Quattro® X Suture Anchor with BroadBand™ Tape Post Market Clinical Follow-up Study (incl. Instruments) -

Retrospective and prospective, consecutive, multicenter, non-randomized, non-controlled study

Protocol number: CME2021-24SM
Protocol date: 27 April 2022
NCT number: NCT05690776

1 STUDY SYNOPSIS

<copy this information from last approved protocol>

Complete Protocol Title	Quattro® X Suture Anchor with BroadBand™ Tape Post Market Clinical Follow-up Study (incl. Instruments)
Protocol Number	CME2021-24SM
Short Protocol Title	Quattro® X with BroadBand
Sponsor	Zimmer Biomet, Warsaw, Indiana, United States
Manufacturer	Cayenne Medical Inc.
Study Device(s)	Quattro X Suture Anchors with BroadBand Tape - 5.5mm Quattro X Suture Anchor Double-Loaded with BroadBand Tape (Non-Sliding) - 6.5mm Quattro X Suture Anchor Double-Loaded with BroadBand Tape (Non-Sliding) - 5.5mm Quattro X Suture Anchor Double-Loaded with BroadBand Tape (Sliding) - 6.5mm Quattro X Suture Anchor Double-Loaded with BroadBand Tape (Sliding) Quattro X Suture Anchor Reusable Instruments (Non-Sterile) - Awl, 5.5/6.5mm Quattro X Suture Anchor - Tap, 5.5mm Quattro X Suture Anchor - Tap, 6.5mm Quattro X Suture Anchor
Study Objectives/Endpoints	The objective of the study is to collect data confirming safety, performance and clinical benefits of the Quattro® X Suture Anchor with BroadBand™ Tape and Instruments when used in rotator cuff repair. The primary endpoint of this study is the assessment of performance by analyzing soft tissue to bone healing in the shoulder (rotator cuff). Healing will be assessed by the investigator using PROMs and clinical outcomes of the patient. The clinical benefit will be assessed by functional outcomes measured using standard and well-established scoring systems (e.g. Constant & Murley and EQ-5D-5L) at 1 year post-operative. The safety will be assessed by monitoring the incidence and frequency of device- and/or procedure-related adverse events.

Indications/Target Population	Subjects treated with the Quattro® X Suture Anchor with BroadBand™ Tape for rotator cuff repair, according to the IFU and who meet all of the inclusion and none of exclusion criteria.
Inclusion/Exclusion Criteria	The indications/contra-indications are in line with the Instruction for Use (IFU). <u>Inclusion Criteria:</u> Quattro® X Suture Anchors are intended for use for the reattachment of soft tissue to bone for Rotator Cuff Repairs. 1. Subject treated with the Quattro® X Suture Anchor with BroadBand™ Tape for rotator cuff repair; 2. Older than 18 years and skeletally mature; 3. Willing and able to comply with the study procedures; 4. Subject is capable of understanding the doctor's explanations, following his instructions and is able to participate in the follow-up program; 5. Subject is able to read and understand the ICF and has voluntarily provided written informed consent. <u>Exclusion Criteria:</u> 1. Presence of infection; 2. Insufficient or immature bone; 3. Insufficient blood supply or previous infections which may hinder the healing process; 4. Foreign body sensitivity; 5. Subject is vulnerable (prisoner, mentally incompetent or unable to understand what participation to the study entails, a known alcohol or drug abuser, anticipated to be non-compliant); 6. The subject is unwilling or unable to give consent or to comply with the follow-up program; 7. Subject meets any contraindications of the appropriate Instruction for Use.
Study Design	Retrospective and prospective, consecutive, multicenter, non-randomized, non-controlled study
Clinical Phase	Post-market
Sample Size	Maximum of 109 study subjects implanted with the study device.
Length of Study	1 year

