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Rapid prototyping of replica knee implants for in vitro testing

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Abstract: The understanding of the complex biomechanics of the knee is a key for an optimal implant design. To easily investigate the influence of prosthetic designs on knee biomechanics a rapid prototyping workflow for knee implants has been developed and evaluated. Therefore, different manufacturing technologies and post-treatment methods have been examined and overall seven different replica knee implants were manufactured. For evaluation, the manufacturing properties such as surface accuracy and roughness were determined and kinematic behaviour was investigated in a novel knee testing rig. It was carried out that PolyJet-Modelling with a sanded surface resulted in changed kinematic patterns compared to a usual CoCr-UHMWPE implant. However, fused deposition modelling using ABS and subsequent surface smoothening with acetone vapor showed the lowest roughness of the manufactured implants and only minor kinematic differences. For this reason this method constitutes a promising approach towards an optimal implant design for improved patient-satisfaction and long lifetime of the implant. Finally the workflow is not only limited to the knee.

Keywords: biomechanics; knee simulator; rapid prototyping; total knee arthroplasty.

1 Introduction

Total knee arthroplasty is with over 149,000 implantations annually one of the standard orthopaedic procedures in Germany [1]. Nevertheless, each year over 25,000 implants have to be explanted and replaced. One of the main causes is aseptic loosening, which is supposed to be due to the induced changes of the individual biomechanical

situation [2]. Therefore investigations on the effect of different implant geometries on knee biomechanics are essential to optimize implant design and subsequently the clinical outcome.

Experimental cadaveric testing rigs represent a generally accepted procedure for biomechanical studies. In these setups artificial muscle forces and/or external movements are applied on the specimen and different sensor systems are used to measure knee kinematics and/or muscle and joint forces. Thus, e.g. prototype implants can be *in vitro* evaluated. Problematic is the expensive and time consuming manufacturing process of these new implants, when multiple designs have to be evaluated [3]. Since there are different requirements for *in vitro* tests than for *in vivo* implantation, especially in terms of durability and biocompatibility, rapid prototyping technologies might have the potential to offer an easy and fast access to various implant designs [4] and [5] investigated the use of rapid prototyping for *in vitro* knee experiments and concluded that replica prostheses manufactured by PolyJet-Modelling can reproduce the original implant kinematics, although higher friction levels under low axial loads have been determined. Despite their promising results, these studies only regarded the femoral component and one material and manufacturing technology.

In the context of this study the use of different technologies for rapid-prototyping of tibial and femoral components for in vitro testing was investigated.

2 Material

As a reference model, a patient-specific iTotal knee implant (ConforMIS, Inc., Bedford, USA) has been used. Based on the corresponding CAD data overall 7 replicates (Figures 1 and 2) have been manufactured using different commercially available rapid prototyping technologies:

- Selective Laser Sintering (SLS): PA (External provider: DTM Sinterstation2500Plus) layer thickness: 0.1 mm
- Fused Deposition Modelling (FDM): PLA & ABS(+) (Ultimaker 2 & Stratasys Dimension Elite) layer thickness: 0.1 mm & 0.178 mm

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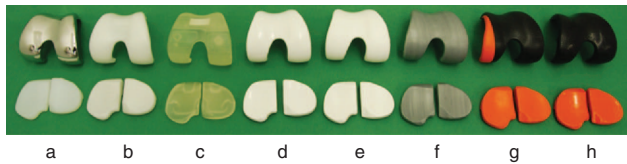


Figure 1: Reference and manufactured knee implants: (A) Reference: CoCr/UHMWPE (ConformIS); (B) SLS: PA – sanded; (C) PJM: RGD720 – sanded; (D) FDM: ABS – acetone; (E) FDM: ABS – sanded; (F) FDM: PLA – sanded; (G) FDM: ABS+ – sanded; (H) FDM: ABS+ – acetone.

- PolyJet-Modelling (PJM): RGD 720 (Stratasys Objet Eden 350V) layer thickness: 0.016 mm

Because surface quality is a crucial factor of the implants, post-treatment of the articulating areas was necessary. On the one hand, the surfaces were smoothed manually using stepwise fine (500) and ultrafine (1000) sandpaper. On the other hand, ABS is dissoluble in acetone, so a smoothening was applied by exposing the material to acetone vapor. Therefore 40 ml of acetone and the ABS(+) implant were placed inside a closed container for 60 min at room temperature.

