A STUDY ON STABILITY OF AN ALL POLYETHYLENE PRESSFIT ACETABULAR CUP

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by

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Declaration

‘This thesis is the result of the author’s original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.’

Signed: Date:

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"Order and simplification

are the first steps towards

the mastery of a subject"

Thomas Mann (Lübeck 1875 – †Zürich 1955)

Abstract

The primary stability of a pressfit acetabular cup is crucial for its proper performance due to the lack of screws or cement. The primary stability is only given by the pressfit, whereas the secondary fixating derives from osseointegration of the implant. While cemented cups are able to be fully loaded after surgery, uncemented pressfit cups need time for bone ongrowth and therefore micromotion has to be minimized. Mathys Orthopaedics Ltd released in 2002 the first titanium-coated pressfit polyethylene monobloc acetabular cup, which promises similar characteristics to bone, and therefore reduced micromotion and enhanced osseointegration, yet the initial stability is unknown. The "RM Pressfit vitamys" acetabular cup is available with various articulations for the same cup size and as a result with different wall thicknesses. Therefore two different articulations are tested for their stability.

An in-vitro test was conducted with "RM Pressfit vitamys" acetabular cups from Mathys Orthopaedics Ltd. Therefore reamed polyethylene foam with the density of 0.5 g/cm³ was used to mimic human acetabulum bone. Two different cups sizes (28 and 32mm articulation) were placed into the bone substrate with 7kN and three different failures were induced 7 times in series by pulling out,

twisting out and levering out the cup out of its cavity with a uniaxial testing machine.

There was no statistically significant difference ($p<0.05$) between the 28mm and 32mm pressfit cup in the pull out and lever out test. The torsion test showed a difference of $p=0.016$ (28mm (57 ± 5.8) and 32mm (46.5 ± 8) in Nm and Mean ± SD).

The results indicate that the overall stability of the cup matches the values from previous studies with full titanium alloy cups. Furthermore, the benefit of a greater femur head doesn't compromise the stability in terms of a thinner polyethylene wall.

Keywords: Acetabular cups, press-fit cup, cementless, cup stability, polyethylene cup, hip cup, initial stability, lever out, torsion, pull out, total hip arthroplasty

Zusammenfassung (German)

Die Primärstabilität einer pressfit Hüftpfanne ist von entscheidender Bedeutung für seinen ordnungsgemäßen Einsatz aufgrund des fehlenden Zements und Schrauben. Die Primärstabilität ist nur durch die Einpresstechnik gegeben, während die sekundäre Fixierung durch Osseointegrations des Implantats erfolgt. Während zementierte Hüftpfannen volle Belastung nach der Operation aufnehmen können, benötigen zementfreie pressfit Pfannen Zeit für das Anwachsen am Knochen und daher müssen Mikrobewegungen minimiert werden. Mathys AG Bettlach veröffentlichte im Jahr 2002 die erste titanbeschichtete pressfit Polyethylen-Monobloc-Hüftpfanne, die ähnliche Eigenschaften wie Knochen verspricht und daher Mikrobewegung reduziert und Osseointegration verbessert. Die "RM Pressfit vitamys" Hüftpfanne ist in verschiedenen Kopfdurchmessern mit gleicher Pfannengröße erhältlich, folglich existieren unterschiedliche Wandstärken. Daher wurden zwei verschiedene Hüftpfannen der gleichen Pfannengröße auf ihre Stabilität hin getestet.

Ein in-vitro Test wurde an “RM Pressfit vitamys” Hüftpfannen der Firma Mathys AG Bettlach durchgeführt. Dabei wurden Polyethylen-Schaum mit einer Dichte von 0.5 g/cm³ ausgehöhlt um dem Beckenknochen nachzuempfinden.

Zwei unterschiedliche Hüftpfannengrößen (28 und 32mm Innendurchmesser) wurden mit 7kN in Polyethylen-Schaum gepresst und drei unterschiedliche Tests siebenmal nacheinander durchgeführt. Auskippversuch, Torsionsversuch und Ausziehversuch wurden mittels einer Materialprüfmaschine durchgeführt

Es gab keinen statistisch signifikanten Unterschied ($p < 0,05$) zwischen der 28mm und 32mm pressfit Hüftpfanne in dem Auskipp- und Ausziehversuch. Der Torsionsversuch zeigte einen Unterschied von $p = 0,016$ (28 mm (57 ± 5,8) und 32 mm (46,5 ± 8) in Nm und Mittelwert ± SD).

Die Ergebnisse zeigen, dass die Gesamtstabilität der Polyethylene Hüftpfanne mit den Werten aus früheren Studien und mit titanlegierten Pfannen vergleichbar ist. Außerdem, die Vorteile eines größeren Kopfdurchmessers gefährden nicht die Stabilität in Form einer zu dünnen Polyethylenaußenwand.

Stichwörter: Hüftpfannen, Pressfit Pfanne, zementfrei, Pfannenstabilität, Polyethylen Pfanne, Primärstabilität, Auskippversuch, Torsionsversuch, Ausziehversuch, Hüftendoprothetik

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1 Introduction

1.1 General

Hip replacement surgery is one the most successful procedures in all of medicine and the importance of it will continue to grow due to increasing percentage of elderly also known as the baby boomers in our population, an increase in life expectancy overall which will lead to needing hip replacement in later years and also the development of third world countries which will make this procedure more affordable for them.

The increasing demand of the hip replacement surgery is due to extreme wear and tear of the joint. The procedure itself has improved over the decades making recovery of the patients after surgery easier and in addition longevity of the joints has increased.

- In Scotland alone, there has been 65% increase in the decade of 2001-2011 in hip replacement surgeries. Just looking at data of this decade, the numbers increased from 4,219 to 6,956 respectively and still growing according to the Scottish Arthroplasty Report 2012

- In the United States, approximately 332,000 hip replacement surgeries are performed every year according to the Centers for Disease Control and Prevention (CDC).

The desire for increased mobility and quality of life in higher age are the reasons why hip replacement procedure is increasing in demand every year making it one of the most performed surgeries.

1.2 History

One of the first attempts of hip replacement in history was carried out in Germany in 1891 by Professor Themistocles Glück. At the time, he used ivory to replace femoral heads damaged by tuberculosis. In the 19th and 20th century, many surgeons experimented with different tissues.

American surgeon Marius Smith-Petersen was the first to create a mold made of glass. Unfortunately, the glass implant was not strong enough to bear the forces of the hip joint movement. He joined hands with Philip Wiles and used stainless steel with the support of bolts and screws as an alternative material for a hip implant. In 1953, George McKee succeeded to use metal-on-metal prosthesis, which gave a 74% survival rate lasting 28 years (Gomez and Morcuende, 2005).

All of the attempts mentioned above paved the way to Sir John Charnley's discoveries, which we still use today in modern medicine. Prosthetics that we use today are derived from his low friction arthroplasty design, which consists

of a metal femoral stem, a polyethylene acetabular element and acrylic bone cement. The small size of the femoral head and reduced surface area prevented joint wear and tear. However, a too small femur head causes luxation as well as impingement and decreases the overall stability.

Over the centuries, the technological improvements have resulted in making hip arthroplasty one of the most successful surgical procedure in medical history (Knight et al., 2011).

1.3 Project Rationale

If a total hip replacement is required, the surgeon has a variety of acetabular cups he can choose from. The top four of the cups which are implanted the most are Pinnacle (Depuy), Trident (Stryker), Trilogy (Zimmer) and Exceed ABT (Biomet). All these cup are pressfit with a metal alloy as a shell ("Prostheses used in hip, knee and ankle replacement procedures 2011", 2012).

Recently released and still controversial are the polyethylene monoblocs from Mathys. They promise better elasticity and less micromotion, which leads to better bone ongrowth and better stability. Yet, no study has tried to quantify the in-vitro stability and compare it to conventional acetabular cups.

This study should evaluate the stability of polyethylene acetabular cups as a coequal hip implant to conventional cups. According to previous studies, this study measured peak failure forces in pulling out, lever out and twisting the cup out of its cavity and compared it with their direct competitors, the conventional

metal shell cup. (Adler et al. 1992; Hadjari et al. 1994; Ries, Harbaugh et al.1997; Kuhn et al. 1999; Macdonald et al. 1999a; Olory et al. 2004; Wetzel et al. 2005; Schreiner et al. 2007; Antoniades et al. 2013).

1.4 Research Questions

This study investigates the recently released (2011) and unique acetabular cup "RM Pressfit vitamys", which is based on a polyethylene monobloc with titanium coating and a pressfit. What all pressfit acetabular cups have in common is that the initial stability is crucial for its proper performance and directly related to revision rates of hip surgery. Due to the lack of research on these polyethylene monoblocs, this study addresses following question.

Question I

Does the use of polyethylene for an entire acetabular cup compromise the stability in comparison to conventional acetabular cups on the subject of peak failure forces/moments in a pull out, lever out and torsion test?

Furthermore as a result of the usage of polyethylene (vitamin E stabilized) with an elastic modules of 800N/mm²and a tensile strength of 37N/mm² compared to the more common acetabular cup made of a titanium alloy (6Al-4V ELI9) with 113800N/mm² and 795N/mm² (E-modulus and tensile strength) the question has to be raised if due to thinner or thicker wall thickness the stability of a polyethylene acetabular cup is compromised. Especially considering the

advantages of a greater articulation such as less impingement and luxation but more overall stability. The disadvantages of a greater articulation on the other side leads to more wear debris. Therefore, the second research question must be addressed to the wall thickness of polyethylene acetabular cups.

Question II

Are there any differences between 28mm and 32mm articulation in polyethylene monobloc acetabular cups on the subject of stability through pull out, lever out and torsion tests?

A repeated test on a used polyethylene pressfit acetabular cup could also give some indication of plastic deformation. While inserting cups into reamed acetabulum during a surgery, high forces interact with the pressfit cups.

