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OF NEW JERSEY

Rutgers IRB: PRO2021002151

STUDY INFORMATION

- **Title of Project:**
  Conservative Management of High Ankle Sprains; A Twenty year follow up study
  Rutgers IRB: PRO2021002151

- **Principal Investigator Name**
  Charles J. Gatt, Jr, MD

- **Principal Investigator Div. & Dept.**
  Department of Orthopaedic Surgery, Rutgers, Robert Wood Johnson Medical School]

- **Principal Investigator Contact Info:**
  [cjgatt@rwjms.rutgers.edu]
  [2 World Fair Drive, Somerset, NJ 08873]
  [732-537-0909]

- **Study Coordinator**
  Eric Nussbaum, MEd, LAT, ATC
  Department of Orthopaedic Surgery, Rutgers, Robert Wood Johnson Medical School.
  Email: ericn@uognj.com,
  Cell: 908-300-5833

- **Protocol Version and Date:**
  [v3, 9.9.2022]

Charles J. Gatt, Jr, MD, **PRO2021002151**
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1.0 Research Design

1.1 Purpose/Specific Aims

To determine the impact of a standardized, conservative treatment protocol for the management of "High Ankle Sprain" (HAS) on the well-being of former athletes who suffered a HAS twenty years later.

A. Objectives

Determine the long-term impact of conservative treatment for HAS on the long term function of athletes who suffer a HAS.

B. Hypotheses / Research Question(s)

Hypothesis:

Patients who have suffered a HAS, and who underwent a standardized treatment and rehabilitation program, will express abnormal ankle function as measured by patient reported outcome measures (SEFAS, PROMIS-10, SANE) and note advanced osteoarthritis of the ankle, as measured on Xray at >15 years after injury.

Research Questions:

- What is the long term impact of High Ankle Sprain(HAS) that was treated conservatively with standardized rehabilitation program on ankle function?

- How satisfied are patients who have suffered a HAS and who were treated conservatively with a standardized rehabilitation approach, with their current daily ankle function >15 years following injury?

- What is the long-term incidence of Osteoarthritis in ankles that have suffered a HAS and who were treated conservatively?

1.2 Research Significance (Briefly describe the following in 500 words or less)

High ankle sprains (HAS) involve non-fracture related injury to the ankle syndesmosis HAS are reported to occur in 20%-75% of all ankle sprains in the athletic population. HAS result in functional disability, chronic pain, an increased incidence of re-current ankle sprain, and require more treatment vs lateral ankle sprains. HAS can result in long-term disability and early onset of osteoarthritis. These injuries are generally treated conservatively with the use of immobilization, but more recent treatment recommendations include ankle arthroscopy and use of a "tight rope", suture tape or transcortical screw to stabilize the ankle syndesmosis. Surgical management often results in decreased motion, heterotopic oscification of the interosseus membrane, syndesmotic ligaments which can further impact function. Long term follow up of HAS injuries is lacking from the existing literature and findings from this study may impact the appropriate acute management of HAS for future patients.

1.3 Research Design and Methods

We will attempt to contact athletes who suffered a high ankle sprain and who were conservatively treated utilizing a conservative/aggressive rehabilitation approach. These athletes formally participated in one of two previously published studies (Nussbaum ED, AJSM 2001{n=60}, Nussbaum ED, Poster Presentation, 5th Annual International Ankle Congress 2006 {n=22}) (total n=82) at which time a tenderness length and

disability time was recorded. These potential subjects, will be notified and asked to volunteer to participate in the study. Participants will be asked to complete an online RedCap survey that will include demographics, validated ankle PROMs (SEFAS, and Promis-10.) Participants will also be asked to complete a 4 view standing x-ray series (Bilateral standing AP, 2- Uni-lateral images and a Bilateral Mortise views which will be completed at University Orthopaedic Associates (UOA; Clinical home of PI). Results of online PROM scoring, will be compared with previous notation of tenderness length (height of proximal tenderness on the lower leg), days of initial disability from the original injury. In addition, use of an x-ray evaluation including measurements of joint congruity. (Tibio-talar medial clear space, tibio-fibular overlap, tibio-talar joint space and anterior fibular positioning {Gillman Line}), as well as the occurrence of osteoarthritis will be scored using the Kellgren-Lawrence Score (K-L Score) will be collected and analyzed. Results will be statistically evaluated for variance, correlation and strength of recommendation.

A. Research Procedures

We will attempt to locate participants through the use of directed social media,(Facebook, Twitter) and Rutgers University alumni registry.

