



**Trapezio – metacarpal arthroplasty:
comparison of ARPE® prosthesis with the literature**

PROTOCOL NUMBER (Study ID): ORTHO.CR.E16

PROTOCOL VERSION: V1.0 dd 12 Nov 2012

GENERAL INFORMATION

Study Sponsor: BIOMET Global Supply Chain Center B.V.

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TITLE	Trapezio-metacarpal arthroplasty: a comparison of ARPE prosthesis with the literature
SHORT TITLE	Arpe prospective study
DESIGN	Non-controlled, prospective cohort study in single centre
STUDY DURATION	2013- 2020
STUDY CENTRE	Single centre in Belgium
POPULATION	Inclusion of 100 subjects at single centre
PRIMARY Research objectives	The primary objective is to compare functional outcome at 3 years after trapezio-metacarpal arthroplasty with trapeziectomy and trapeziectomy with ligament reconstruction and tendon interposition. Literature values obtained by a recently published meta analysis ¹ will be used.
SECONDARY Research Objectives	<p>Secondary objectives are:</p> <ul style="list-style-type: none"> - to compare functional outcome at 1 and at 5 years after trapezio-metacarpal arthroplasty with trapeziectomy and trapeziectomy with ligament reconstruction and tendon interposition - to determine pre- and postop HR QOL - Incidence of RLL at each f/up time point. <p>Literature values from the same meta analysis¹ will be used.</p>
OUTCOME Measures	Patients will be assessed at preoperatively, and at 1, 3 and 5 years postoperatively. Outcomes as described by Li et al ¹ will be measured: grip strength, tip pinch strength, key pinch strength, pain, occurrence of adverse events, hand function.
Follow-up time	Patients will be part of a longitudinal follow-up program with follow-ups at 1, 3, 5 years.
Enrollment time	2 Years

STATISTICS

SAMPLE SIZE CALCULATION

Based on a publication from Davis et al² we expect the standard deviation in the study population for key pinch, tip pinch, and grip strength to be 0.82, 1.65 and 10.3, respectively. Setting alpha at 0.05 and beta at 0.10, and assuming a MIREDIFF (Minimally Relevant Difference) of 0.5 x Standard Deviation, an attrition rate of 10%, and data to be approximately normally distributed, the required sample size will be 96 (\approx 100) subjects.

STATISTICAL PROTOCOL

Continuous variables (e.g. age) will be summarized using the mean and standard deviation (SD). If the distribution of measurements is asymmetrical, the median and the interquartile range will be provided. For ordinal and nominal data proportions should be employed. Inferential statistics will be based on the unpaired t-test, or the Mann-Whitney test, depending on normality of the data.

REFERENCES

1. LI YK, WHITE C, IGNACY TA, THOMA A. COMPARISON OF TRAPEZIECTOMY AND TRAPEZIECTOMY WITH LIGAMENT RECONSTRUCTION AND TENDON INTERPOSITION: A SYSTEMATIC LITERATURE REVIEW. *PLASTIC AND RECONSTRUCTIVE SURGERY*. 2011 JUL;128(1):199-207. PUBMED PMID: 2139956
2. DAVIS TR, PACE A. TRAPEZIECTOMY FOR TRAPEZIOMETACARPAL JOINT OSTEOARTHRITIS: IS LIGAMENT RECONSTRUCTION AND TEMPORARY STABILISATION OF THE PSEUDARTHROSIS WITH A KIRSCHNER WIRE IMPORTANT? *THE JOURNAL OF HAND SURGERY, EUROPEAN VOLUME*. 2009 JUN;34(3):312-21. PUBMED PMID: 19321528.