With a cycle test where cups are continuously used for the same test, the change in lever out, pull out and twist out forces/moments indicate permanent deformation within the cup which would compromise the inner sliding ability of the corresponding replacement femur head which in turn leads to high abrasion and inflammation and therefore a shorter lifetime of an implant. A comparison between two different wall thicknesses, especially with weaker polyethylene, regarding this problem could show deviations.

Following stages were required in order to answer posed questions.

i. Identify a testing machine to measure forces and moments

ii. Develop and build a test rig, which is capable of conducting pull out, lever out and torsion tests

iii. Modify polyethylene acetabular cups to achieve an attachment for transmitting torque, pushing and pulling force (lever moment)

iv. Identify a suitable material, which mimics the properties of acetabular bone

v. Identify a reproducible clinically relevant procedure to ream bone material and insert acetabular cup

2 Literature Review

2.1 Anatomy

The hip joint is a ball-and-socket joint making it one of the largest in the body as depicted in Figure 2-1. The joint consist of the acetabulum (part of the pelvic bone) and the femoral head (upper part of the femur bone). The socket being the acetabulum and the ball is the femoral head. Articular cartilage found covering the ball and socket provides cushioning, which makes movements easier. To eliminate friction by lubricating the joint there is a synovial membrane around the joint, which contains synovial fluid. Last but not the least, there are ligaments to stabilize the joint by the connecting the ball and socket.

The hip joint is one of the strongest joints in our body, making it possible for us to walk, jump and run. It plays a part in maintaining balance and a good body posture. It can endure our body weight while still being flexible to provide a wide range of motion.

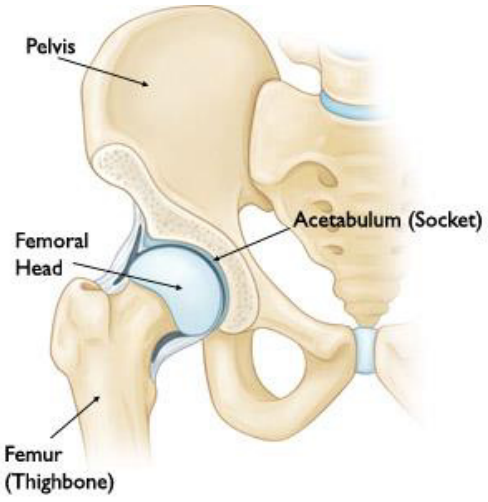


Figure 2-1 - Anatomy Of A Normal Hip

("Total Hip Replacement", 2011)

Hip replacement surgery is suggested to people who have pain that is limiting their day-to-day activities such as walking or even just bending over, if the pain is continuous during resting, or if the patient is unable to move their leg or lift it due the stiffness at the joint. Some common causes for the hip pain are osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis and childhood hip disease.

An increased damage of the joint cartilage is known as coxarthrosis, making it the most common hip joint disorder. This disorder is divided into two forms, primary in which the causes are unknown and secondary. Secondary occurs after rheumatism, congenital malformations, circulatory disorders or accidents. The pain caused in this disorder is due to the joint not fitting resulting in bone debris depositing at the edges and inflammation. Along with pain,

stiffness at the joints limits movements such as walking thus resulting in decreased quality of life

2.2 Cemented Vs. Uncemented Cups

In cemented hip replacement, cement is used to attach an implant to the bone. When used as a bond between the bone and the implant, the cement tends to loosen up. This is due to either the active lifestyle of the patient or heavy weight of the patient thus making cemented hip replacement a less desirable option in the young, active or over weight patients. However, this is an option for patients with less activity in their lives or poor quality of bone.

Cementless hip replacement uses a porous titanium coating making it possible for the bone to grow into the coating, which provides a stronger bond between the bone and the implant. This option is considered best for patients leading an active lifestyle or is receiving the implant at a younger age thus needing something more stable to maintain their normal lifestyle and giving the advantage of bone conservation.

2.2.1 Cemented

Acetabular cups which are cemented are using polymer polymethylmethacrylate for the attachment. It is a two component compound which once mixed together cures to the acetabulum. Cemented cups are still favoured in patients who are older. Due to osteoporosis, elderly patients are not

able to get a pressfit cup. Cemented cup are the earliest form of fixation and still have a big advantage over uncemented cup; they can be fully loaded after surgery and therefore possess the better primary stability.

2.2.2 Uncemented (Pressfit)

After noticing that cemented cups tend to suffer from of aseptic loosening, a different method had to be invented. Cementless cups can be arrange in different categories as Figure 2-2 illustrates. Cementless cups work with the method of biomedical bonding to the bone. Different shapes are available which offer a different indication or philosophy of fixation. Pressfit cups work with an oversize of equators diameter. Thereby the bone is pressed and the cup locks up. Screw cups are screwed into the acetabulum. Both cups usually come with a porous coating of titanium. Titanium oxide is known for providing a suitable surface for bone ongrowth.

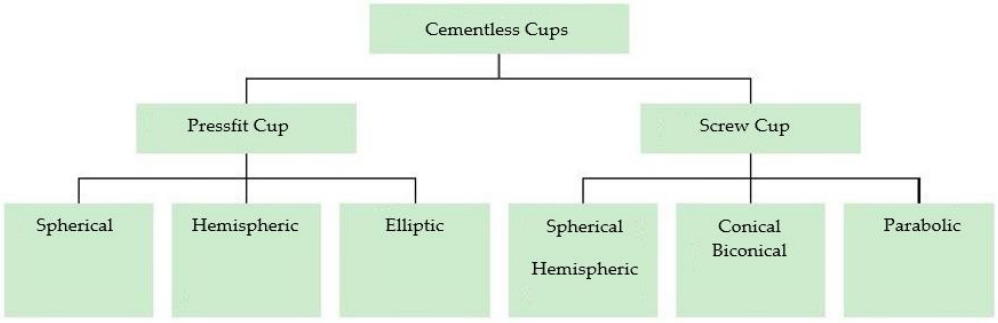


Figure 2-2 - Cementless Cup Variation

2.2.3 Comparison

The key advantages of uncemented acetabular cups are numerous (Lutz, 2014; Neumann et al., 2001):

- Revisions which are applicable to every tenth hip replacement are easier to handle
- Better secondary fixating (osseointegration) due to bone ongrowth
- Less aggressive abrasion particles
- Nontoxic components compared to cemented cups which have "toxic" catalysts in the mixtures
- Easy revision compared to cemented cups and their complex measures of removal
- No high temperatures used compared to partially high temperature of cementation during curing with the possible result of necrotic damage
- Biologically adapted form with cementless polyethylene cups; similar elasticity
- Absorption of pulses with forwarding to surrounding tissue due to
- Therefore functional adaptation of surrounded tissue

2.3 Test on Stability

Testing the stability of acetabular cups is a highly discussed topic in biomedical engineering. Several authors attempted an in-vitro test to evaluate the performance of an acetabular cup.

Antoniades et al. (2013) performed a test on initial stability on two different pressfit cups. The cups differ in terms of shape. One cup was a peripheral self-locking cup, the other a hemispherical cup. Bone substrate made out of polyethylene foam with a density of 0.22g/cm³ mimic old patient and 0.45g/cm³ young patient acetabulum were reamed on a lathe. The reamed bone substrate was used to seat the two different cups under displacement control. Two test were applied, lever out and pull out. The stability was examined by measuring the peak failure forces and moments.

Macdonald et al (1999a) decided to use three different types of substrate. Polyurethane foam for cancellous bone, glass fibre epoxide for acetabular cortical bone and cadaveric acetabular bone. He inserted the cups into reamed cavities of 2mm oversize. Peak loads for failure during pull-out, lever-out and axial torque was the testing methods. He justified his decision of failure testing as in Section 3.3 mentioned.

Ries, Harbaugh et al (1997) created a model to test strain distribution and stability of pressfit acetabular cup using a finite element. Following a mechanical test of manufactured prototype models. These aluminium cups models were placed into reamed foam cavities. Lever out and pull out tests were

performed and initial stability was determined by the peak forces and the moments attained.

Olory et al (2004) used as synthetic bone resin blocks. Reamed cavities were used to insert 11 cementless cups. The initial stability was defined by the maximum force required to pull the cups out its cavity.

Schreiner et al (2007) used the basic design of a hemispherical pressfit cups to identify the stability of acetabular cups regarding different surface finishes. Polyurethane foam was used to mimic the acetabulum. Stability was tested on a simple lever out method.

Wetzel et al (2005) conducted an in-vitro test with lever out failures. Five different acetabular pressfit cups in hemispheric shape were seated into polyurethane foam blocks.

Kuhn et al (1999) did an in-vitro study on pressfit parameters. Under-reamed polyvinyl-chloride substrate was used with six different acetabular cups made out of titanium alloys. After inserting the cup; they were levered out to test for stability.

Adler et al (1992) conducted an in-vitro test regarding lever out and torsion. Polyethylene foam with two different densities as well as bovine bone was used as bone substrate. Different parameters on the acetabular cups were surface structure and design. The test also included different degrees on pressfit parameters, cavity size and defects.

2.4 Summary

Overall, it can be said that the stability of acetabular cups were tested in the past sufficiently. A high variety in different approaches to the three main test procedure, which are pulling out, lever out and twisting out, were found Different substrates were used to mimic acetabular bone.

However, there has been no published data on the in-vitro stability of polyethylene monobloc cups, may to the reason, that this particular cups design is only one decade old with their first implantation in 2001 (RM Pressfit) or due to difficulties in finding a proper attachment methods.

3 Methodology

This study deals with the stability of polyethylene monobloc pressfit cup "RM Pressfit vitamys", an in 2009 released acetabular cup, which has no publicly published results on in-vitro primary stability. Many difficulties emerge due to the simple fact, that these acetabular cups do not have any attachment systems out of the box.

