Nad Siroros*, Yu Liu, Sophie Lecouturier, Markus Tingart and Jörg Eschweiler

A pilot study: development of bone-preserving-biomimetic artificial femoral head cover

Abstract: Patients with hip arthrosis are increasing each year where total hip replacement is an effective solution when other non-invasive or surgical methods are no longer an effective solution. A pilot study of a new bone-preserving-biomimetic artificial femoral head cover was initiated. The purpose of the new implant is to be an alternative to the current hip arthroplasties. A special polyurethane (PU) femoral head cover was mechanically tested. Experiments were performed to investigate the implants mechanical behaviour and response to tensile load and study on the locking mechanism design concept of the prosthesis. The femoral head cover had a 45 mm outer diameter. Two suture techniques were selected to represent possible locking mechanisms. The experiment consisted of five cyclic loadings followed by a pull-to-failure test. The results show that each specimen has a consistency response and different suture technique results in a different outcome. This experiment intended to study the response of specimens as a whole part, not the material itself. Factors are influencing the outcome such as the femoral head cover positioning and suture rupture pattern. From this pilot study, some points need to be further considered. The information obtained in this experiment would influence further development achieving towards the goal of this alternative hip arthrosis treatment.

Keywords: Hip arthroplasty, hip prosthesis, femoral head prosthesis

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***Corresponding author: Nad Siroros:** Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30, 52074, Aachen, Germany
e-mail: nsiroros@ukaachen.de
Yu Liu, Sophie Lecouturier, Markus Tingart and Jörg Eschweiler: Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30,52074 Aachen, Germany
e-mail: yliu@ukaachen.de (Y. Liu), slecouturier@ukaachen.de (S. Lecouturier), mtingart@ukaachen.de (M. Tingart), joeschweiler@ukaachen.de (J. Eschweiler)

1 Introduction

The hip joint is one of the largest joints in the human body. Patients with arthrosis face substantial or impending permanently restricted joint function due to joint destruction or pain [1]. In 2018, Germany had approximately 240,000 primary total hip replacement (THR) documented [2], while the USA in 2017 has a record over 600,000 THR performed [3]. THR is a surgery to replace a worn-out or damaged hip joint. The surgeon replaces the old joint with a prosthesis. Even though the THR rate has a small and steady increase during the past decades, the prediction towards 2040, in Germany, estimates 27% increase in THR compare to 2010 [4].

The idea of hip resurfacing arthroplasty (HRA) or hip surface replacement is not new and many studies dated back as far as 1925 [5], became popular in the 1960s, and regained its popularity in the 2000s [6]. The implants itself are mostly made of hard material and other hard composites like metal. The advantages of the HRA over THA are, for example, bone preservation, lower dislocation rates, and easier revision surgery. However, the disadvantages such as implant failure, and femoral neck fracture can be found [6]. In an early design, material like some form of glass and acrylic was used but cannot withstand the load and fail. Therefore, an idea to develop a bone-preserving-biomimetic artificial femoral head prosthesis has been initiated in collaboration with revomotion GmbH Cologne, and Fraunhofer UMSICHT (MioHip-project). This approach intends to develop a first design concept and prototype, respectively, of an elastic femoral head cover that mimics human cartilage and minimise bone loss and soft tissue removal to enhance intervention effectiveness. This also beneficial to the patients in case of addition revision or THR in the future since the bone was preserved. Figure 1 shows the conceptual design of a femoral head cover and its locking mechanism.

This paper aims to investigate the mechanical femoral head cover behaviour. Furthermore, the response to a simple tensile loading as a whole implant rather than focusing on mechanical properties testing was investigated. This paper presents the initial mechanical experiments and the first results of this design concept.

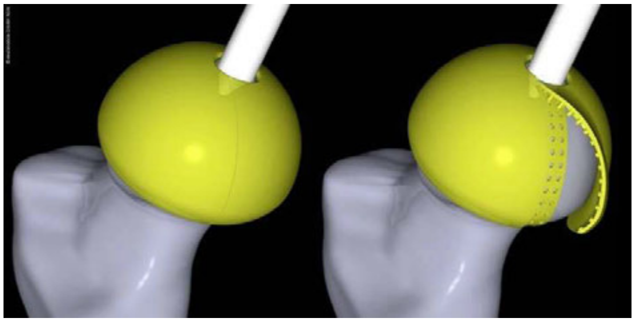

Figure 1: design concept of a femoral head cover and its locking mechanism

2 Material and methods

Nine specially developed femoral head covers, as testing specimens, were provided by revomotion GmbH. The implants were an incomplete sphere with an outer diameter of 45 mm and approximately 2 mm thickness. The implants were made of PU. (The samples were manufactured by revomotion GmbH with their own PU mixture and only nine samples were available because of the manufacturing limitations).

The experimental setup consisted of a newly developed testing platform implement to a standard testing machine (ZwickRoell, Germany) with a 10 kN load cell for tensile tests. The testing platform consisted of two c-arm-like metal parts, attached to the testing machine. It was designed to positioned the artificial femoral head in a way that its center of mass is in-line to the tensile force to minimise any possible moment, as shown in Figure 2. The artificial femoral head was 3D printed, using Ultimaker 3 extended (Ultimaker B.V., Netherlands), according to the size of testing specimens (41 mm inner diameter). The femoral head was designed as a fifth-eight of a sphere and cut into half.

