# Research protocol

## Project title

**Clinical outcome, pain, and range of motion between fixed and mobile bearing Attune total knee arthroplasty. A prospective single-center trial.**

## Project summary

Despite numerous scientific investigations, the tribological advantages of mobile bearing inserts have not been sustainably confirmed or refuted for modern knee prostheses in clinical studies. Simultaneously, total knee prostheses have substantially improved, especially in terms of the quality of polyethylene and fixation methods. Recent long term randomized controlled trials with large cohorts and literature reviews reported of no differences in durability, function, range of movement and migration. Modern total knee prostheses, such as the presented implant type (Attune®) provide a transition from stability and rotational freedom. This is the first study to analyze subjective and objective measurements between FB and MB inserts of this well-established TKA system.

## General information, Research Contact

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**References (of literature cited in preceding sections)**

Ferguson KB, Bailey O, Anthony I, James PJ, Stother IG, M J G B. A prospective randomised study comparing rotating platform and fixed bearing total knee arthroplasty in a cruciate substituting design--outcomes at two year follow-up. Knee. 2014 Jan;21(1):151-5. doi: 10.1016/j.knee.2013.09.007.

Kalisvaart MM, Pagnano MW, Trousdale RT, Stuart MJ, Hanssen AD. Randomized clinical trial of rotating-platform and fixed-bearing total knee arthroplasty: no clinically detectable differences at five years. J Bone Joint Surg Am. 2012 Mar 21;94(6):481-9. doi: 10.2106/JBJS.K.00315.

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McGonagle L, Bethell L, Byrne N, Bolton-Maggs BG. The Rotaglide+ total knee replacement: a comparison of mobile versus fixed bearings. Knee Surg Sports Traumatol Arthrosc. 2014 Jul;22(7):1626-31. doi: 10.1007/s00167-012-2351-5.

Abdel MP, Tibbo ME, Stuart MJ, Trousdale RT, Hanssen AD, Pagnano MW. A randomized controlled trial of fixed- versus mobile-bearing total knee arthroplasty: a follow-up at a mean of ten years. Bone Joint J. 2018 Jul;100-B(7):925-929. doi: 10.1302/0301-620X.100B7.BJJ-2017-1473.R1.

Namba RS, Inacio MC, Paxton EW, Ake CF, Wang C, Gross TP et al. Risk of revision for fixed versus mobile-bearing primary total knee replacements. J Bone Joint Surg Am. 2012 Nov 7;94(21):1929-35. doi: 10.2106/JBJS.K.01363.

Van der Voort P, Pijls BG, Nouta KA, Valstar ER, Jacobs WC, Nelissen RG. A systematic review and meta-regression of mobile-bearing versus fixed-bearing total knee replacement in 41 studies. Bone Joint J. 2013 Sep;95-B(9):1209-16. doi: 10.1302/0301-620X.95B9.30386.

Fransen BL, van Duijvenbode DC, Hoozemans MJM, Burger BJ. No differences between fixed- and mobile-bearing total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2017 Jun;25(6):1757-1777. doi: 10.1007/s00167-016-4195-x.

## Study goals and objectives

The purpose of this study was to compare fixed and mobile bearing inserts in order to draw conclusions regarding clinical benefits.

## Study design and Methodology

Between January 2015 and December 2016, a total of 544 primary total knee arthroplasties were implanted at one single orthopedic center. During this period another prospective level II study was conducted selecting patients of this time interval (n=200). The remaining 344 patients were eligible for the presented study. All patients either received a fixed or mobile bearing insert. The decision whether a patient received a MB of FB insert was made prior to the surgery based in a non-randomized setting. During the operation the selection of insert type was not changed in any case. Patients with a secondary arthritis, previous knee surgeries except arthroscopies, and varus/valgus-deformities of more than 20° were excluded. Moreover, we only included patients treated with one well-proved and worldwide used type of implant (Attune®, DePuy-Synthes, Warsaw, Indiana). All implants were tibial and femoral fixed with cement.

## Data management and statistical analysis

All data were analyzed by SPSS Version 22.0 (IBM Corporation, New York, USA). Descriptive statistics for continuous variables were reported as the mean and standard deviation (SD). Categorical variables were reported as count and proportions. For comparisons of categorical variables, the chi-square exact test was used. Data were tested for normality using Kolmogorov-Smirnov test. Differences between pre-operative and post-operative data were observed with Mann-Whitney U test and Wilcoxon signed-rank test. An a priori power analysis initially was performed and a p-value less than 0.05 was defined as statistically significant.