First, a testing machine was chosen which is practical enough to do all the testing on. Subsequently a test rig was developed and built to the extent required for a push in, push out, lever out and twisting mode. The acetabular cups therefore had to be modified to be able to transmit required forces and moments. A suitable material for the bone substitute was identified and modified in order to reproduce clinically relevant results.

3.1 Materials Testing Machine

For the required testing procedures, the Instron E10000 (Instron, UK) was used. All data were recorded with an acquisition rate of 100 Hertz, which appeared to be the best compromise between quantity and quality for the given

load rates. The Instron E10000 had inbuilt pneumatic wedge grips, on which the testing rig was orientated for gripping the pushing/pulling rod as well as torsion cap.

The Instron E10000 is a linear-torsion dynamic test instrument with a load cell integrated in upper crosshead for loads up to ±10kN and torque up to ±100Nm. The accuracy is ±0.5% of indicated load or ±0.005% of load cell capacity, whichever is greater. The stroke length is 60mm (respectively ±135° for torsional) and the machine can be flexibly operated with its actuator in a range of 877mm where the lower crosshead (or base plate) is fixed and the upper moving as shown in Figure 3-1.

Figure 3-1 - Instron E10000 With Test Rig

The computer software WaveMatrix™ was used to determine the method of seating control. Several options were available such as constant displacement or constant load. The decision was made in favour of a load-controlled procedure because of the reasons described in Section 3.5. WaveMatrix™ generated .xls file, which were operated by Microsoft Excel 2013 and as a result tables and graphs were produced. The peak failure forces and moments were object of interest and used to compare both cup sizes.

3.2 Test Rig

The test rig as illustrated in Figure 3-2 consist of parts custom made for this particular study and parts taken over from a previous similar study about conventional acetabular cups made out of titanium alloy (Antoniades et al., 2013).

The basic outline was inherited such as base plate and lever out pulley tower, however all parts depicted in Figure 3-3 were custom made for the polyethylene cups. Initially the locking nut (LN) was supposed to transmit the torque during the torsion test but failed in doing so because of reason mentioned in Section 3.3.3. The test rig was built in such a way that it was able to push the cup in through the lower surface of the cup holder frame pressing against the upper surface of the cup while during the pull out/lever out phase only the thread was used. Hence the thread in the acetabular cup was spared 7kN during the seating phase. The 4 screws in the cup holder frame were corresponding in size with the four holes in the cup to transmit the torque. The

locking cap was built after the failure of the locking nut in torsion test, which tended to destroy the polyethylene thread (Section 3.6.3). The bone substrate was held in place by an aluminium cap. The entire base plate was screwed onto the Instron E10000.

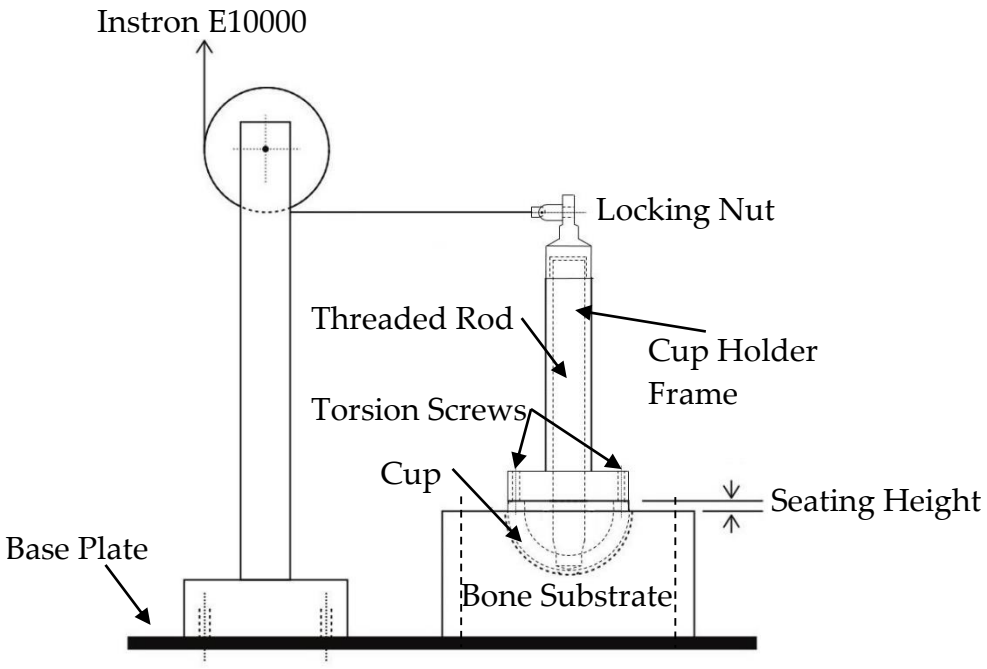


Figure 3-2 - Schematic Drawing Of Test Rig While Lever Out Test

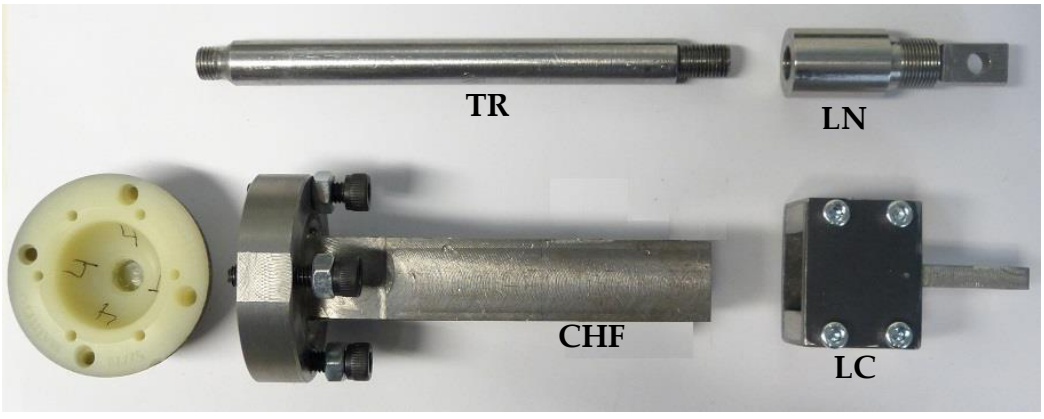


Figure 3-3 - Test Equipment With Threaded Rod (TR), Locking Nut (LN), Locking Cap (LC) and Cup Holder Frame (CHF)

3.3 Acetabular Cups

This study deals with the acetabular cup "RM Pressfit vitamys" from Mathys, which is based on a polyethylene monobloc with titanium coating and a press fit as depicted in Figure 3-4. This cup is based on its predecessor "RM Classic", which pressfit is achieved through two spikes and was in 1983 the first time implanted. In 2002, Mathys released the "RM Pressfit" and it was first implanted in September 2002. The "RM Pressfit" lost the spikes and the pressfit is achieved by oversizing the cup's equator. In 2009, the "RM Pressfit vitamys" was released. It is based on the "RM Pressfit" but to the ultra high molecular weight polyethylene (UHMW-PE) the vitamys cup also contains vitamin E, which stabilizes the UHMW-PE and leads to less wear and higher tensile strength (Mathys Orthopaedics Ltd, 2010) .

Figure 3-4 - Mathys "RM Pressfit vitamys" 52mm Cup (28mm Articulation)

The RM Pressfit series is a clinically proven acetabular cup. Long term result promises a great alternative to conventional acetabular cups and show low revision rates (Ihle et al., 2008; Pakvis et al., 2011; Lafon et al.,2014).

However, in contrast there are no published papers on the in-vitro stability of polyethylene acetabular cups. This might have to do with the fact that the RM pressfit series doesn't allow any attachment without alterations to the object.

Therefore, a method of attachment had to be designed. Glues and adhesive liquids of any kind were not feasible as a result of the slippery polyethylene surface, which was made to have low friction for the femur head. A fully penetrated cup was also no feasible because it could compromise pressfit parameters of the cup and this method would be less clinically relevant with a significant modification to the outer surface.

In a pre-test run, a 46mm hip cup was used to determine the strength of a thread inside the acetabular cup. The reason behind the test was to evaluate the length of a possible thread, which could be cut into the polyethylene but not through the entire thickness. During this test, the cup was fixed with a stainless steel plate and the threaded rode was pulled out of the cup. The result showed, that a 4mm thread could take about 1.15kN before it failed. This number confirmed the decision to cut an 8mm thread into the 28mm and 32mm articulation cups because the 52mm cups had a wall thickness of about 9mm (32mm) and 11mm (28mm). With an 8mm thread, the projected maximum pull force would be 2.3kN since the gain is linear to the thread length. This ensured a not fully penetrated acetabular cup for the testing. Antoniades (2013) showed

that the pulling force of the Stryker acetabular cups was about 1.5kN (mean) in high dense substrate (0.45g /cm³). The expected pulling out force was lower than the Stryker cups due to usage of polyethylene instead of titanium alloy.

To sum up, Figure 3-5 shows the finished concept. Both cups 28mm and 32mm were cut with the same thread length of 7.5mm and diameter of UNF 3/8". Both cups were not penetrated fully. The drilling was executed with a lathe to ensure a centre position. The thread was cut by a single operator manually.

Figure 3-5 - Polyethylene Cup With Threaded Hole And Attachment

3.4 Bone Substrate

As a substitute for human acetabular bone, polyethylene foam was used from Otto Bock. Pedilen® Rigid Foam 450 is a two-component foam, which expands when mixed together with the swelling factor of 2.2. Both components were poured into paperboard cylinder with a diameter of 100mm and height of

55mm. The targeted density for the bone substrate was 0.50g/cm³, which lies in the range of acetabulum bone from younger patients (Adler et al., 1992; Litsky and Pophal, 1994; Pitto et al., 1997). The bone substrate was reamed with an acetabular reamer as depicted in Figure 3-6. The reaming was performed on a Colchester Master 2500 with a speed of 235rpm. The speed was decided by the single operator and represents the best compromise between melting chippings and inaccurate formed cavity. The reamer was pushed forward with constant displacement on the lathe against the bone substrate. Stopping point was defined when the reamer fully plunged into bone substrate and reamer was in alignment with surface of bone substrate.

