Infraspinatus strength assessment and ultrasound evaluation of posterior capsulotenodesis after arthroscopic Hill-Sachs remplissage in traumatic anterior glenohumeral instability: a retrospective controlled study protocol

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I. INTRODUCTION
Traumatic shoulder instability is a common disabling injury, especially in young active subjects for the high risk of of recurrence after the first episode of dislocation that produces clinical, social and working disability. After a shoulder dislocation the humeral head impacts on the anterior edge of the glenoid, and induces a fracture of the postero-superior profile of the humeral head, known as Hill-Sachs lesions [1]. The Hill-Sachs fracture is found in 47% of cases after the first episode of dislocation and until to 90% in recurrent instability [1]. As the number of dislocations increase as the lesions become larger and deeper, with high risk of additional recurrence. Burkhart and De Beer [2] introduced the term “engaging Hill-Sachs lesion”, to describe a bone defect enough large to determine the block of the humeral head on the anterior edge of the glenoid when the arm is abducted and externally rotated. This kind of large and deep defects have been associated with high postoperative risk of recurrence after arthroscopic Bankart repair. Later, Itoi et al [3] introduced the concept of “glenoid track” to emphasize that an Hill-Sachs lesion has a risk of engagement and dislocation if it extends medially over the medial margin of the glenoid track. The filling of the humeral head defect using the posterior capsule and the infraspinatus tendon was described as open surgical procedure by Connolly in 1972 [4] and subsequently in 2004 Wolfe and Pollack [5] described the arthroscopic technique of Hill-Sachs "remplissage" (from french “filling”) in combination with anterior bankart repair.

II. PURPOSE OF THE STUDY
Aim of the current research protocol was to quantify the infraspinatus strength in the operated patients compared with a comparative healthy group after arthroscopic remplissage and anterior Bankart repair at a mean follow-up of 45 months.

III. PATIENTS AND METHODS
Design
This is a retrospective single center controlled trial on a consecutive series of patients underwent arthroscopic anterior Bankart repair and posterior remplissage. Overall population will be enrolled at the Unit of Shoulder and Elbow Surgery of D. Cervesi Hospital in Cattolica – Italy – to perform a clinical and ultrasound (US) examination.

Study population
All the 40 subjects who performed arthroscopic remplissage between January 2007 and December 2010 will be contact to be enrolled. Overall clinical data (demographics, preoperative, intraoperative and postoperative) and results of US assessment at last follow-up will be collected. A population of 30 healthy subjects randomly enrolled in our outpatients office during orthopedic examination for sports activity were used as control group.
Clinical outcomes measures and US evaluation

The patients enrolled in the study will be assessed with two clinical tests [6]:
Infra spinatus strength test (IST): the patient standing with the arm adducted and the elbow flexed at 90°, applies the maximum external rotation force
Infra spinatus scapular retraction test (ISRT): the examiner is placed behind the patient, using one hand to retract manually the scapula while the other hand resist to the external rotation force applied by the patient
Infra spinatus strength in both tests will be recorded the Lafayette handheld dynamometer (Lafayette Instruments, Lafayette, Ind, USA).
Shoulder function will be assessed using the Constant-Murley score (CS) [7], the Rowe scale [8] and the Simple Shoulder Test (SST) [9]. The CS included a subjective questionnaire for pain, the ability to perform daily living activity (DLA), an objective evaluation of active range of motion (ROM) and strength. Pain will be scored on a 15 point scale (0 severe pain, 15 no pain), while DLA will be scored on a 20 points scale, with lower scores associated with greater impairment on DLA. ROM will be measured using a standard goniometer between the upper arm and the upper part of the thorax. The SST consists of 12 questions with dichotomous response options. For each question, the patient indicates whether he or she is able to do the activity or not. The scores are summarized into a total score, which ranges from 0 (worst) to 12 (best) for shoulder functioning.
Rowe scale is an objective scoring system where the points are divided among three major categories: stability (50 points), motion (20 points), and function (30 points). The total scores are interpreted as excellent (100-90), good (89-75), fair (74-51) and poor (50 or less). Since none of the patients enrolled performed a postoperative MRI evaluation of the operated shoulder after the clinical evaluation, an US (Esaote MyLab™GOLD 70 XVision ultrasound machine, 7.5-18 MHz) of the operated shoulders will be performed to verify if the capsule and infra spinatus tendon are represented and healed in the humeral head where they were fixed during the surgical procedure.
Clinical scores collected at last follow-up will be compared with preoperative and the values of infra spinatus strength of the operated shoulder will be compared with controlateral shoulder and with the values of strength collected in the control group.

Inclusion criteria

Age and gender: male and female ≥ 18 years
Infomed consent of the patients to be enrolled in the study
Preoperative diagnostic and surgical procedure: patients with recurrent traumatic anterior shoulder instability evaluated with MRI or/and TC of the affected shoulder. Surgical procedure of posterior Hill-Sachs remplissage and anterior Bankart repair with bioabsorbable anchors.
The location and the size of the Hill-Sachs deformity will be assessed on axial images through the proximal humerus and graded as minimal, mild, moderate, or severe [10].

Exclusion criteria

Cognitive limitations that precluded a valid consent to be included in the study
Unwilling to be enrolled
Lost to follow-up

Statistical analysis

A descriptive analysis will be performed by calculating mean, standard deviation and frequency table, apart for the operated and the control group. All the variables (ROM, clinical tests, and clinical scores) were compared with t test for paired data. The difference of the infra spinatus strength in the operated limb, controlateral limb and in the control group will be compared. In the control group we will choose the dominant or non-dominant shoulder according to the dominance of the operated shoulder. The difference between preoperative and postoperative clinical scores and other variables examined in the study will be compared setting the significance at 5%.

Risks and adverse events

No risks are expected with the routine diagnostic exams performed in the the two groups. Eventual adverse events occurred during the study will be properly recorded and reported.

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