Materials and Methods	Retrospective inclusion of 109 subjects who are eligible for rotator cuff repair with the Quattro® X Suture Anchors with BroadBand™ Tape. Prospective follow-up visit at 1 year postoperative.
Data Collection	Paper/Electronic
Statistical Reporting	Data collected will be summarized and reported to each participating investigator. Statistical analysis will be conducted by Zimmer Biomet or its designee. Survivorship will be evaluated using Kaplan-Meier.
Scores/Performance Assessments	
Standards	The PMCF is compliant with the below: • ISO 14155: 2020 - Clinical investigation of medical devices for human subjects - Good clinical practice. • The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects. • European Regulation (EU) 2017/745
Study Funding	Funding for this clinical study is made available by Zimmer Biomet to support clinical data collection, other expenses associated with the conduct and execution of this study protocol as outlined in the fully executed Clinical Trial Agreement.

2 STATISTICAL ANALYSIS PLAN

2.1 Sample Size

The overall success rate will be calculated based on the percentage of subjects who have successful healing. The following hypothesis will be tested by the exact binomial test

H0: E1 – E0 ≤ - δE

Ha: E1 – E0 > - δE

Where:

E0 = 85%, the expected success rate of similar devices

E1 = the success rate in the Quattro® X Suture Anchor with BroadBand™ Tape treatment group

δE = 0.10, non-inferiority margin for healing

In addition, one-sided 95% exact confidence Interval (CI), lower limit of the success rate, will be calculated.

Based on the hypothesis test above, 103 subjects will provide approximately 80% power for the one-sided exact binomial test at 0.05 significant level. The sample size was calculated using SAS for Windows version 9.4. To account for an expected 5% loss-to-follow up, 109 patients will be enrolled.

2.2 General Statistical Methods

Continuous data, such as age, will be summarized by using means, medians, standard deviation, minimum, maximum, and 95% CI over the time periods of interest. Categorical data, such as gender or surgical approach, will be summarized by counts and percentages. Implant survival will be summarized using a Kaplan-Meier method and presented with rates (as percentages) and confidence intervals (CI). Statistical analyses will be performed using SAS 9.4. The binomial distribution tests will have 80% probability of computing a one-sided 95% lower confidence bound on survivorship of each device with a non-inferiority margin of 0.09. Patient confidentiality will be protected at all times, and patient identifiers will not be included in data summaries.

Handling of Missing and Incomplete Data: Data will be considered “censored” for the primary endpoint if the survivorship outcome cannot be determined or is unavailable for a subject. Every effort will be made to collect the data necessary to evaluate the primary endpoint. Patients who have been lost to follow-up will not be included in the primary study analysis at the end of 1 year. However, the data already collected will be used in interim analysis and survivorship calculations.

Sensitivity analyses will be performed to assess the impact of missing data on the primary study analysis. These analyses may include a best-case and worst-case imputation as well as a tipping point analysis.

2.3 Data Analysis

The Per Protocol population will be defined as those subjects that undergo a successful implantation of the Quattro® X Suture Anchor with BroadBand™ Tape. Analyses on the primary and secondary endpoints will use this population as well as any exploratory analyses.

The primary endpoint will be determined at the only clinical assessment, about one year from the index surgery. The absence of a revision surgery or re-tear not previously noted on the case report form will denote a success (within 425 days from index surgery). All other cases will be a failure and have a documented revision surgery or re-tear.

Secondary analyses will include a summary of any clinical scores captured at baseline and the one year assessment; change from baseline analyses may be developed. In addition, a summary of medications and patient satisfaction may also be assessed.

Any potential exploratory analysis that assess outcomes be categories (gender, age, etc.) will use appropriate statistical test for the type of variable (i.e. t-tests, ANOVA, Fisher's Exact, etc). All testing will use a Type I error of 0.05 and no p-values will be adjusted for multiplicity.

Adverse events will also be captured at the one year assessment. Only AEs that occur on or after the index surgery and before any potential revisions or re-tears will be summarized. Adverse events will be presented as the number of cases for each AE and the number of times the give AE occurred. Finally, a complete listing of all AEs will be presented.