### Expected outcomes of the study

We believe that fixed bearing platforms may provide a better postoperative stability in TKA.

### Project management

P.R. is responsible for the study concept and design and writing the main manuscript. G.H. and L.L. are doing the statistical work-up. G.A.B. will prepare all figures and tables. F.R., G.G, A.L. and P.S. ascertain the clinical data. All authors will review the manuscript until the final version.

### Ethics

The study was approved by the ethics committee of the Medical University of Graz (30-352 ex 17/18).

### Informed consent forms

The informed consent was obtained from all subjects or, if subjects are under 18, from a parent and/or legal guardian.

## Research protocol: part 2

### Budget

The present study was performed at the Medical University of Graz without a specific budget and without specific financial support.

### Curriculum Vitae of investigators

The CV of the main investigator and first author as well as the CV of the corresponding and last author of the paper are added at the end of the research protocol.

### Financing and insurance

No Funding is planned in this present study.

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Date of Birth: 30.09.1986, Graz
Academic Degree: Dr. med. univ., MSc

## CURRENT ACTIVITY

- **Orthopedic and Trauma Specialist** — Since 2020
  Deputy head of Hip Surgery
  University Clinic for Orthopedics and Trauma, LKH, Graz

## WORKING EXPERIENCE

- **Resident for Orthopedics and Trauma** — 2019-2020
  Charité Berlin, Medical University of Berlin
- **Resident for Orthopedics and Trauma** — 2016-2019
  University Clinic for Orthopedics and Trauma, LKH, Graz
- **Resident for Trauma Surgery** — 2014-2016
  University Clinic for Trauma Surgery, AKH Wien
- **Teaching practice: Dr. Johann Jagenbrein** — 2013 – 2014
  Orthopedic Surgeon
- **Trainee Doctor, Trauma Hospital Lorenz Böhler** — 2013
  Department of Trauma Surgery

## EDUCATION

**Studies of human medicine at the Medical University of Graz** — 2007–2013
**School leaving exam at the BRG Petersgasse, Graz** — June 2005

## FURTHER MEDICAL EDUCATION, THESIS

**Master studies of** „Advanced Orthopedics and Trauma“ (Donau Uni Krems) — 2015-2019

**Diploma thesis**

- Quality of life after volar plate fixation of intraarticular distal radius fractures in a long-term view.
  Supervision: PD. Dr. Gerald Gruber und Prof. Dr. Andreas Leithner

## WORKING EXPERIENCE, FURTHER EDUCATION

**Tennis Instructor** at the GAK-Tennis, Graz — 2008-2012
**Ski Instructor** at the Ski school of Lech am Arlberg — 2006-2012
**Military Service at the Austrian Army, Kirchnerkaserne, Graz** — 2006

## LANGUAGES

**German:** Mother tongue
**English:** Fluent spoken and written

## INTERESTS

**Sport** (Tennis, Running, Golf, Skiing, Soccer)**, Economy, Art, History, Politic**

# Short Bio – Patrick Sadoghi, MD, PhD, MBA

Patrick Sadoghi, MD, PhD, MBA has finished his tenure track as associated Professor for Orthopedics and orthopedic Surgery at the Medical University of Graz in Austria, where he currently works as the head of the division of knee surgery at the Depatment of Orthopaedics and Trauma. He was trained at Ludwig-Maximilians University Munich, Germany, the Medical University of Graz, Austria, and attended various clinical fellowships in the United States. He has finished his PhD thesis on Platelet-rich Plasma in collaboration with the Childrens´ Hospital Boston and his MBA masterthesis on cost-effectiveness in arthroplasty in collaboration with the school of public health at Harvard T.H. Chan. He is specialized in all aspects of reconstructive knee surgery with a very high clinical and academic background, with his team combining over 900 cases per year, and performs renowned research in the fields of knee implant, joint preservation, and orthopedic sports medicine. He was granted all relevant national and several international awards and is editorial board member of the most renowned journals in his expertise such as *the Journal of Arthroplasty*, *Arthroscopy*, and *KSSTA*. He lives with his wife Birgit Sadoghi, MD, a dermatologist, and his son Lorenz in Graz, Austria.