Potential participants will be contacted and made aware of the study, and invited to contact the research coordinator (EN) to appraise them about the study, it's risks and benefits. After reading the study protocol, weighing the risks and benefits, and having all their about the study answered, they will complete the RedCap Survey which includes an acknowledgement of their willingness to participate via an electronic signature on the RedCap intake form. Once the acknowledgement is completed, they will complete the demographic information, and ankle PROMs online. They will schedule a time to visit UOA, 2 Worlds Fair Drive, Somerset, NJ to have xrays completed. Appropriate radiation draping will be utilized to minimize radiation exposure. Subjects will be surveyed after completion of the xrays to note any adverse issues from scanning. Results of imaging review (Kellgren-Lawrence; K-L score), and PROMs (PROMIS-10, SEFAS) will be reviewed and compared with initial injury findings. Findings will be statistically analyzed in order to determine the long-term impact of conservative treatment on high ankle sprain (HAS) injury

B. Duration for Study and Each Subject

The duration of the study will be 1-2 years or until all participants have been contacted, enrolled or declined study participation.

1.4 Preliminary Data

Preliminary data would include results of online PROMs and notation of subjects with Osteoarthritis on identified on Xray.

-Results of follow up will be compared with initial injury outcomes (Tenderness length/days of disability)

1.5 Sample Size Justification

We will be working from a list of 82 potential participants. A strong sample would be >70% (54 subjects)

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

- History of any ankle procedure after the HAS
- History of any addition ankle injuries since the HAS
- Patient BMI
- Health issue that would negatively impact activity
- Level of current physical activity
- Original tenderness length
- Original days of disability

B. Dependent Variables or Outcome Measures
- K-L Score
- SEFAS Score
- PROMIS-10 Score

1.7 Specimen Collection

NA

A. Primary Specimen Collection

N/A

B. Secondary Specimen Collection

N/A:
- **Types of Specimens**:
- **Annotation**
- **Transport**:
- **Storage**:
- **Disposition**

1.8 Data Collection

A. Primary Data Collection
- **Location**:
- Data collection will occur via online survey via RedCap. Data will be stored on the University Cloud. Description and acknowledgement to participate in the study will be provided via an online registration/consent process utilizing the RedCap survey tool..
- Digital Xrays will be completed at UOA, 2 Worlds Fair Drive, Somerset, NJ and uploaded into our secure Medstrat imaging server. .

- **Process of Data Collection**:
- After acknowledging to voluntarily participate in the study, study participants will complete the online RedCap survey.. .

- **Timing and Frequency**:
- SurveyData collection will be collected one time during the study. A one- time xray evaluation will be conducted.

- **Procedures for Audio/Visual Recording**:
- N/A.

- **Study Instruments**:
- SEFAS – is a validated Foot and ankle PROM.
- PROMIS 10 – Is a validated, abbreviated assessment of patient well-being.
- K-L Score – Is a validated score for radiographic evaluation of osteoarthritis
-
- **Ethnographic Studies, Interviews, Or Observation**:
- N/A

- **Subject Identifiers**:

- Each participant will be assigned a study number upon agreeing to participate in the study and completing the RedCap Survey tool. Personal identifiers will not be collected for any of the PROMs.

B. Secondary Data Collection

- **Type of Records**:
- Review of initial data sheet from 2000 focusing on original tenderness length measurement and days of initial disability.
- .
- **Location**:
- UOA, 2 Worlds Fair Drive, Somerset, NJ

- **Inclusion/Exclusion**:
- **Inclusion:** Part of the original study population who suffered a HAS that was documented and recorded in one of two published studies.
- **Exclusion**: Not originally part of the study population who suffered a HAS which was treated conservatively utilizing a conservative/aggressive rehabilitation approach.

- **Data Abstraction Form(s):**

1.9 Interviews, Focus Groups, Surveys, and/or Observations – N/A

A. Administration

- **Timing and Frequency**
  Completion of the RedCap Survey will be completed one time online. The time required to complete the survey should be between 5-10 minutes. An appointment will be made with the subject to complete 4 standing xrays (one visit) after they have completed the survey and given their consent to participate in the study.
- **Location**
  Surveys will be hosted online utlilizing a RedCap Survey tool.
- **Procedures For Audio And Visual Recording**
  NA.
- **Person Identifiers**
  NA

B. Study Instruments

- **Evaluation Instrument Details**
  Study Instruments: Self-Assessment Foot Ankle Score (SEFAS)12 questions, PROMIS – 10 (10 questions) and K-L Osteoarthritis Score (based on measurements from xrays) have all been validated (see bibliography) and utilized with patients who have suffered ankle injuries/osteoarthritis. Information gathered from the PROMs, and K-L Score (utilized to determine the extent of ankle Osteoarthritis) will be used to evaluate the pain/function/disability of the subjects.
- **Study Instruments For Ethnographic Studies**
  NA
- **Oral Histories Or Interviews General Framework**
  NA
- **Referral Information**
  If applicable, all problems, including imminent danger or suicide should be reported to the PI or study coordinator.
  .