The test-implants were divided into three groups of three specimens. In the first group, all implants remain uncut. The other two groups, the test-specimens were longitudinally cut and sutured by a medical expert with surgical suture material (Ethicon Prolene polypropylene, MPP7756) with two different stitching techniques. The first one was a simple interrupted suture and the second one was a running subcutaneous suture [7], shown in Figure 2, representing two conceptual locking mechanisms. The use of these two suture techniques derived from a button-up/zipping idea and a pull-and-lock idea.

In the experiment, each specimen was implemented to the testing platform. No special standards for testing such PU implants and locking mechanism are available up to date. The testing machine was set to perform, firstly, five cyclic loads at rate 30 mm/min with 20 mm travel distance and instantly followed by a pull to either failure or at a limited condition (80 kN force or 50 mm travel distance). However, from visual observation in the preliminary experiments, slippage of the femoral head cover and suture rupture before 20 mm in running subcutaneous suture specimen was found. To preserve this phenomenon:

1. At the end of each cycle, the position of the implant was adjusted to the setup position.
2. Only in the subcutaneous suture testing, the maximum distance was set to 5 mm.

The testing machine recorded the force and the travel distance. Besides, experimental footage was recorded for visual observation.

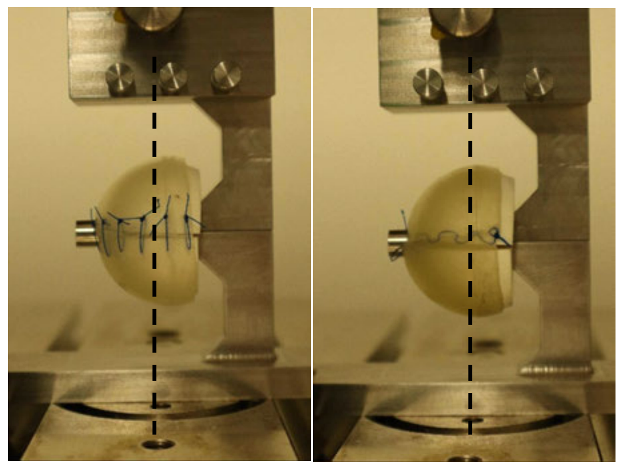

Figure 2: Test setup and specimens with simple interrupted suture (left) and running subcutaneous suture (right). The dashed line shows the alignment of the testing platform.

3 Results

After all nine specimens were tested, the results were as follows:

1. All uncut specimens withstood the cyclic loading. During pull-to-failure, the first two specimens reached a limited distance at 50 mm, but the third specimen tear/snap at approximately 45 mm traveling distance.
2. For specimens with a simple interrupted suture technique, only the first specimen withstood five cyclic loadings whereas the second and the third specimen had a suture rupture during the fifth and the third cycle, respectively. The first specimens failed during pull-to-failure at approximately 21 mm travel distance.

3. For specimens with running subcutaneous suture technique, only the first and the third specimen withstood cyclic loading but the second specimen had a suture rupture during the second cycle. The first and the third specimen failed during pull-to-failure at approximately 13 mm and 11 mm travel distance.

The failure in cut specimen caused by the suture rupture, not the material itself, shown in Figure 3. From visual observation, the suture rupture pattern varied among the tested specimens. This means the suture was not ruptured at the same force, pulling distance, or suture point. In table 1 was shown the average maximum force at the end of each cycle, and the maximum force caused the failure of each specimen.

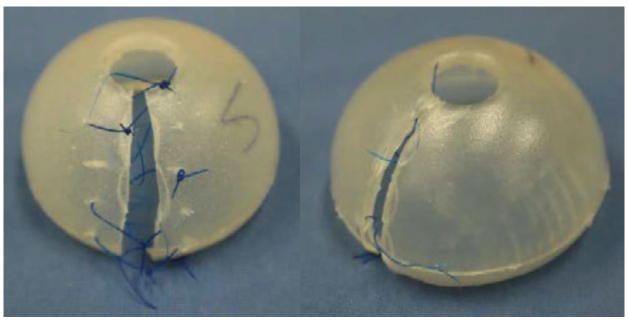

Figure 3: simple interrupted suture rupture (left) and running subcutaneous suture rupture (right)

Table 1: Average maximum force at the end of each cycle, and the maximum force caused the failure of each specimen

		$F_{ave, peak, cycle}$ (N)	$F_{max, failure}$ (N)
Uncut	1	463.6	678.38*
	2	416	578,17*
	3	456	639,91
Simple interrupted	1	557.2	582.72
	2	550.5	-
	3	470.5	-
Running subcutaneous	1	115.2	259,38
	2	180	-
	3	185.6	354,43

*Did not fail but reach 50mm travel distance limit

Figure 4 shows an example of specimens' behaviour comparison during tensile loading. The results show the consistency behaviour of the specimens during cyclic loading. The curve of each specimen shares the same behavioural trends in the beginning. Towards the peak, the simple interrupted suture has a steeper slope than the uncut specimens.

