**Outcome Results of Anterior Cruciate Ligament Reconstruction using Closed Loop Button versus Variable Loop Button Fixation Surgical Techniques**

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**Abstract:**

The objective of this study is to evaluate and compare patient outcomes for two different surgical techniques used for femoral graft fixation of the anterior cruciate ligament (ACL) in the knee (EndoButton and RetroButton are grouped into a closed loop technique and the ACL TightRope RetroButton is a variable loop technique). Those patients who had an ACL reconstruction using either of the aforementioned techniques performed by the primary investigator between the dates of January 2009 and April 2012 will be identified by a search of procedure codes. Data collected from a chart review and subsequent research-related office visit will be documented: KT-1000 (a device that is used to quantify the anterior translation of the tibia on the femur in order to test the integrity of the graft), Lysholm, Tegner, and SF-12 scores. The KT-1000 test will be compared to a KT-1000 test of the non-operative side.Current symptoms and physical exam of the patients will be obtained. Finally, these patient outcomes will be compared for the two surgical techniques.

**Introduction & Background**

Anterior cruciate ligament (ACL) injuries continue to be the most common serious injury of the knee seen by the orthopedic surgeon. 1-3 An estimated 50,000-175,000 primary ACL reconstructions are done each year in the United States, and ACL reconstruction ranks as the 6th most commonly performed orthopedic procedure.1 ACL ruptures are often associated with symptomatic instability, which if left untreated, can lead to progressive degeneration and long-term disability.2 Good- to excellent results (90%) have been reported by primary ACL reconstruction.2 However, (~10%) continue to experience symptoms despite ACL repair. Therefore, we propose to evaluate commonly used graft fixation surgical technique choices used to produce those results in order to see if they have any impact on outcome.

There are many factors that contribute to a successful outcome in ACL reconstruction, such as graft choice, tunnel placement, graft fixation methods, and graft incorporation. Graft fixation and incorporation into the bony tunnels are considered essential for the stability of an ACL reconstruction.4,5 Suspensory fixation with titanium “button” devices (EndoButton by Smith & Nephew or RetroButton by Arthrex) has gained popularity due to its simplicity, reliability, and the excellent tensile strength afforded by the device. This study examines two different methods of button fixation, which can differ in terms of simplicity and the amount of ACL graft entering the length of the tunnel. Ultimately, it is believed that graft incorporation and pull out strength will improve with more graft length in the tunnel6.

In both devices that are being compared, the surgeon must drill tunnels in both the tibia and femur, creating a pathway through which the graft, button, and sutures can pass. The tibial tunnel is a simple tunnel, and the width of the tibia is made using a reamer. This whole tunnel will be wide enough that the graft may pass through it. The femoral tunnel is more complex. To begin, the surgeon will create a narrow tunnel through the full width of the lateral femoral condyle using a guide pin. The distance of this tunnel is referred to as the trans-osseous distance. Once this is completed, a reamer will be used to widen the tunnel from the medial aspect only partially through the femur, creating a socket referred to as the femoral socket. It is important to note that the femoral socket will be shorter than the trans-osseous distance, with the socket terminating into a narrow tunnel which transverses the rest of the trans-osseous distance.

**1** 

Once the bony tunnels have been created, the fundamental concept of both button techniques is the same. In these procedures, the graft is attached via a pre-assembled loop to a pill-shaped button, which can be easily oriented and pulled through the bony tunnels, starting through the tibia and ending through the femur. Once the button passes through the cortex of the femur, it can be flipped and re-oriented so that it may not pass back through the tunnel, thus holding the graft in place and preventing it from backing out of the tunnel. (Picture 1) At this point, the graft will be snug within the femoral socket, and the loop to the button will be passing through the narrow tunnel at the end of the socket. The final step is to fixate the graft at the tibial incision using an interference screw.