Figure 3-6 - 52mm Acetabular Reamer

Afterward all bone substrates were measured with a telescoping gauge for cavity diameter and depth gauge for cavity depth as shown in Figure 3-7. Furthermore, the bone substrate height was also measured. All dimension were measured to the nearest off 0.01mm with the assistance of a digital calliper.

Figure 3-7 - Depth And Telescoping Gauge For Cavity Determination

Once the induced testing procedure were done every used bone substrate were used to determined density and modulus of elasticity. Therefore, 10 randomly picked bone substrates were cut and sliced into 20x20x20mm cubes as Figure 3-8 illustrates. Weight divided by volume resulted into determination of density. The weighting scale was measuring to the nearest off 0.0001g.

Figure 3-8 – Sliced Cubic Bone Substrate For Measurement Of Properties

The elastic modulus was determined by the method of Antoniades (2013). The cubic bone substrates were put into the Instron testing machine. A compression test was conducted with constant load rate of 150N/s and a maximum load rate of 1500N. The recorded displacement was calculated into

strain and the delta force as well. Considering the cross-section of the cube and the linear section of the stress strain curve resulted into the modulus. The procedure is shown in Figure 3-9.

Figure 3-9 - Determination Of Elastic Modulus In Compression

3.5 Seating Method

Two different principles were available on how to seat the acetabular cup into the bone substrate based on previous studies. Adler (1992) and Baleani (2001) used a load control approach while Antoniades (2013) used the displacement control approach. Antoniades (2013) used the method because of unsatisfying seating during load control method.

The target was to achieve a complete seating as recommended and where the edge of the implant is in alignment with the stopping point of the reamer when it is fully plunged into bone cavity. The edge of the acetabular cup was

supposed to be in line with the surface of the bone substrate. First attempt in pre-testing used the displacement-controlled method. The distance was calculated manually beforehand and values were transmitted to the computer. It was not possible to achieve a satisfying seating. The load cell of the Instron is only able to take loads up to 10kN but it always exceeded the critical point which led to emergency stops.

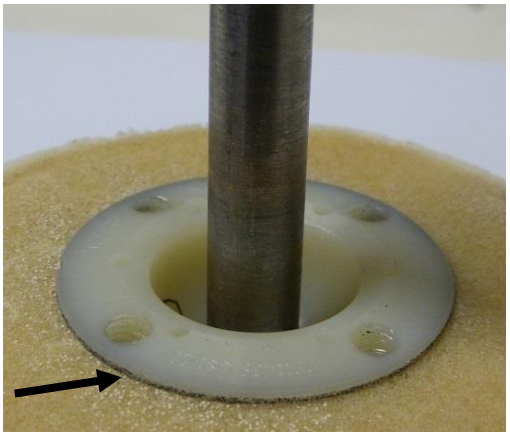


Figure 3-10 - Seating Height

After evaluating the load controlled method in 1kN steps from 1kN to 9kN, it was decided to run with 7kN. The 7kN load control achieved the best compromise between seating height and push in force in a sample of 10 successive tests with three different bone substrates. The result is depicted in Figure 3-10 and shows a seating height between 0.5mm and 1.25mm overall.

The load-controlled method also has the advantages of being more reproducible and the output values such as pull out and leaver out forces as well as torsion moments are more comparable. This is also a reason why the decision fell against the controlled displacement method with a deliberate

seating height of 1.5mm. During the displacement-controlled method in pre-testing, the forces were scattering even with an intentional 1,5mm seating height.

In conclusion, the load-controlled method was used for all three test. The load rate was 500N/s over 14 seconds to achieve 7kN. Afterwards a 15 seconds holding phase was exerted and then the load was reduced to zero.

Of all the literature revised, Schreiner et al (2007) used similar load controlled push-in force with 6000N to conduct a study on different types of rough coating on the acetabular cup. Antoniades et al. (2013) performed a test with a range from 5.13-13.76kN push-in force with a displacement-controlled approach. Wetzel et al. (2005) used a load-controlled method with fixed 10kN to evaluate 5 cups on a lever-out test.

3.6 Failure Test

The test rig was built to conduct three different failure test on acetabular cups. The pull out, lever out and torsion test are commonly used and well established in the biomedical engineering field. Macdonald (1999) used these three test and stated their clinical relevance for a pre-clinic study. Therefore **failure in a torsion** test derives from friction between femur head and inner surface of acetabulum, **failure in lever out** derives from impingement or articulation forces and **failure in pull out**, which is unlikely in a human body, derives primary from a damaged or loosened pressfit after implantation with

high loads which are likely to smash the inner layer of the reamed acetabulum's cavity. The majority of published stability testing on acetabular cups focuses on these premises. (Adler et al. 1992; Hadjari et al. 1994; Ries, Harbaugh et al.1997; Kuhn et al. 1999; Macdonald et al. 1999a; Olory et al. 2004; Wetzel et al. 2005; Schreiner et al. 2007; Antoniades et al. 2013)

3.6.1 Pull Out Test

The pull out test was conducted with the locking nut. As Figure 3-11 depicts, the locking nut was clamped into the wedge grips. Initial situation was a seated acetabular cup into bone substrate with a density of 0.50g/cm^3. The seating was achieved by constant load method and a maximum load at 7kN as described in Section 3.5. After seating, the pull out sequence was initiated with a constant displacement of 0.5mm/s. Both displacement and load was recorded and peak failure force was used for further investigations.

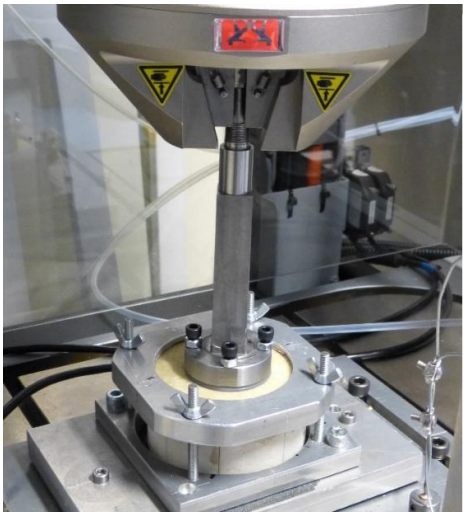


Figure 3-11 - Test Rig During Pull Out Test

3.6.2 Lever Out Test

The lever out test was conducted with a steel rope whose one end was attached to the locking nut and the other end was clamped into the wedge grips as Figure 3-12 illustrates. The initial situation was equal to the pull out test. Once the cup was seated as described in Chapter 3.5, the entire base plate was dismounted from the Instron and turned around to ensure a 90° angle for the rope through the pulley. The constant displacement rate was set up at 1mm/s and therefore higher than in the pull out test as a result of creeping behaviour observed in pre-test. Both displacement and load was recorded and peak failure force was used for further investigations.

Figure 3-12 - Test Rig During Lever Out Test

3.6.3 Torsion Test

The torsion test was initially done in pre-test with the locking nut. The locking nut was suppose to tighten up during angular displacement. Once tight it was assumed that the surface friction between locking nut and cup holder frame would be great enough to move the entire assembly and twist the cup out of its cavity. However, during angular displacement the locking nut moved and pulled the threaded rod to a point where it started to injure the thread of the polyethylene cup.

During the pre-test procedures, the locking cap was developed and manufactured. It prevented any use of the damageable thread. The locking cap transmitted the torque from Instron onto the cup holder frame and finally then onto the acetabular cup through the four screws as illustrated in Figure 3-13. In contrast to the pull out and lever out method, for seating of the cup the locking nut was not used. Instead, the entire procedure was accomplished by the use of the locking cap.

The initial situation was equal to the pull out test. Once the cup was seated, the constant angular displacement sequence was initiated with 1°/s. Both angular displacement and torque was recorded and peak torque which was used for further investigations.

Figure 3-13 - Test Rig During Torsion Test

3.7 Summary

The entire study included 50 manufactured bone substrate with a density of 0.50g/cm³ and 8 polyethylene acetabular cups, out of which 7 were 52mm"RM Pressfit vitamys" cups distributed among four 28mm and three 32mm articulation and one 46mm"RM Pressfit" cups with 28mm articulation.

The 46mm "RM Pressfit" cups with 28mm articulation was a used to determine a method on how to attach a rod onto the cup to transmit torque and pulling forces. This cup was never seating due to absence of a 46mm reamer. However, the 46mm cup helped to determine the thread length and size (Section

3.3), which was cut into the middle of the inside of the cup. A minor test showed, that a thread of 8 mm would be able to pull >2kN. This test verified the method of using a thread of UNF 3/8" (common thread size for titanium alloy acetabula cup) and clarified that the entire cup doesn't have to be fully penetrated with a thread since the wall thickness of the "RM Pressfit vitamys" is approximately 11mm for 28mm articulation respectively 9mm for 32mm articulation.

Out of the remaining seven 52mm "RM Pressfit vitamys" cups one 28mm cup was used to determine the seating method. The decision was made in favour of a load-controlled procedure. This cup was also used to verify all three tests and therefore 8 out of 50 bone substrates were used. The remaining materials were 42 bone substrates and 6 acetabular cups, which were tested. Each of these single cups were used for seven consecutive tests of the same kind. Therefore the 42 bone substrates were distributed as Table 3-1 depicts.

	28mm Cup #1	28mm Cup #2	28mm Cup #3	32mm Cup #1	32mm Cup #2	32mm Cup #3
Pull Out Test	7	-	-	7	-	-
Lever Out Test	-	7	-	-	7	-
Torsion Test	-	-	7	-	-	7

Table 3-1 – Number Of Tests Per Cup

In order to test for significant difference between the two test groups of 28mm and 32mm articulation a two-tailed t-test was performed with a significance level of 0.05.