2.0 Project Management

2.1 Research Staff and Qualifications

PI – has been involved in multiple research projects, Holds an academic position in the Rutgers, RWJMS and is chair of the department of orthopaedic surgery.

Study Coordinator – has been involved in multiple research projects and hold a clinical instructor position in the Department of Orthopaedic Surgery, Rutgers, RWJMS. All study participants have completed CITI training.

UOA Setting – has been utilized for multiple research projects in the past.

2.2 Research Staff Training

NJ Licensed Clinical xray staff will be appraised about the specific views that we will require for the study in order to maintain consistent imaging. All staff performing the xray imaging are licensed and professionally trained and uphold the standards of the State of New Jersey, Board of Medical Examiners.

2.3 Resources Available

Use of appropriate lead draping to minimize scattering impact from radiating energy used to complete the 4 standing xrays.

2.4 Research Sites

All subjects will complete a RedCap survey online and will complete all radiographs at **University Orthopaedic Associates, 2 Worlds Fair Drive, Somerset, NJ 08873**

3.0 Multi Center Research

NA

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Study participants will be selected from an existing list of study participants from 1998-2004 that has been maintained by EN (original author).

B. Recruitment Details

Study team will attempt to contact participants through social media. (Dialogue Uploaded)

C. Subject Screening

NA

- **Inclusion Criteria**
  Patients who participated in the original study (n=82), who suffered a HAS and completed specific conservative treatment for their HAS.
- **Exclusion Criteria**
  Did not participate in original studies.

D. Privacy Protections

Once patients enroll in the study, they will be given a study ID number and no identifiable information will be recorded with data collection.

4.2 Obtaining Identifiable Information About Non-Subjects

NA

4.3 Number of Subjects

A. Total Number of Subjects
Potentially a total of 82.subjects

B. Total Number of Subjects If Multicenter Study
NA

C. Feasibility

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  Online at enrollment. Patients will be contacted and notified about the study and what it details. Potential subjects may opt not to participate. Those who are interested learning more about the study will read the study description, have the opportunity to have questions answered, prior to signing the formal consent online.
- **Ongoing Consent**
  NA
- **Individual Roles for Researchers Involved in Consent**
  EN – Study coordinator – locate and enroll participants utilizing original list of participants from study which was completed in 2000.(Ref article Nussbaum ED, Prospective evaluation of syndesmotic ankle sprains. AJSM 2001)
- **Consent Discussion Duration**
  5 -15 minutes.
- **Coercion or Undue Influence**
  There will be no coercion to enroll partipants.
- **Subject Understanding**
  A supplemental video will be utilized to summarize the basic requirements, risks and procedures of the study. (Video will be embedded in the RedCap Survey tool)
- **Protecting Privacy**
  Personal identifiers will not be connected with survey results and maintained on a secure server maintained in the cloud or secure network.

B. Waiver or Alteration of Consent Process - NA

- **Waiver or Alteration Details**
- **Destruction of Identifiers**
- **Use of Deception/Concealment**
  a. Minimal Risk Justification

  b. Alternatives
  c. Subject Debriefing

C. Documentation of Consent

- **Documenting Consent**
  N/A
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  - Patients will review study design/requirements/ and may have their questions clarified prior to participating in the study. Consent to participate be completed by the subject

an online acknowledgment on the RedCap Survey before they complete any information related to the study.

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  NA
- **Non-Parental Permission**
  NA.
- **Assent Process**
  NA
- **Documentation of Assent**
  NA
- **Reaching Age of Majority During Study**
  NA

B. Enrolling Wards of the State

NA.

- **Research Outside of NJ Involving Minors**

C. Enrolling Non-English-Speaking Subjects

NA.

- **Process for Non-English-Speaking Subjects**
- **Short Form Consent for Non-English Speakers**

D. Enrolling Adults Unable to Consent / Decisionally Impaired Adults

NA

- **Assessing Adult Capacity to Consent**
  NA
- **Selecting a Surrogate & Consent Process**
  NA
- **Subject Assent**
  NA
- **Selecting a Witness to the Surrogate Consent Process**
  NA
- **Removing a Subject**
  Upon notification by the subject, the PI will be notified, and all associated data will be removed from the study collection.

E. Special Consent Considerations

NA

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

Subjects will NOT be charged for radiographic imaging.

B. Compensation/Incentives

Participants will receive a $15 VISA Gift card as a token of our appreciation for participation in the study.

C. Compensation Documentation

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Subject Risks of Harm

There is no more than minimal risk involved with participation in this study. Study participation involves the use of four xrays which does pose a very small risk for radiation exposure.