The main differences between the two procedures are in the type of loop used and the manner in which the button and graft are pulled through the bony tunnels. The first technique uses either the EndoButton or RetroButton and a fixed loop length (known as fixed loop button technique). The fixed loop length requires the surgeon to acquire a series of precise measurements when drilling the femoral tunnel. The loop length requires 10-15 mm of extra slack in order to allow the button to flip into position. The different aspects of the femoral tunnel must be taken into consideration in order to properly pass, flip, and fixate the graft, which is pulled directly into place by suture strings. A closed-loop design may not deploy successfully if the graft tunnel is drilled short, and thus not allowing the device to clear the femoral tunnel. Alternatively, having a large loop may lead to a small graft length in the femoral tunnel. The second technique is the ACL TightRope RetroButton technique and uses a variable loop length (known as variable loop button technique). The variable loop length employs a series of ropes that can essentially be used as a pulley system to advance the graft snugly all the way to the end of the femoral socket for a tight fit. (Picture 2 & 3) This technique reduces the guess work needed in measurements and also allows the graft to be advanced further into the femoral tunnel than the fixed loop technique.

**2**

**3** 

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The following outcomes measures will be documented to evaluate each surgical technique: the KT-1000, Tegner, SF-12, and Lysholm questionnaire. The KT-1000 is the most common testing device that is used to quantify the anterior translation of the tibia on the femur in order to test the integrity of the ACL.8-10 This value is compared to KT-1000 measurements from the non-operative side. This test will be done after an ACL reconstruction in order to document the amount of passive restraint of the reconstruction. It has been reported that a KT-1000 test greater than 5mm compared to the non-operative side would report a failure of the reconstruction 8. This test is accomplished by securing a device to the front of an individual’s knee that is lying on their back with their knee flexed to 25 degrees. A maximal force as well as an 85 N force is pulled at the front of the lower leg and then the displacement of the knee is measured. This force is determined by an audible beep, giving objectivity to the exam.10

The Lysholm questionnaire provides a reproducible and reliable method to evaluate a patient after knee surgery.11 This questionnaire subjectively rates squatting, stair climbing, pain and other activities, and emphasizes the patient’s opinion of function and signs of instability. The score ranges from 1 to 100, and improvement is demonstrated by an increase in score, and a score of 100 suggests no functional impairments or difficulties. Scores in ACL impaired knees have been shown to be low, but they increase significantly with ACL reconstruction.11 The Lysholm Scales, originally designed for knee ligament injuries, demonstrate good reliability.11 The Tegner activity scale gives a numerical value to a patient's level of activity, ranging from 0 to 10. Zero represents a patient who is impaired because of knee problems, and 10 will indicate a patient who competes at the professional level. Scores in ACL impaired knees have been shown to be low, but they increase significantly with ACL reconstruction 12.The Lysholm and Tegner Activity Scales originally designed for knee ligament injuries demonstrate good reliability 11,12. The SF-12 survey was constructed from the 36-item short-form and the survey is a series of questions to provide a physical and mental summary and evaluate quality of life. This shortened survey has shown to be a reliable and valid subset of the SF-36 13.

We have been unable to identify any studies in current literature directly comparing the clinical outcomes of these two fixation techniques. As of now, there is a dearth of research specifying a superior technique, although most surgeons have personal preferences. The purpose of this study is to report clinical outcomes and KT-1000 measurements of an ACL reconstruction by the primary investigator using the closed loop and variable loop design. Our hypothesis is that there will be no statistically significant difference between these two designs in clinical measurement as documented by the KT-1000 test and functional level.

**Objectives**

1. To evaluate and compare patient outcomes for a closed loop button and variable loop button surgical techniques used for femoral graft fixation of the anterior cruciate ligament (ACL).

**Hypothesis**

1. The variable loop surgical technique can give a similar (as measured by a KT-1000 score and questionnaire scores) outcome measurement as the closed loop technique.

**Study Design & Methods**

1. **Study Design:** Prospective observational research study

**Data Collection:**

**Chart Review:** A medical record review will be conducted at Emory Department of Orthopedics by the Principal investigator and the co-investigators. Patients who had an ACL reconstruction using either of the aforementioned techniques performed by a single surgeon between the dates of January 1, 2009 and January 1, 2012 will be identified by a search of procedure codes. Our target accrual number for enrolled subjects will be 60. Data collection will include patient’s age, gender, physical exam findings pre and post operatively to include Lachman test, pivot shift test ( both tests are used to assess the integrity of an ACL and are routinely used in all knee exams), range of motion, effusion, other pathologic findings at the time of surgery, KT-1000 scores, return to activity status, and need for repeat surgery. These are all part of normal post operative care and evaluation. The surgical technique that is used for the reconstruction will be described in detail. The data collected will be in a locked cabinet at the Emory Facility, and will also be stored in an excel spreadsheet, which will be password protected, stored on an Emory University hard drive, and accessible only by IRB approved study personnel.