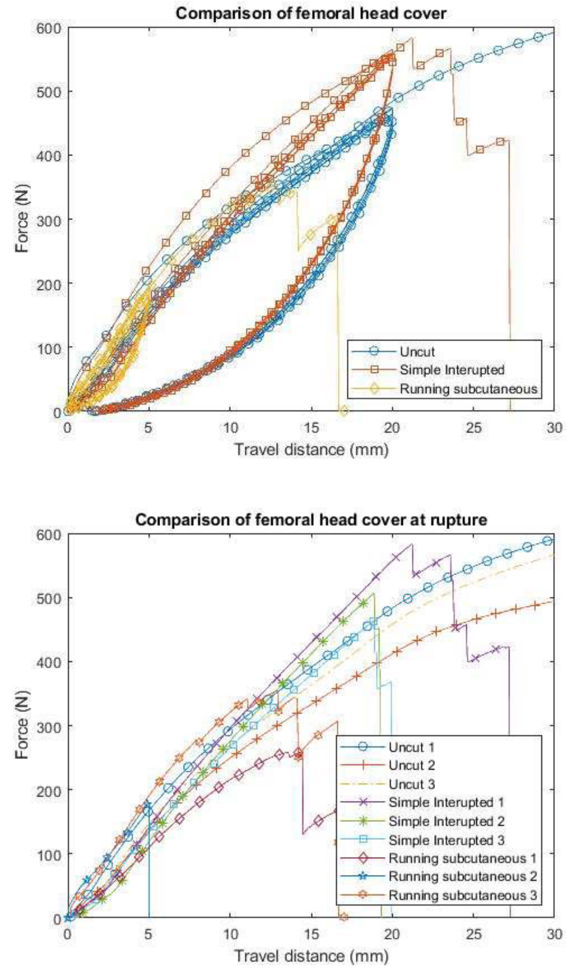

Figure 4: comparison of force-travel distance curve of each femoral head covers (above) and the curve of rupture point of each specimen (below)

4 Discussion

A new alternative for THR has been presented with a design concept to preserve bone, minimal soft tissue removal (i.e. femoral head ligament), and mimic the human cartilage surface. Here, mechanical testing was performed to investigate the femoral head covers' behaviour and response.

Firstly, the curves shown in Figure 4 does neither represent a stress-strain curve nor showing non-linear behaviour of the material. It shows the behaviour of the specimens as a whole of how each specimen response to the given tensile loading. However, the curve of each specimen shows a consistency response, and we can hypothesise that the material is still in its elasticity range and never reach its maximum loading. The Mullins effect is an aspect of the mechanical response in filled rubbers in which the stress-strain curve depends on the maximum loading previously encountered, therefore, can be ignored.

In Table 1, there are some points to notice, which are:

1. For the uncut specimens, the first two reached the pull-to-failure limit with approximately 100N difference, and the third specimen was subjected to a lower force when rupture compare to the first specimen.
2. For specimens with a simple interrupted suture technique, only the first specimens survived towards the cyclic load, but the force at rupture of the other two specimens was lower than that in the first specimen.
3. For specimens with running subcutaneous suture technique, both the first and the third specimen survived the cyclic loading, but the force at peak and force at failure were different (approximately 70N and 95N difference, respectively). The second specimen ruptured at 180N, which was less than the force occurring in the third specimen.

There are many parameters involved in these outcomes where the two parameters believed to potentially influence the outcome were the specimen positioning and the suture itself. In both preliminary and actual experiments, some movement or change in position of the femoral head cover during each cycle was found. The specimens had to be manually adjusted after every cycle. A small difference in position, i.e. at a small angle, results in different peak force outcomes. Secondly, the failure of cut specimens caused by suture rupture. This means the selected suture was not strong enough and its rupture pattern could also influence the outcome. Suture consistency is also a factor influencing the rupture pattern since all suture was done by hand. Therefore, the suture position and tension are not perfectly identical among the test specimens. However, the suture was intended to be used as only a locking mechanism representation and it is strong enough to show how the locking mechanism may function.

The reason that a simple interrupted suture could bare more load was simply that it consisted of six sutures while running subcutaneous suture has only one suture running inside the specimen (see Figure 2). However, from visual inspection was observed that during subjected to tensile loading the running subcutaneous suture kept the cut closer than the simple interrupted suture. Therefore, this locking mechanism concept can be developed further to a more realistic, reliable, and effective mechanism for the femoral head cover design.

Since in this pilot study, there was only a limited number of specimens for the experiments, a larger number of testing specimens will lead to better experimental evaluation. There exist many design parameters for further development. The concerns such as the friction on the outer surface, the bone-prosthesis interaction, locking mechanism development, and patient-specific prosthesis manufacturing should be defined toward the future development

After all, this study introduces an initial study for THR alternatives with a biomimetic approach intended to contribute to a qualitative and sustainable improvement in medical care in orthopaedics.

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