

## Institutional Review Board Statement

Name of Journal: World Journal of Orthopaedics

Manuscript No: 46153

Manuscript Type: Retrospective Cohort Study

Corrections in alpha angle following two different operative approaches for CAM-type femoral acetabular impingement – Ganz surgical hip dislocation vs anterior mini-open

Emanuel C Haug, Wendy M Novicoff, and Qunjun Cui

Institutional Review Board Statement: This study was reviewed and approved by the University of Virginia Institution Review Board, ID# 18513

Sincerely,



Emanuel Haug

Date **03-04-2019**

Corresponding to:

Qunjun Cui, G.J. Wang Professor of Orthopaedic Surgery and Vice Chair for Research, Department of Orthopaedic Surgery, University of Virginia School of Medicine, Charlottesville, VA 22903, United States. qc4q@hscmail.mcc.virginia.edu



**IMPROVEMENT PROJECT: EXEMPT APPLICATION FORM**

Template Version Date 07/22/15

**INSTRUCTIONS AND INFORMATION**

*Enter responses electronically. Email this completed form and the Protocol Cover Sheet to [IRBHSR@virginia.edu](mailto:IRBHSR@virginia.edu) for IRB Review.*

**IRB-HSR #:18513** (Will be assigned by IRB Staff during pre-review.)

**PI Name:** Quanjun Cui, MD

**PI Email:** [qc4c@virginia.edu](mailto:qc4c@virginia.edu)

**PI Phone #** 434-243-0266

**Name of Person Submitting this form:** Wendy Novicoff, Ph.D.

**Contacts Email** [wmn2v@virginia.edu](mailto:wmn2v@virginia.edu)

**Contacts Phone #** 434-924-9914

**Protocol Title:** Alpha Angle Correction Following Two Different Approaches for Femoroacetabular Impingement – Ganz vs Anterior Mini-Open.

**Version Date:** 10/29/2015

- 1. Provide a brief summary of the completed Improvement Project, a summary of the findings and your plans to share the findings outside of UVa (less than 200 words).** We examined the patients in that Dr. Cui had treated for femoroacetabular impingement (FAI) to compare outcomes following the two surgical approaches that are normally used. All data were collected retrospectively (after treatment decision, surgery, and follow-up had been completed), and no patient's treatment was affected. Our research question was: "Do different surgical approaches (Ganz surgical hip dislocation and the anterior mini-open approach) offer varying magnitudes of alpha angle correction on a lateral view radiograph post-surgery? We found that the change post-surgery in alpha angles for both procedures was significant, and the anterior mini approach led to an overall greater change in alpha angle. Requesting permission to publish data.

**Website:** <http://www.virginia.edu/vpr/irb/hsr/index.html>

**Phone:** 434-924-2620 **Fax:** 434-924-2932 **Box** 800483

**2. I confirm all of the following by checking below:**

- All data was collected from clinical records at UVa for an **Improvement Project** (e.g. *Performance Improvement, Practice Improvement, Quality Improvement*).
- The completed Improvement Project did not involve an interaction/intervention with an individual, including any observation of a minor.
- No data was received from outside of UVa
- If any data was collected from students information governed by the federal FERPA regulations, such as information from Student Health, the Registrar’s Office, the Office of Assessment and Studies, or the Student Information System (SIS) a date of birth was not collected.
- All **HIPAA identifiers\*** as noted in the table below that may have been included in the data from the Improvement Project have now been removed/destroyed from all copies of the data.
- Any data from this project that is shared outside of UVa will only be shared in an aggregate or de-identified manner.

**\*HIPAA identifiers: Limited Data Set criteria per HIPAA under 164.514(e)**

1. Name
2. Postal address information, other than town or city, state, and zip code
3. Age or DOB if over 89 years of age
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security number
8. Medical Record number
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother’s maiden name, first 3 letters of last name.)
19. Any other information that could be used alone or in combination with other information to identify an individual. (e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code . )

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## Data Use Agreement

### IRB-HSR Protocol #18513

INSTRUCTIONS: Data being used in this protocol may meet the criteria of a Limited Data Set. To comply with HIPAA regulations the principal investigator of this protocol must sign this memo regarding Limited Data Sets. This memo must be filed with your regulatory files and kept for 6 years from the date of this determination.

This memorandum is designed to permit you to use and disclose a "Limited Data Set" of patients' health information for UVA in compliance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164, subparts A and E.1.

1. Except as otherwise specified in this memorandum, you may use and disclose the Limited Data Set for research purposes only as described above. You represent that the Limited Data Set is the minimum amount of data necessary for the conduct of the Research.
2. You agree not to use or disclose the Limited Data Set for research purposes other than as permitted by this Agreement or as otherwise required by law.
3. You agree to use appropriate safeguards as described above to prevent the use or disclosure of the Limited Data Set other than as provided for by this Agreement.
4. You agree to promptly report to the IRB for Health Sciences Research Office any use or disclosure of the Limited Data Set not described in this memo of which you become aware.
5. You agree not to attempt to identify the patients to whom the information contained in the Limited Data Set pertains in order to contact those individuals for purposes of research.

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

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Phone: 434-924-2620 Fax: 434-924-2932 Box 800483

## For IRB-HSR Use Only

**IRB-HSR #**

**18513**

**Protocol Title :** Alpha Angle Correction Following Two Different Approaches for Femoroacetabular Impingement – Ganz vs Anterior Mini-Open.

The IRB-HSR confirms that this project meets the criteria of research which is exempt from federal regulations under 45CFR46.101 (b)(4).

The health information to be collected in this study may meet the criteria of Limited Data Set. Please sign and save the enclosed Data Use Agreement with your study files for 6 years.

If you need to modify the procedures in this project you must notify the IRB-HSR first to determine if the project continues to meet the criteria for exempt research.

For additional information regarding educational resources for research see <http://www.virginia.edu/vpr/irb/hsr/education.html>

Signed  Date 10/31/15  
IRB-HSR Staff Member

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