**Outcome measures:**  The following outcomes measures will be used: the KT-1000, TLysholm questionnaire, Tegner Activity Level Scale, and SF-12 questionnaire. Many patients will already have completed the KT-1000 test as a part of normal testing done after an ACL reconstruction. However, if a patient agrees to participate, at their research appointment another KT-1000 measurement will be obtained.

**Participant Selection**

**Inclusion Criteria**

1. **Stage of disease:** Patient must have had a successful anterior cruciate ligament rupture requiring reconstruction using either the closed loop button or the variable loop button device.
2. **Age:** 18 years and older
3. **Performance status:** Patients with no other previous illnesses that prevented them from ambulating normally (without help of devices).

**Exclusion Criteria**

1. **Other injures**: Patients with multiple ligamentous injuries or fractures.
2. **Other surgical procedures:** Patients with previous knee surgery, revision ACL reconstructions, or any osteotomies that are performed at the same time of ACL reconstruction will be excluded.
3. **Other diseases:** Patients with a history of connective tissue disorders, infection, or arthrofibrosis will be excluded.

**Recruitment:** Prospective participants will be contacted by mail or phone with information about the research project and invited to participate. A single research appointment will be made for respondents. At that visit, the risks, benefits, and participant responsibilities will be explained to the patient and they will be given an opportunity to have their questions answered. If they agree to participate, they will sign a consent form and HIPAA Authorization form and a copy will be given to them for their records. Following consent to participate, packets of each survey will be given to the patient to fill out. KT-1000 test will be performed on all participants at their research appointment.

Adverse Event Reporting

Although no adverse events from participation in this research are expected since it is of minimal risk, the IRB will be notified of reportable adverse events within the time-frames specified in IRB regulations if such should occur.

Potential Risks

As in all human-subject research, the risk of the potential for the loss of confidentiality is present in this study. All research-related procedures included in this study are of minimal risk, (physical exam, interview, questionnaires, and KT-1000 test). Participants could experience anxiety while answering questions, however they will be instructed via the consent process to let the research personnel know if that occurs and it if it affects their ability to answer questions on the questionnaires.

Data and Safety Monitoring Plan

Since the procedures in this study can be classified as minimal risk (physical exam, interview, and answering a questionnaire), safety of patients and accuracy of data will be monitored by investigators Should a patient safety issue or data accuracy problem be identified by the investigators, it will be reported to the IRB as required.

Procedures to Maintain Confidentiality

Participants will be enrolled by a member of the IRB-approved research team. Study information will be recorded on data collection sheets which will be stored in a locked file cabinet. Data will be transcribed into a password-protected database that is kept on a University hard drive and accessible only to study personnel. Data collection will include:

1. Age
2. Gender
3. Physical exam findings pre and post operatively

Range of motion, effusion (swelling), Lachman stress test, and pivot shift test

1. Pathologic findings at the time of surgery
2. KT-1000 scores
3. Return to activity status
4. Repeat surgery/ies
5. Description of surgical technique
6. Data from questionnaires

Patient identifiers will be maintained until data collection is complete. At that time, data sets will be de-identified by removing identifiable information and data will be analyzed. Paper records of study participation such as consent forms will be kept in a secure, locked file cabinet for as long as the law requires. Government agencies and Emory employees overseeing proper study conduct may look at study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Research Compliance, the Office for Clinical Research, the Clinical Trials Audit & Compliance Office, the Radiation Safety Committee. A copy of the participant’s consent form will be placed in the Emory University Healthcare medical record.

Potential Benefits

The benefit for future patients in this is to enhance clinicians’ knowledge of common fixation techniques in ACL reconstruction procedures. This is important because surgical fixation and stability of the graft is important to the functional success of this reconstruction.