- **Existing Condition/Disorder**
  No impact
- **Additional Considerations**
- **Minimizing Risks**
  All participants will be appropriately draped w/ radiating protective gear by Xray staff to minimize radiation exposure.
- **Certificate of Confidentiality**
  NA
- **Risks of Harm to Non-Subjects**
  NA

B. Potential Direct Benefits to Subjects

Patients will have a radiological assessment of their ankles and they will be helping to advance the care of HAS.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

NA

5.2 Family Educational Rights and Privacy Act (FERPA)

NA

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

NA

A. Special Populations - NA

5.4 General Data Protection Regulation (GDPR)

NA

5.5 NJ Access to Medical Research Act (Surrogate Consent)

NA

6.0 Data Management Plan

6.1 Data Analysis

All online survey data will be stored onto data sheet via RedCap survey. Data will be analyzed to note any distinguishing trends and statistical testing will be completed by Rutgers University statistics department (RUBIES) to help determine validity of findings. Results of xray findings will be recorded onto recording sheet and then uploaded into HAS spread sheet. Recording sheets will be saved in a bound and secure notebook that will be maintained in a locked and secure cabinet at UOA. Data from the HAS spread sheet and from RedCap will be merged for statistical evaluation.

Planned statistical analyses:

Relevant, previously collected and all new follow-up continuous/numeric study measures will first be summarized using range, mean and standard deviation (SD), and median with interquartile range (IQR), while categorical measures will be summarized using frequency and percentage.

In order to assess how the "tenderness length" and "days of disability/days to return to sport" at the time of initial injury are associated with the 20 year follow-up outcome measures, we plan to use either Pearson or Spearman correlation testing (depending on variable normality) for continuous vs continuous measures, and we will plan to use either t-tests or Wilcoxon Rank Sum tests (depending on variable normality) for continuous vs categorical measures. As needed, continuous measures may be transformed into categories for clearer interpretation of the measurement relationships.

6.2 Data Security

Data will be stored on a password protected spreadsheet which will include no patient identifiers.

6.3 Data and Safety Monitoring

NA

A. Data/Safety Monitoring Plan

Data will periodically be evaluated to determine the function of the RedCap survey by the study coordinator or PI. Issues or concerns will be immediately reported and addressed by the PI and Study coordinator.

B. Data/Safety Monitoring Board Details

NA

6.4 Reporting Results

A. Subject Results Reporting

Results of xrays will be shared with the subjects following a review by the study PI.
. Specific questions about their radiographs will be answered by the PI.

B. Aggregate Results

We will share results with all patients after the data has been analyzed and a formal publication of the results made

C. Professional Reporting

Results will be submitted to a refereed journal for review and publication.

D. Clinical Trials Registration, Results Reporting and Consent Posting

NA

6.5 Secondary Use of the Data

Data that does not contain any personal identifiers will be made available by formal request.

7.0 Research Repositories – Specimens and/or Data

NA

8.0 Approvals/Authorizations

- Non-Rutgers Site
- Radiation safety approval.

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9.0 Bibliography

1) Nussbaum ED, Hosea T, Seiler S, et al, “Prosepective Evaluation of syndesmotic ankle sprains without diastasis”. Am J Sports Med 2001; 29(1):31-5
2) Poster Presentation- Syndesmotic Ankle Sprains among Adolescents; Presented at the 5th Annual International Ankle Congress, JOSPT Cases;JOSPT :March 1, 2013:43(3): A1-A27 https://www.jospt.org/doi/10.2519/jospt.2013.0301
3) Coster MC, “Comparison of the Self-Reported Foot Ankle Score(SEFAS) with the American Orthopedic Foot Society Score (AOFAS)”. Foot Ankle International 2014;35(10):1031-1036
4) Klopas H, “Current Concepts in Osteoarthritis of the ankle”. Surg Technol Int 2019; 10(35):280-294
5) Holzer N, “Radiographic evaluation of posttraumatic osteoarthritis of the ankle: the Kellgren-Lawrence scale is reliable and correlates with clinical symptoms”. Osteoarthritis Cartilage 2015;3: 363-9
6) Kellgren JH, Lawrence JS, Radiological assessment of osteoarthritis. Ann Rheum Dis 1957; 16:494
7) Tourne Y, Diagnosis and treatment of tibiofibular syndesmosis lesions.Orthop Traumatology Surg Research 2019; 105:S275-S286
8) Shah AS, “Radiographic Evaluation of the Normal Distal Tibiofibular syndesmosis”. Foot Ankle International 2012; 33(10):870-876
9) Croft S, Radiographic Evaluation of the Ankle Syndesmosis. Can J Surgery 2015; 58(1):58-62