4 Result

4.1 Bone Substrate Properties

In the interest of a reproducible and clinically relevant procedure, all 42 bone substrate were measure for their cavity depth, substrate height, and cavity diameter. The measurements for modulus of elasticity and density originate only from 10 samples, which were randomly picked out of the total 42 as Table 4-1 depicts.

	E-Modul [N/mm²]	Density [g/cm³]	Depth [mm]	Diameter [mm]	Height [mm]
Sample Size	10	10	42	42	42
Mean	181.294	0.499	26.154	51.391	54.388
SD	15.359	0.010	0.456	0.267	0.495

Table 4-1 - Bone Substrate Properties

The use of a 52mm reamer produces 51.4 ±0.3mm (Mean ±SD) cavity diameter, which results into a tight pressfit. The density of 0.4994 ±1g/cm³ matches the bone density of young patients' acetabulum, where pressfit acetabular cups are mainly used (Adler et al., 1992; Litsky and Pophal, 1994; Pitto et al., 1997; Antoniades et al., 2013). The modulus of elasticity of 181.3

±15.4MPa is also representing cancellous bone of the acetabulum (Li and Aspden, 1997).

4.2 Pull Out Test

The recorded displacement and load resulted into a graph comparable to Figure 4-1, where jumping behaviour of the cup is visible at accomplished pull out and peak failure force.

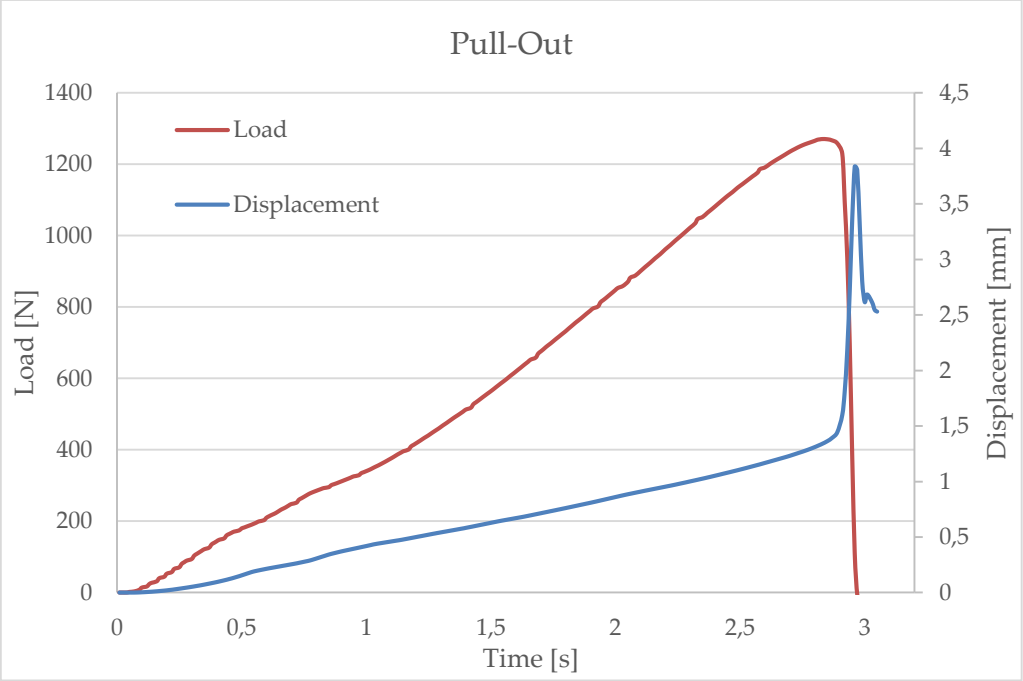
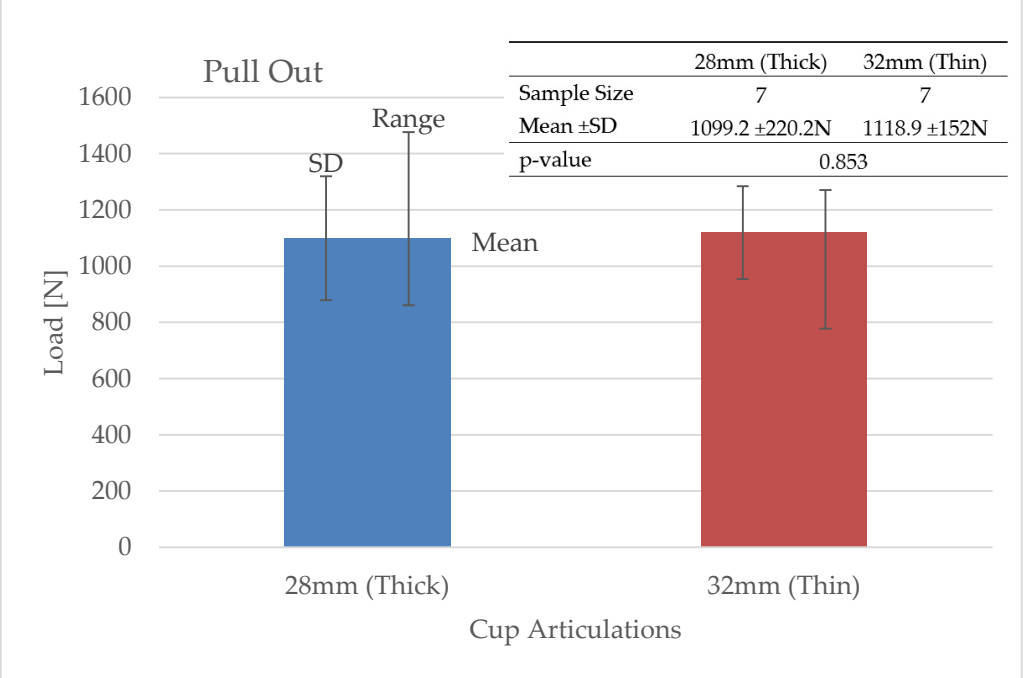


Figure 4-1 – Graph Of Typical Cup Behaviour During Pull Out Test

The 28mm cup had a 1.7% lower mean pull out force than the 32mm cup but this was not statistically significant (p=0.853), Figure 4-2.



	28mm (Thick)	32mm (Thin)
Sample Size	7	7
Mean ±SD	1099.2 ±220.2N	1118.9 ±152N
p-value	0.853	

Figure 4-2 - Pull Out Force 28mm & 32mm

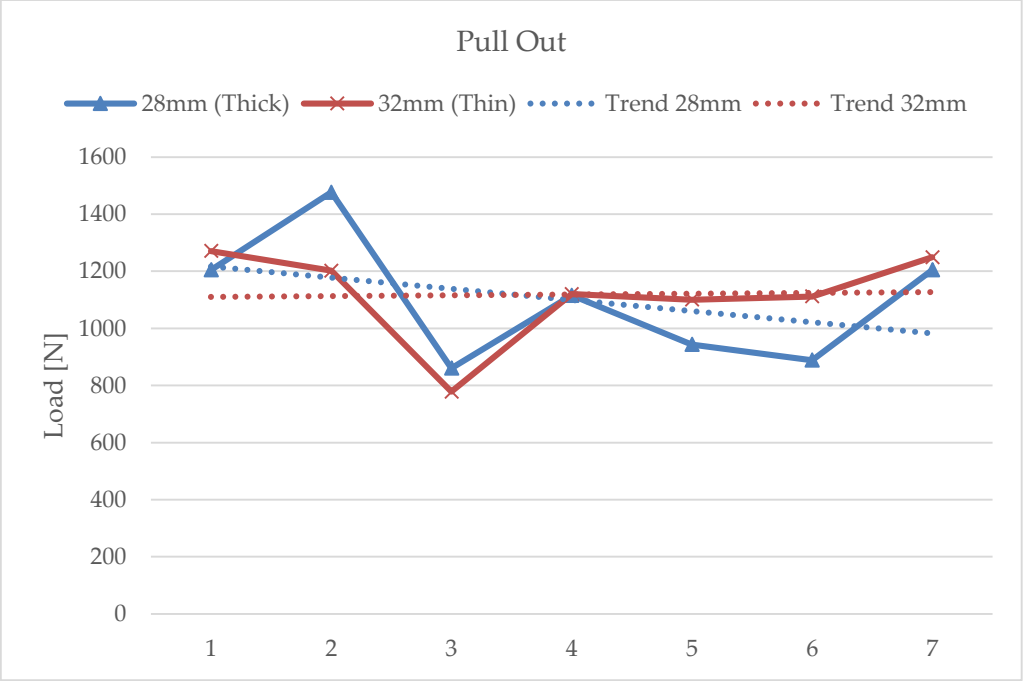


Figure 4-3 - Pull Out Force Over Seven Cycles 28mm & 32mm

The closer examination of the peak failure forces during the 7-cycle pull out test depicted in Figure 4-3 illustrates no difference between both cups throughout the usage of the polyethylene cup by visual inspection. The trend line, which was determined by the method of linear least squares shows the thicker 28mm cup with a slight loss in stability while the 32mm remains steady.

4.3 Lever Out Test

The recorded displacement and load resulted into a graph comparable to Figure 4-4, where compared to the pull-out test less drop off occurs after accomplished peak lever-out failure.