For the biomechanical kinematic analysis, a knee simulator recently developed at our institute has been used (Figure 2). The modular setup allows different configurations for a wide variety of studies.

The knee joint can be moved passively, by an electrical engine (EC45, Maxon Motor, Sachseln, Switzerland) or actively by up to 5 artificial pneumatic muscles (DMSP20/40, Festo, Esslingen, Germany) whereby forces are transmitted by bowden cables to the specimen. The muscle activations can be force or length controlled. Next to the muscle length sensors (WS10SG, ASM GmbH, Moosinning, Germany) and force sensors (KM30z, ME-Messsysteme, Henningsdorf, Germany), the movement of the knee joint (Femur, Tibia, Patella) is tracked by an optical tracking system (Polaris Spectra, NDI, Ontario, Canada) and ground reaction forces are measured by a 6D force torque sensor (ATI, Apex, USA). All sensor and actor data, as well as muscle and motor control and visualization are managed by a real-time control system (MicroAutoBoxII, dSPACE, Paderborn, Germany). This way a full set of measurement data is acquired and biomechanical analysis can be performed.

3 Methods

To evaluate the performance of the rapid prototyped implants in comparison to the original reference implant three different aspects have been investigated: The surface

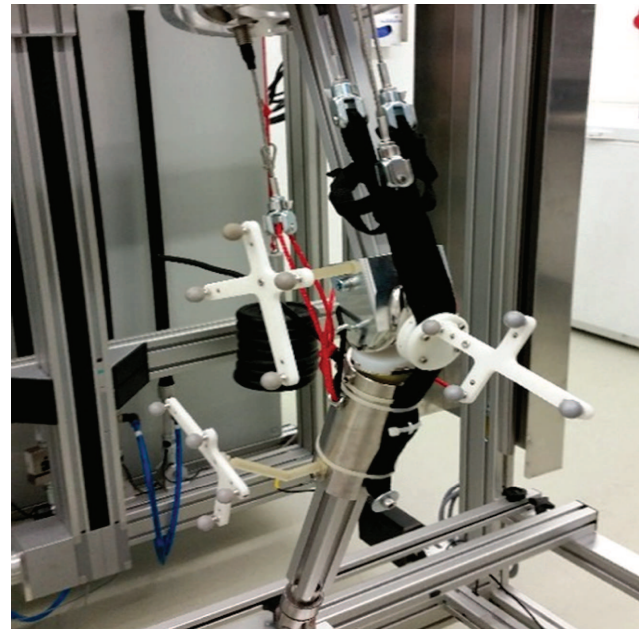


Figure 2: MediTEC knee simulator with artificial specimen.

accuracy (1), surface roughness (2) and the resulting kinematics (3).

- (1) The surface accuracy of the femoral components was determined by an optical 3D Scanner (HandySCAN 700, Creaform, Levis, Canada), which has a resolution of 0.2 mm. The 3D data was then compared to the original CAD data which was used for the manufacturing.
- (2) The quality of the surface was measured in accordance with the standard DIN EN ISO 4288 by a tactile stylus instrument (Talysurf120, TaylorHobson, Leicester, England) at 5 different parts of the femoral component, lengthwise and across the direction of flexion/extension motion.
- (3) The kinematic analysis was performed on the knee simulator with an artificial specimen, with the aim to test stability and assess kinematic differences between the replica implants and the reference.

The femoral component of the implants was placed on an aluminium adapter and the tibial inlays were placed on the original tibial tray. The articulating surfaces were lubricated with petrolatum. Femoral and tibial parts were connected by elastic rubber bands, representing the collateral ligaments, cruciate ligaments were neglected. A matching original UHMWPE patella was used for the whole study which was positioned considering a normal Insall-Salvati ratio of 0.82 on a tension belt representing the quadriceps tendon. Five muscle strings were simulated: 3 parts of the M. Quadriceps [M. vastus lateralis (VL), M. rectus femoris

(RF) and M. vastus intermedius (VI) (combined), M. vastus medialis (VM)) and 2 hamstrings (M. biceps femoris (BF), M. semimembranosus (SM)).

Optical trackers were mounted on the femur, tibia and patella and characteristic landmarks were palpated to reconstruct bony coordinate systems according to Grood and Suntay [5].