Statistical Analysis

**Descriptive statistics (mean ± SD or percentage) will be given for all variables. Participants will be broken up into closed loop button and variable loop button techniques.** Mann-Whitney test will be used to compare all numerical variables between the two groups of techniques. Chi-square/Fisher exact test will be used to test whether a significant relationship between the two techniques exists for all the categorical variables. **Comparisons were** considered significant at a p level of less than 0.05

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**Appendix 1.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Lysholm Score** | | | | | | |
| **For each question please select one answer with a circle:** | | | | | | |
|  |  |  |  |  |  |  |
| **Limp** | | |  | **Load** | | |
| No | | 5 |  | Full load | | 5 |
| Little or occasionally | | 3 |  | Going supports or stick | | 3 |
| Strongly or always | | 1 |  | Load not possible | | 0 |
|  |  |  |  |  |  |  |
| **Swelling** | | |  | **Stair rise** | | |
| None | | 10 |  | No problem | | 10 |
| With heavy effort | | 6 |  | A little impairs | | 6 |
| When usual effort | | 2 |  | Step for step | | 2 |
| Constantly | | 0 |  | Not possible | | 0 |
|  |  |  |  |  |  |  |
| **Squats** | | |  | **Blocking** | | |
| No problem | | 5 |  | No blocking and no feeling of getting jammed | | 15 |
| Little impairs | | 4 |  | Feeling of getting jammed, however no blocking | | 10 |
| Not over 90° | | 2 |  | Gently blocking | | 6 |
| Not possible | | 0 |  | Frequent blocking | | 2 |
|  |  |  |  | Blocked joint on investigation | | 0 |
|  |  |  |  |  |  |  |
| **Instability** | | |  | **Pain** | | |
| Never "giving way" phenomenon | | 25 |  | None | | 25 |
| "Giving way" rarely during the sport or other heavy effort | | 20 |  | Irregularly and small during heavy effort | | 20 |
| "Giving way" frequently during the sport or other heavy effort (or not possibly to participate in it) | | 15 |  | Clear/minted during heavy effort | | 15 |
| "Giving way" occasionally during activities of the everyday life | | 10 |  | Clearly during or after going more than 2 km | | 10 |
| "Giving way" often during activities of the everyday life | | 5 |  | Clearly during or after going less than 2 km | | 5 |
| "Giving way" with each step | | 0 |  | Constantly | | 0 |
|  |  |  |  |  |  |  |
| Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

**Appendix 2**

**Tegner Activity Level Scale**

**Please indicate in the spaces below the HIGHEST level of activity that you participated in BEFORE YOUR INJURY and the highest level you are able to participate in CURRENTLY.**

**BEFORE INJURY: Level\_\_\_\_\_\_\_\_\_\_ CURRENT: Level\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| **Level 10** | **Competitive sports- soccer, football, rugby (national elite)** |
| **Level 9** | **Competitive sports- soccer, football, rugby (lower divisions), ice hockey, wrestling, gymnastics, basketball** |
| **Level 8** | **Competitive sports- racquetball or bandy, squash or badminton, track and field athletics (jumping, etc.), down-hill skiing** |
| **Level 7** | **Competitive sports- tennis, running, motorcars speedway, handball**  **Recreational sports- soccer, football, rugby, bandy, ice hockey, basketball, squash, racquetball, running** |
| **Level 6** | **Recreational sports- tennis and badminton, handball, racquetball, down-hill skiing, jogging at least 5 times per week** |
| **Level 5** | **Work- heavy labor (construction, etc.)**  **Competitive sports- cycling, cross-country skiing,**  **Recreational sports- jogging on uneven ground at least twice weekly** |
| **Level 4** | **Work- moderately heavy labor (e.g. truck driving, etc.)** |
| **Level 3** | **Work- light labor (nursing, etc.)** |
| **Level 2** | **Work- light labor**  **Walking on uneven ground possible, but impossible to back pack or hike** |
| **Level 1** | **Work- sedentary (secretarial, etc.)** |
| **Level 0** | **Sick leave or disability pension because of knee problems** |

**Appendix 3**

**SF**-**12® Patient Questionnaire**

Page 1 of 3

**Patient Initials \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_\_ Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ Patkey: \_\_\_\_\_\_**

**Surgeon Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Examination Period:** \_\_\_\_\_ Preop (1) \_\_\_\_\_ 3 Year (4)

\_\_\_\_\_ Immediate Postop (2) \_\_\_\_\_ 5 Year (5)

\_\_\_\_\_ 1 Year (3) \_\_\_\_\_ Other (specify) (6): \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SF**-**12®:**

