



PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Buttonfixation of the long head of the biceps- clinical follow-up

Trial Acronym

BIZBUTTON

URL of the trial

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Brief Summary in Lay Language

clinical prospective case series after performing mini-open or arthroscopic tenodesis (fixation) of the Long head of the biceps (LHB) with suture button technique.

There are many kinds of fixation techniques for the LHB. The used technique in this study is a suture plate unicortical suprapectoral fixation. This means that a suture plate (titan) is put below the cortical bone of the groove in which the LHB usually is running. Onto the button, the before cut LHB is sutured to the groove. The technique is biomechanically tested. The study controls cosmesis, functional results, patients' satisfaction strength and sonographic controls.

Brief Summary in Scientific Language

clinical prospective case series of mini-open or arthroscopically done biceps tenodesis using an unicortical fixation via suture button. Scheibels BicepsScore, Constant Score, Satisfaction and cosmesis were recorded pre- 6 and 52 weeks post-op. also ultrasound controls were performed

Organizational Data

- DRKS-ID: **DRKS00007548**
- Date of Registration in DRKS: **2015/01/07**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: [---]*
- (leading) Ethics Committee Nr.: [---]*

Secondary IDs

- Universal Trial Number (UTN): **U1111-1164-6045**

Health condition or Problem studied

- ICD10: **M75.2 - Bicipital tendinitis**

Interventions/Observational Groups

- Arm 1: **prospective case series of isolated LHB-tenodesis. no controll-group. Scheibels LHB-Score, Constant-Score, Cosmesis, Satisfaction, force measuring using an isoforce control. Also sonographic controls were done. Examinations performed pre-OP, 6 and 52 weeks post-op. an xray was done after 6 weeks**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

acquiring constant score, Scheibels LHB Score (shoulder function) and patients satisfaction pre, 6 weeks and 52 weeks after operation. Clinical controls and questionnaire based scores. Sonographic controls. Single xray control 6 weeks post-op

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**



Locations of Recruitment

- Medical Center **St.Vinzenz-Klinik, Pfronten**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/10/01**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **20 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

all kind of indication for biceps tenodesis: SLAP-Lesion, Tendonitis, partial rupture, Biceps Instabilität.

Exclusion criteria

addiitonal rotatorcuff repair

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**



Contact for Scientific Queries

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

■ Recruitment Status: **Recruiting complete, follow-up continuing**

■ Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.