Knee flexion (approx. 30° – 100°) was induced by either a passive vertical translation of the hip section with a stabilizing basic tonus of the quadriceps (RF+VI 150 N, VL 37.5 N and VM 37.5 N) or an active movement by the quadriceps. In both cases SM and BF applied a basic tonus of 40 N each. The active quadriceps force was generated by length control of the RF+VI and an adaptive force control of VL and VM based on the actual measured RF+VI force and then scaled by 25% each (based on [7]).

With this setup the following experiments have been performed and compared to the kinematics of the reference implant:

1. Passive Movement: Replica femoral component + original tibial component
2. Passive Movement: Original femoral component + Replica tibial component
3. Passive Movement: Matching femoral component + tibial component
4. Active Movement: Matching femoral component + tibial component

Each setup was repeated several times whereby only the last measurements were considered to avoid running-in effects.

4 Results

The surface accuracy of the femoral components showed no deviation in the articulating areas within the measuring accuracy of 0.2 mm. Higher deviations were measured in areas where support structures had to be removed.

The surface roughness of the femoral components could be improved by post-treatment with manual sanding and acetone vapor (Figure 4). However, the reference component showed a $R_a = 0.0123 \pm 0.0028 \mu\text{m}$ and is thereby still 20 times better than the best replica implant.

The lowest roughness was observed for the ABS component treated with acetone vapor with an almost uniform surface roughness of $R_a = 0.23 \pm 0.07 \mu\text{m}$ in direction of movement and $R_a = 0.37 \pm 0.14 \mu\text{m}$ across the direction of movement. Untreated probes showed higher differences between the directions of the measurement due to layer-wise manufacturing process.

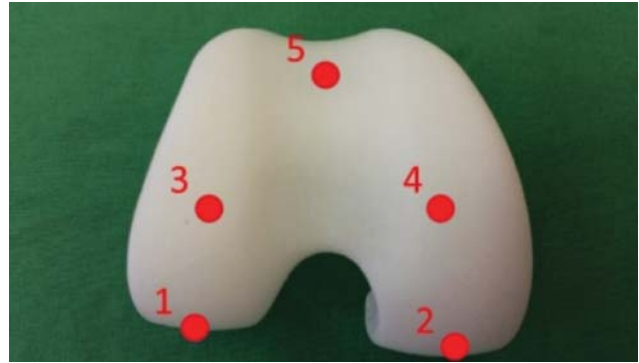


Figure 3: Measurement points for the surface roughness tests.

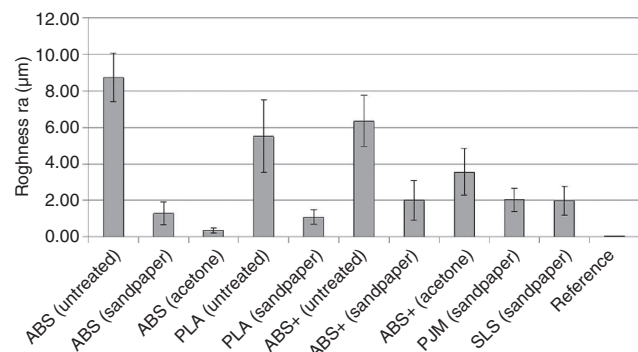


Figure 4: Surface roughness of the femoral component in direction of the knee movement.

The kinematic analysis (experiments 1–4) was successfully performed without any visual damage to the implants, although high active loads with estimated joint forces above 2000 N (sum of applied muscle forces) were applied. Based on the measurement data the implant specific tibiofemoral kinematics with 6 degrees of freedom was calculated. Since the experiments provided a huge amount of quantitative data, only an excerpt is shown in this context. As a characteristic feature of knee kinematics the tibial internal/external rotation is used to rate the performance of the implants (Table 1).

It can be seen that the smallest differences in comparison to the reference showed up with the ABS Acetone implant. Especially the combination of an ABS acetone femoral implant and an original UHMWPE tibial component resulted in a good agreement between reference and replica kinematics (Figure 5).

5 Discussion

An evaluation of different approaches for rapid prototyping of knee implants for *in vitro* kinematics testing was

Table 1: RMSE between reference and replica implants of tibial rotations during experiment (1), (2), (3) and (4). A damage of the patella fixation prevented comparability of ABS+ acetone during experiment (4).