This information will help your doctors keep track of how you feel and how well you are able to do your

usual activities. Answer every question by placing a check mark on the line in front of the appropriate

answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

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

\_\_\_\_\_ Excellent (1)

\_\_\_\_\_ Very Good (2)

\_\_\_\_\_ Good (3)

\_\_\_\_\_ Fair (4)

\_\_\_\_\_ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR

HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing

golf:

\_\_\_\_\_ Yes, Limited A Lot (1)

\_\_\_\_\_ Yes, Limited A Little (2)

\_\_\_\_\_ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:

\_\_\_\_\_ Yes, Limited A Lot (1)

\_\_\_\_\_ Yes, Limited A Little (2)

\_\_\_\_\_ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular

activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:

\_\_\_\_\_ Yes (1)

\_\_\_\_\_ No (2)

5. Were limited in the KIND of work or other activities:

\_\_\_\_\_ Yes (1)

\_\_\_\_\_ No (2)

**PI or CI Initials \_\_\_\_\_\_\_\_\_\_ Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

**SF**-**12®** Page 2 of 3

**Patient Initials \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_\_ Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ Patkey: \_\_\_\_\_\_**

**Surgeon Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Examination Period:** \_\_\_\_\_ Preop (1) \_\_\_\_\_ 3 Year (4)

\_\_\_\_\_ Immediate Postop (2) \_\_\_\_\_ 5 Year (5)

\_\_\_\_\_ 1 Year (3) \_\_\_\_\_ Other (specify) (6): \_\_\_\_\_\_\_\_\_\_\_\_

**SF-12® Cont’d:**

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A

RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:

\_\_\_\_\_ Yes (1)

\_\_\_\_\_ No (2)

7. Didn’t do work or other activities as CAREFULLY as usual:

\_\_\_\_\_ Yes (1)

\_\_\_\_\_ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work

outside the home and housework)?

\_\_\_\_\_ Not At All (1)

\_\_\_\_\_ A Little Bit (2)

\_\_\_\_\_ Moderately (3)

\_\_\_\_\_ Quite A Bit (4)

\_\_\_\_\_ Extremely (5)

The next three questions are about how you feel and how things have been 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 –

9. Have you felt calm and peaceful?

\_\_\_\_\_ All of the Time (1)

\_\_\_\_\_ Most of the Time (2)

\_\_\_\_\_ A Good Bit of the Time (3)

\_\_\_\_\_ Some of the Time (4)

\_\_\_\_\_ A Little of the Time (5)

\_\_\_\_\_ None of the Time (6)

**PI or CI Initials \_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**SF**-**12®** Page 3 of 3

**Patient Initials \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_\_ Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ Patkey: \_\_\_\_\_\_**

**Surgeon Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Examination Period:** \_\_\_\_\_ Preop (1) \_\_\_\_\_ 3 Year (4)

\_\_\_\_\_ Immediate Postop (2) \_\_\_\_\_ 5 Year (5)

\_\_\_\_\_ 1 Year (3) \_\_\_\_\_ Other (specify) (6): \_\_\_\_\_\_\_\_\_\_\_\_

**SF-12® Cont’d:**

10. Did you have a lot of energy?

\_\_\_\_\_ All of the Time (1)

\_\_\_\_\_ Most of the Time (2)

\_\_\_\_\_ A Good Bit of the Time (3)

\_\_\_\_\_ Some of the Time (4)

\_\_\_\_\_ A Little of the Time (5)

\_\_\_\_\_ None of the Time (6)

11. Have you felt downhearted and blue?

\_\_\_\_\_ All of the Time (1)

\_\_\_\_\_ Most of the Time (2)

\_\_\_\_\_ A Good Bit of the Time (3)

\_\_\_\_\_ Some of the Time (4)

\_\_\_\_\_ A Little of the Time (5)

\_\_\_\_\_ None of the Time (6)

12. 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.)?

\_\_\_\_\_ All of the Time (1)

\_\_\_\_\_ Most of the Time (2)

\_\_\_\_\_ A Good Bit of the Time (3)

\_\_\_\_\_ Some of the Time (4)

\_\_\_\_\_ A Little of the Time (5)

\_\_\_\_\_ None of the Time (6)

**PI or CI Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**