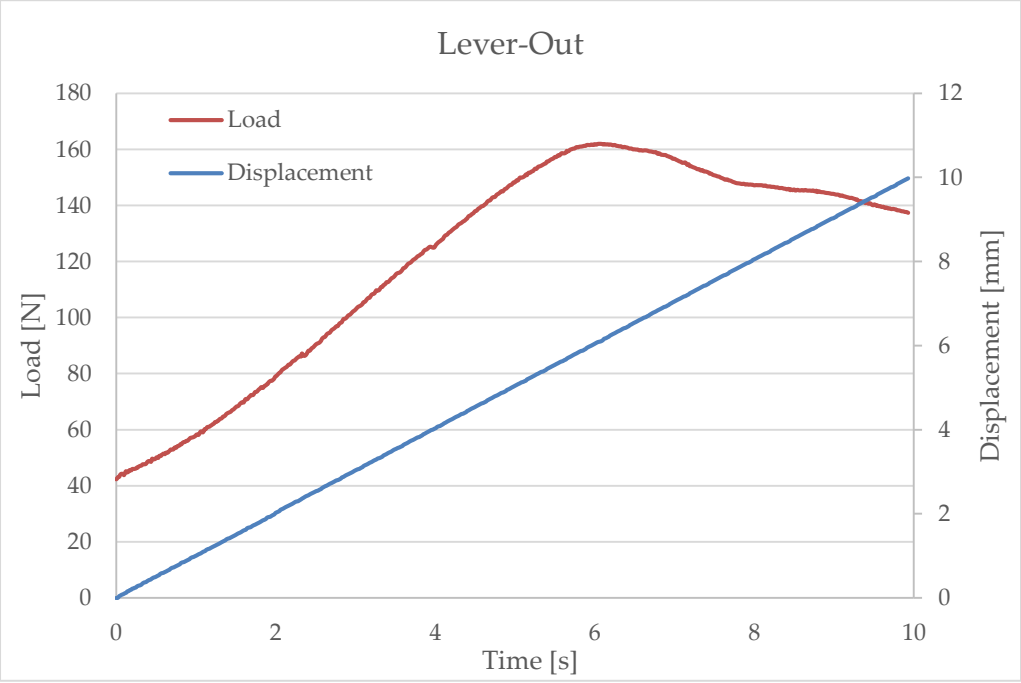


Figure 4-4 - Graph Of Typical Cup Behaviour During Lever Out Test

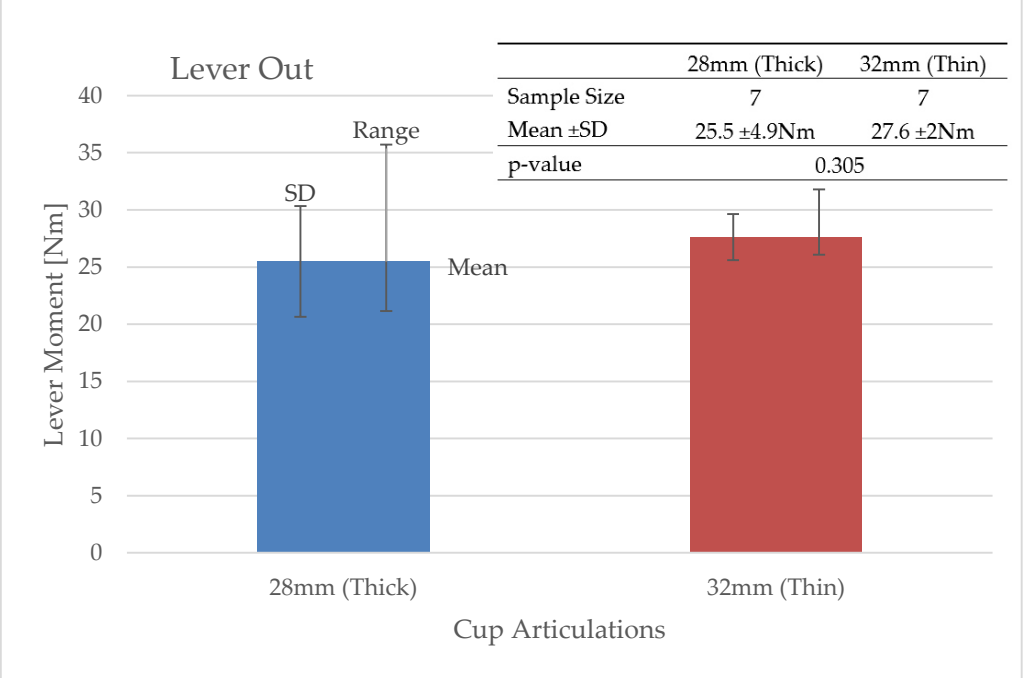


Figure 4-5 - Lever Out Moment 28mm & 32mm

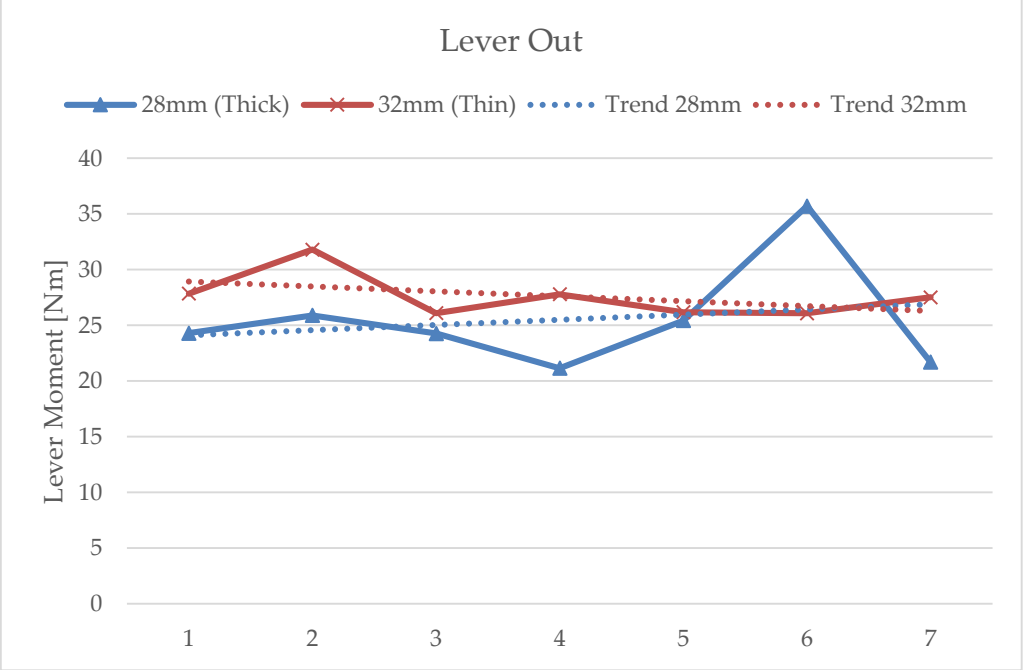


Figure 4-6 - Lever Out Moment Over Seven Cycles 28mm & 32mm

The 28mm cup had a 7.7% lower mean lever out moment than the 32mm cup but this was not statistically significant (p=0.305), Figure 4-5.

The closer examination of the peak failure moment during the 7-cycle lever out test depicted in Figure 4-6 illustrates no difference between both cups throughout the usage of the polyethylene cup by visual inspection. The trend line, which was determined by the method of linear least squares shows the thinner 32mm cup with a slight loss in stability while the 28mm remains steady; as a matter of fact it increases slightly.

4.4 Torsion Test

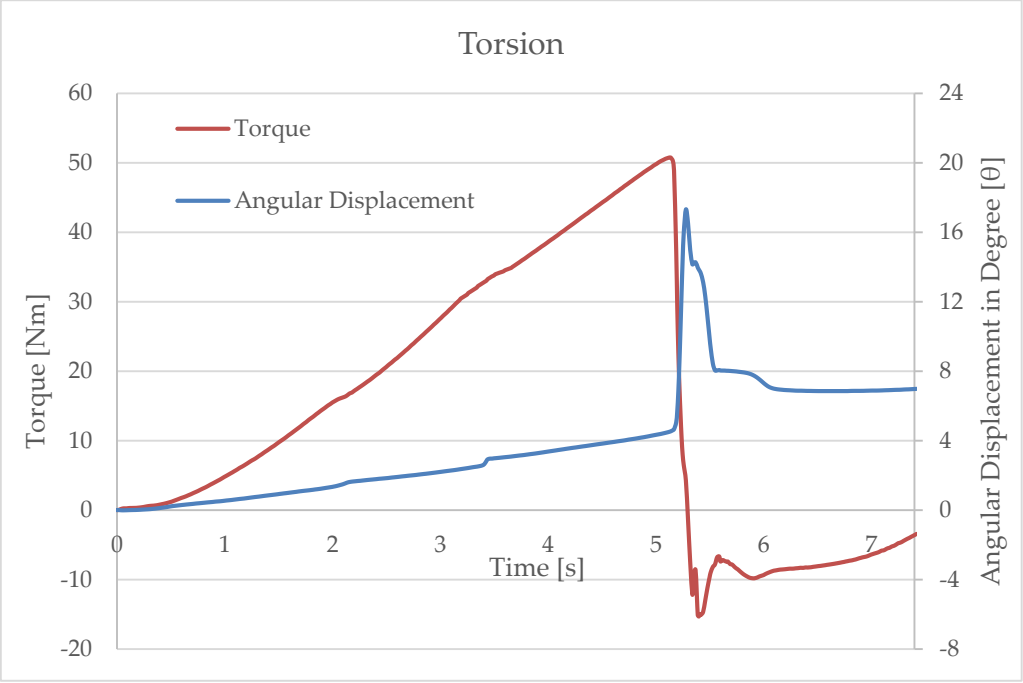


Figure 4-7 - Graph Of Typical Cup Behaviour During Torsion Test

The recorded angular displacement and torque resulted into a graph comparable to Figure 4-7, where micromotion arises already at 2° and 3° angular displacement however peak torque failure occurs afterwards with a great drop off.

The result illustrated in Figure 4-8 for the torsion test shows that the mean peak failure torque for the thicker 28mm cup does have a statistically significant difference (p=0.016) to the thinner 32mm cup in a two-tailed test using a significance level of 0.05. The thicker 28mm cup had a 22.6% higher mean failure torque than the 32mm cup.