Material	Tibial Rotation			
	RMSE (1)	RMSE (2)	RMSE (3)	RMSE (4)
SLS sanded	1.58°	2.08°	1.17°	1.33°
PJM sanded	3.82°	0.98°	2.15°	1.85°
ABS acetone	0.36°	1.23°	1.06°	1.09°
ABS sanded	3.17°	0.70°	1.85°	1.69°
PLA sanded	2.94°	0.53°	2.02°	1.93°
ABS+ sanded	3.14°	0.65°	2.07°	2.03°
ABS+ acetone	0.70°	0.68°	0.87°	–

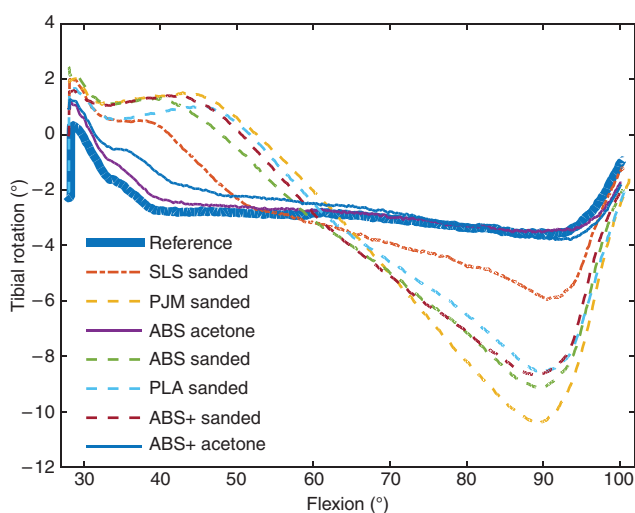


Figure 5: Tibial rotation during knee flexion with different femur components during experiment (1).

presented. The results indicate that with an appropriate manufacturing technology and post-treatment method the knee kinematics of usual CoCr-UHMWPE prostheses can be reproduced.

All manufactured implants showed an acceptable surface accuracy compared to the desired CAD Modell and were strong enough to sustain high joint forces, which occurred during active kinematics. In accordance with the surface roughness tests the ABS implants, which underwent post-treatment with acetone vapor, performed best during the kinematic experiments. PJM implants showed the worst results, which has been used in previous studies of van Haver et al. [4] and Schröder et al. [5]. Schröder et al. stated that friction with PJM implants decreases under high loads down to original implant level during an active movement and can therefore be neglected. Our experiments showed that even under high loads PJM implants are not suitable for this purpose. Our suggestion for an

optimal reproduction of knee kinematics would be the use of ABS acetone implants.

The developed cheap and easy workflow of rapid prototyped replica implants enable further investigations about the kinematic influence of implant design parameters in an experimental testing rig. The reproduction of the findings with cadavers is part of ongoing work. Despite the application to the knee the approach can be used for additional joints to make a contribution to improved patient-satisfaction and extended lifetime of prostheses.

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Author's Statement

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References

- [1] Gesundheitsberichterstattung des Bundes. Available from: <http://www.gbe-bund.de>, 2015.
- [2] Higuera C, Parvizi J. 18 Causes and Diagnosis of Aseptic Loosening After Total Knee Replacement. In *The Unhappy Total Knee Replacement*. Springer International Publishing; (2015). p. 225–37).
- [3] Baldwin MA, Clary CW, Fitzpatrick CK, Deacy JS, Maletsky LP, Rullkoetter PJ. Dynamic finite element knee simulation for evaluation of knee replacement mechanics. *J Biomech.* 2012;45:474–83.
- [4] Van Haver A, De Roo K, De Beule M, Van Cauter S, Labey L, De Baets P, et al. The use of rapid prototyped implants to simulate knee joint abnormalities for in vitro testing: a validation study with replica implants of the native trochlea. *Proceedings Proc Inst Mech Eng H.* 2014;228:833–42.
- [5] Schröder C, Steinbrück A, Müller T, Woiczinski M, Chevalier Y, Weber P, et al. Rapid prototyping for in vitro knee rig investigations of prosthetized knee biomechanics: comparison with cobalt-chromium alloy implant material. *BioMed Res Int.* 2015;2015:185142.
- [6] Grood ES, Suntay WJ. A joint coordinate system for the clinical description of three-dimensional motions: application to the knee. *J Biomech Eng.* 1983;105:136–44.
- [7] Shalhoub S, Maletsky LP. Variation in patellofemoral kinematics due to changes in quadriceps loading configuration during in vitro testing. *J Biomech.* 2014;47:130–6.