Δ	Δ
Walking on even Ground	Δ	Δ	Δ	Δ	Δ	Δ
Walking on even ground without shoes	Δ	Δ	Δ	Δ	Δ	Δ
Walking up hills	Δ	Δ	Δ	Δ	Δ	Δ
Walking down hills	Δ	Δ	Δ	Δ	Δ	Δ
Going up stairs	Δ	Δ	Δ	Δ	Δ	Δ
Going down stairs	Δ	Δ	Δ	Δ	Δ	Δ
Walking on uneven ground	Δ	Δ	Δ	Δ	Δ	Δ
Stepping up and down curbs	Δ	Δ	Δ	Δ	Δ	Δ

Squatting	Δ	Δ	Δ	Δ	Δ	Δ
Coming up on your toes	Δ	Δ	Δ	Δ	Δ	Δ
Walking initially	Δ	Δ	Δ	Δ	Δ	Δ
Walking 5 minutes or less	Δ	Δ	Δ	Δ	Δ	Δ
Walking approximately 10 minutes	Δ	Δ	Δ	Δ	Δ	Δ
Walking 15 minutes or greater	Δ	Δ	Δ	Δ	Δ	Δ

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Home responsibilities	Δ	Δ	Δ	Δ	Δ	Δ
Activities of daily living	Δ	Δ	Δ	Δ	Δ	Δ
Personal care	Δ	Δ	Δ	Δ	Δ	Δ
Light to moderate work (standing, walking)	Δ	Δ	Δ	Δ	Δ	Δ
Heavy work (push/pulling, climbing, carrying)	Δ	Δ	Δ	Δ	Δ	Δ
Recreational activities	Δ	Δ	Δ	Δ	Δ	Δ

How would you rate your current level of function during you usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities.

__ __ __ . 0 %

Martin, R; Irrgang, J; Burdett, R; Conti, S; VanSwearingen, J: Evidence of Validity for the Foot and Ankle Ability Measure. Foot and Ankle International. Vol.26, No.11: 968-983, 2005.

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Running	Δ	Δ	Δ	Δ	Δ	Δ
Jumping	Δ	Δ	Δ	Δ	Δ	Δ
Landing	Δ	Δ	Δ	Δ	Δ	Δ
Starting and stopping quickly	Δ	Δ	Δ	Δ	Δ	Δ
Cutting/lateral Movements	Δ	Δ	Δ	Δ	Δ	Δ
Ability to perform Activity with your Normal technique	Δ	Δ	Δ	Δ	Δ	Δ
Ability to participate In your desired sport As long as you like	Δ	Δ	Δ	Δ	Δ	Δ

How would you rate your current level of function during your sports related activities from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

__ __ __ . 0%

Overall, how would you rate your current level of function?

⌋ Normal Δ Nearly Normal Δ Abnormal Δ Severely Abnormal

Martin, R; Irrgang, J; Burdett, R; Conti, S; VanSwearingen, J: Evidence of Validity for the Foot and Ankle Ability Measure. Foot and Ankle International. Vol.26, No.11: 968-983, 2005.

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

1. In general, would you say your health is:

- 1 - Excellent
- 2 - Very good
- 3 - Good
- 4 - Fair
- 5 - Poor

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2. **Compared to one year ago**, how would you rate your health in general **now**?

- 1 - Much better now than one year ago
- 2 - Somewhat better now than one year ago
- 3 - About the same
- 4 - Somewhat worse now than one year ago
- 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	◯ 1	◯ 2	◯ 3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	◯ 1	◯ 2	◯ 3
5. Lifting or carrying groceries	◯ 1	◯ 2	◯ 3
6. Climbing **several** flights of stairs	◯ 1	◯ 2	◯ 3
7. Climbing **one** flight of stairs	◯ 1	◯ 2	◯ 3
8. Bending, kneeling, or stooping	◯ 1	◯ 2	◯ 3
9. Walking **more than a mile**	◯ 1	◯ 2	◯ 3
10. Walking **several blocks**	◯ 1	◯ 2	◯ 3
11. Walking **one block**	◯ 1	◯ 2	◯ 3
12. Bathing or dressing yourself	◯ 1	◯ 2	◯ 3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
14. **Accomplished less** than you would like	○ 1	○ 2
15. Were limited in the **kind** of work or other activities	○ 1	○ 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	○ 1	○ 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- 1 - Not at all
- 2 - Slightly
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- 1 - None
- 2 - Very mild
- 3 - Mild
- 4 - Moderate
- 5 - Severe
- 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- 1 - Not at all
- 2 - A little bit
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5