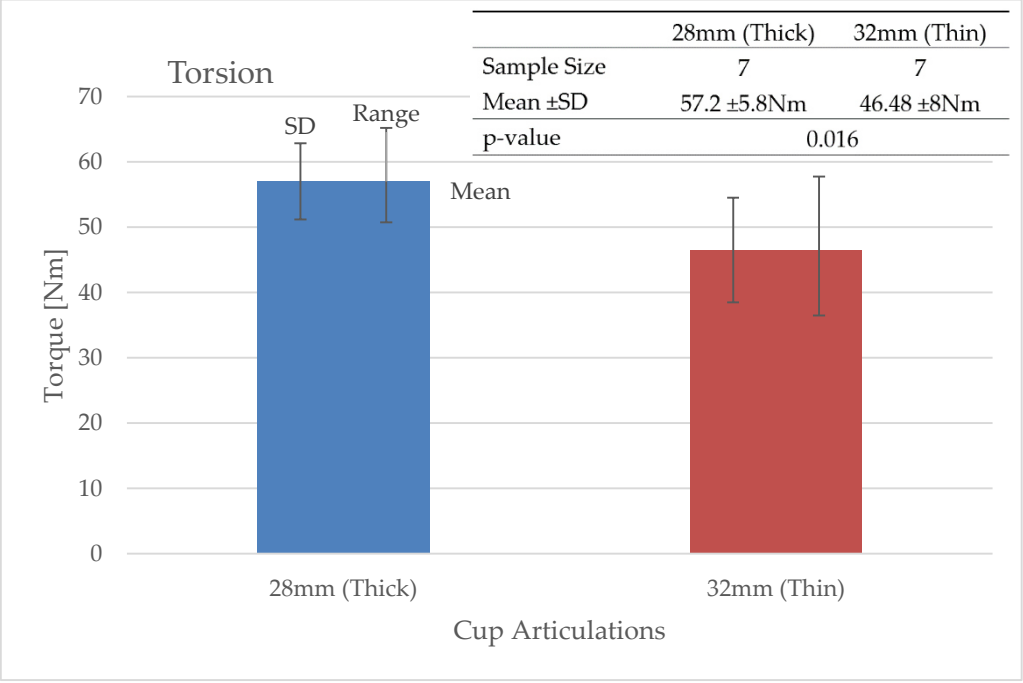


Figure 4-8 - Torsion Moments 28mm & 32mm

The closer examination of the peak failure torque during the 7-cycle torsion test by visual inspection only depicted in Figure 4-9 illustrates a difference between both cups throughout the usage of the polyethylene cup. The thicker 28mm as well as the 32mm experience a noticeable loss in torsional stability clearly visible in the trend line, which was determined by the method of linear least squares. An average of 1.6Nm (28mm) respectively 1.75Nm (32mm) in stability is lost per cycle.

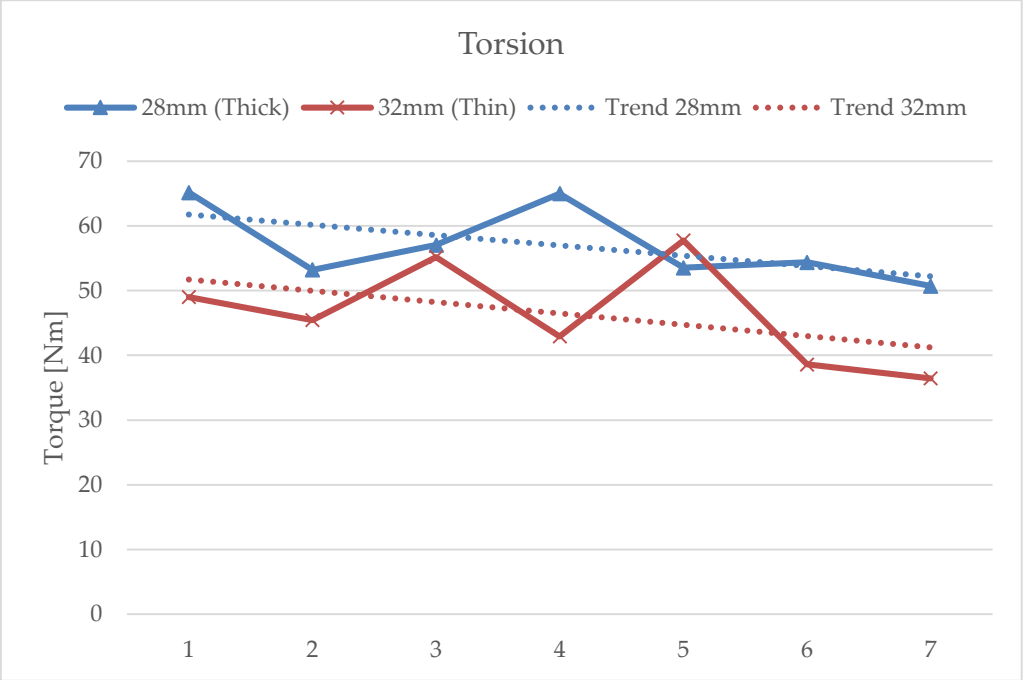


Figure 4-9 - Torsion Moments Over Seven Cycles 28mm & 32mm

5 Discussion

With this study, following research question should have been answered.

Question I

Does the use of polyethylene for an entire acetabular cup compromise the stability in comparison to conventional acetabular cups on the subject of peak failure forces/moments in a pull out, lever out and torsion test?

Question II

Are there any differences between 28mm and 32mm articulation in polyethylene monobloc acetabular cups on the subject of stability through pull out, lever out and torsion tests?

5.1 Bone Substrate

The preparation of the bone substrate was related with a small issue. First, all values from Table 4.1 were close to the desired numbers. No evidence of high

deviations in cavity diameter, cavity depth and density. The modulus of elasticity had a noticeable range and standard deviation. This may have occurred because of a single operator manufacturing the bone substrate throughout many days. Mixing both components together was not followed by any protocol and was prone for errors. However, the density had a smaller deviation and was subject to the same procedure.

5.2 Cup Seating

Cup seating was not achieved as desired. Cavity size appeared to be too small for the cup. Similar problems were mentioned in literature as well (Antoniades et al., 2013; Macdonald et al. 1999a). The reason for undesired pressfit is a result of the reaming procedure. In an operating theatre, the surgeon usually reams the acetabulum manually. The manual work is taken into account while developing an acetabular cup. It is assumed that during the rotation of the drill the cavity size can't be kept steady and uniform.

However, during experimental analyses the lathe creates an almost perfect hemispherical shape, which prevents the cup from being inserted fully under conventional forces. Higher forces were required above 10kN in this study to achieve a fully seated cup. On the other hand, a seating height of 0.5 -1.25mm should affect the outcome values even though the edge of the cups were barely fully coated with porous titanium. A deeper insertion would have given the pressfit more contact area and pressure against the polyethylene foam and therefore more stability against the three induced test conducted.

5.3 **Test**

5.3.1 Pull Out Test

The pull out test showed no statistically significant difference between the two wall thicknesses. The 28mm thicker cup could hold 1099.2 ±220.2N while the thinner 32mm cup could hold 1118.9 ±152N pull out force. The 7-cycle test showed an unsusceptible behaviour. Literature reports ranges of 222 - 2009N for the same test and similar substrate density.

Macdonald et al. (1999a) measured in polyurethane foam with a density of 0.2 g/cm³ four different cups and measured a range of 600 - 2009N pull-out force with variation of oversizing. 2009N was measured with a 2mm oversizing pressfit and an experimental cup to study rim effects.

Ries, Harbaugh et al. (1997) measured a range of 222 - 680N with a displacement controlled seating method with a maximum force of 1800N on six different cup designs.

Antoniades et al. (2013) studied Stryker metal shell cups with bone substrate density of 0.45g/cm³ and measured 1553N for hemispherical and 1424N for peripheral self-locking cups in mean while pulling the cups out. Seating for varied between 5.13 - 13.76kN. This study is the most similar to the test conducted with Mathys polyethylene cup in terms of methods and materials

The metal shell cups in Antoniades study had overall 27% more stability during pull-out.

5.3.2 Lever Out Test

The lever out test showed no statistically significant difference between the two wall thicknesses. The 28mm thicker cup could hold 25.5 ±4.9Nm while the thinner 32mm cup could hold 27.6 ±2Nm lever out moment. The 7-cycle test showed also an unsusceptible behaviour. Literature reports ranges of 2.5 - 50.8Nm for the same test and similar substrate density.

Adler et al. (1992) reports on a range of 2.5 - 47.5Nm for a torsional test on 8 different hip cups on bovine bone and sawbone with a density of 0.5g/cm^3

Ries, Harbaugh et al. (1997) measured a range of 6.4 – 17.85Nm with a displacement controlled seating method with a maximum force of 1800N on six different cup designs.

Kuhn et al. (1999) reports on range of 8 – 35Nm tested on 6 different cups and three different settings from 1-3mm oversizing. The seating method was displacement-controlled and bone substrate made of polyvinylchloride with a density of 0.48g/cm^3 was used.

Macdonald et al. (1999a) tested four different cups with a range of 7 - 38Nm in a similar lever out-test with a rope and pulley in foam with a density of 0.2 g/cm^3.

Olory et al. (2004) used reamed resin blocks whose density is close to bone. A range of 7.63 - 55.79Nm was measured during lever out on 11 acetabula cups with different geometry with flaps.

Wetzel et al. (2005) had a fixed seating force of 10kN load controlled. The values for the lever-out test are located between 39.2 – 50.8Nm in polyurethane foam with density of 0.48g/cm³.

Antoniades et al. (2013) measured a range of 37.2 – 39.8Nm with the same test setup and same bone substrate but with a density of 0.45g/cm³ and higher seating forces of 5.13 - 13.76kN with a displacement-controlled method. Antoniades results are 34% higher in average with metal shell cups but far greater seating force. Therefore, the polyethylene cup is not inferior when it comes to lever out stability.

5.3.3 Torsion Test

The torsion test showed a statistically significant difference between the two wall thicknesses. The 28mm thicker cup could hold 57.2 ±5.8Nm while the thinner 32mm cup could only hold 46.48 ±8Nm torque. Therefore, the 28mm had 22.6% more torsional stability. This is probably due to more overall stiffness of the thicker cup. Both values lie in the range of 1 - 74Nm, which was the result of metal shell acetabular cups in polyethylene foam studies and cadavers.

Macdonald et al. (1999) reports range of 20 - 74Nm for torsional strength tested on foam with a density of 0.2 g/cm³ on four different cups.

Adler (1992) results were between 1 - 6Nm but also dealt with a different seating method with seating force of 1500N held for 2 minustes hard pushing on 0.5g/cm³ dense sawbone. Also Adler defined his failure force not as peak force but as initial failure occurring at 0.4°, when cups first started to yield

Hadjari (1994) results were in the range of 6.93 – 15.05Nm but dealt with screwed cups on fresh cadavers.

Overall the closed study from Macdonald (1999) shows a similar range of torque stability to the polyethylene cups. Macdonald ranges is greater due to the use of four different cups.

In closer examination, the peak failure torque decreased during the 7-cycle test. This may have been due to high abrasion of the titanium coating as clearly depicted in Figure 5.1.

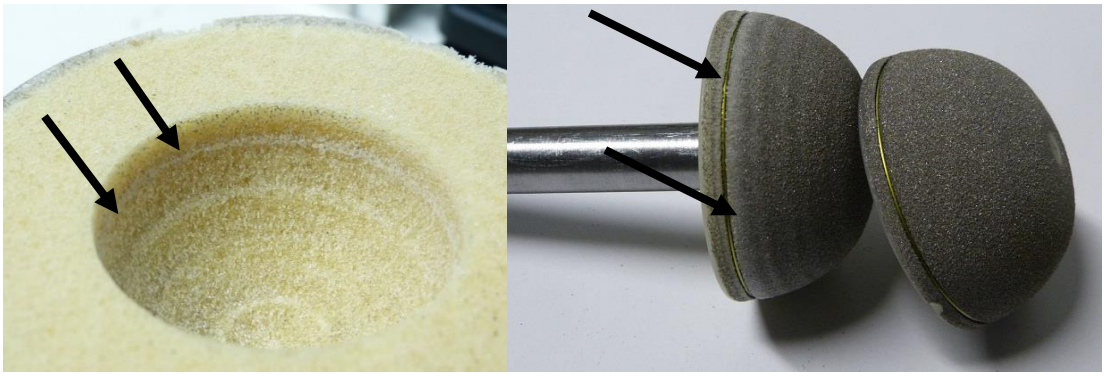


Figure 5-1 – Titanium Coating Wear In Used Cavity And On Acetabular Cup (Compare To New Cup)

5.4 Limitations

The sample size of seven for each cup and test is small and is not fully able to represent a clinical importance. It is difficult to project the result on primary stability onto the list of other hip cups and give them a meaning compared to non-polyethylene pressfit cups.

The use of polyethylene foam as bone substrate has only a limited prediction on stability in-vivo.

Furthermore, the three tests conducted do not fully represent failures, which would occur in-vivo. Therefore, the moments and forces do not translate into human anatomy. Especially considering, that the pressfit achieved with 7kN push-in force is much greater than it would occur in the human acetabulum while surgery.

Seating forces of 7kN are not absorbable through the human pelvis. Such force would lead to fractures. (Kim, Callaghan et al. 1995)

6 Conclusion

This study showed overall, that the polyethylene acetabular cups and their stability are on an equal footing as conventional cups when it comes to primary stability in a in-vitro test. The "RM Pressfit vitamys" did not show any lack of primary stability over cups with a metal alloy.

6.1 Aims and Results

Following stages were successfully achieved and contributed in answering the research question.

i. A testing machine for measuring forces and moments was identified
ii. A Test Rig was developed and built, which was capable of conducting pull out, lever out and torsion tests
iii. The polyethylene acetabular cups were modified to achieve an attachment for transmitting torque, pushing and pulling force (lever moment)

iv. A suitable material, which mimics the properties of acetabular bone, was identified
v. A reproducible procedure to ream bone material and insert acetabular cup was developed

Furthermore, following research questions were satisfactorily answered.

i. The use of polyethylene doesn't compromise the overall in-vitro stability of a acetabular cup
ii. The polyethylene cups generate similar in-vitro stability as their metal alloy derivative
iii. The durability test (seven cycles) showed that the polyethylene cups have endurance strength against deformation
iv. There was no significant difference between two wall thicknesses (28mm and 32mm articulation) during pull out and lever out test
v. There was significant difference between two wall thicknesses (28mm and 32mm articulation) during torison test

Additionally, the following abnormalities were observed.

i. The durability test (7 cycles) showed that the polyethylene cups tend to lose titanium coating
ii. High push in forces were required to seat the acetabular cups. Presumably due to more accurate cavity sizes than common in surgical practice. (the reamer size is likely take into account

deviations caused by manual reaming without support from the surgeon)

iii. No detailed and sufficient reason was found for the significant difference between two wall thicknesses (28mm and 32mm articulation) during torison test.

6.2 Clinical Relevance

A thicker wall thickness in polyethylene acetabular cups provide more torsional stability. It does not mean, that it overcomes the problems of smaller femur head such as impingement, luxation and decreased angular freedom in movement.

6.3 Outlook

In the future, following improvements should be done in order to get more clinical relevant data for a more distinct recommendation on available acetabular cups.

i. Conduct test with mammalian bone
ii. Directly compare conventional acetabular cups with polyethylene cups in one study

iii. Identify a more clinically relevant and more reproducible method on reaming cavities manually which mimics more the operating theatre

iv. Add another method to the failure procedures such as torsion and lever at the same time which mimics heavy impingement on the joint

v. Use the testing machine with a hammering mode, which mimics real surgery. Consider a "Joule Controlled" method.

vi. Investigate the stability further in terms of wall thickness in polyethylene acetabular cups. Especially a direct comparison between available 28mm, 32mm and 36mm articulation.

vii. Extend durability test with a greater number of cycles and measure for deformation inside the cup. Plastic deformation within the cup would compromise the inner sliding ability of the corresponding replacement femur head which in turn leads to high abrasion and inflammation and therefore a shorter lifetime of an implant

7 References

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9 Appendices

9.1 Raw Data Instron E10000

Test #	28mm (Thick) Torsion [Nm]	28mm (Thick) Lever Out [kN]	28mm (Thick) Pull Out [kN]	32mm (Thin) Torsion [Nm]	32mm (Thin) Lever Out [kN]	32mm (Thin) Pull Out [kN]
Test 1	65.15892	0.14297	1.20498	48.99960	0.16385	1.27090
Test 2	53.21822	0.15235	1.47684	45.44903	0.18703	1.20181
Test 3	57.03454	0.14280	0.86018	55.18700	0.15355	0.77813
Test 4	64.97226	0.12439	1.11585	42.92589	0.16344	1.12013
Test 5	53.52598	0.14963	0.94333	57.75027	0.15398	1.10045
Test 6	54.36428	0.21002	0.88864	38.60749	0.15344	1.11162
Test 7	50.71838	0.12765	1.20476	36.44328	0.16190	1.24904

9.2 Data (partly converted)

Test #	28mm (Thick) Torsion [Nm]	28mm (Thick) Lever Out [Nm]	28mm (Thick) Pull Out [N]	32mm (Thin) Torsion [Nm]	32mm (Thin) Lever Out [Nm]	32mm (Thin) Pull Out [N]
Test 1	65.16	24.31	1204.98	49.00	27.85	1270.90
Test 2	53.22	25.90	1476.84	45.45	31.80	1201.81
Test 3	57.03	24.28	860.18	55.19	26.10	778.13
Test 4	64.97	21.15	1115.85	42.93	27.78	1120.13
Test 5	53.53	25.44	943.33	57.75	26.18	1100.45
Test 6	54.36	35.70	888.64	38.61	26.09	1111.62
Test 7	50.72	21.70	1204.76	36.44	27.52	1249.04

9.3 Bone Substrate Data

Sample	E-Modul [N/mm²]	Density [g/cm³]	Depth [mm]	Diameter [mm]	Height [mm]
1	174.15	0.4994	25.92	51.18	54.14
2			25.02	50.66	54.60
3	160.66	0.4918	25.95	51.52	54.10
4			26.90	51.43	53.65
5			26.30	51.50	53.88
6			26.13	51.17	54.31
7			25.21	50.82	54.06
8			26.30	51.40	53.85
9			26.63	51.55	54.10
10	158.72	0.5030	26.34	51.18	54.62
11			25.92	51.66	55.04
12			26.66	51.49	54.73
13			26.12	51.23	54.44
14			25.52	50.99	52.29
15	179.75	0.4957	26.26	51.00	54.32
16	172.62	0.4800	26.71	51.66	54.49
17			26.59	51.35	54.36
18	180.00	0.5118	26.45	51.42	54.26
19			25.86	51.63	54.81
20	197.30	0.4948	26.06	51.48	54.47
21			26.57	51.07	54.86
22			25.91	51.81	54.90
23			25.30	51.57	54.34
24	194.15	0.5172	26.40	51.46	54.46
25			26.55	51.54	53.93
26	204.55	0.4963	26.44	51.48	54.51
27	191.03	0.5041	26.08	51.72	54.27
28			25.69	51.38	54.23
29			26.77	51.44	55.39
30			25.76	51.62	54.18
31			25.88	51.14	53.97
32			25.84	51.79	54.83
33			25.50	51.07	54.97
34			26.08	51.66	54.38
35			26.36	51.63	54.37

Sample	E-Modul [N/mm²]	Density [g/cm³]	Depth [mm]	Diameter [mm]	Height [mm]
36			26.31	51.15	54.28
37			25.77	51.86	54.83
38			25.99	51.22	55.03
39			26.40	51.22	54.62
40			26.28	51.44	54.15
41			26.81	51.37	54.62
42			26.93	51.45	54.64
MEAN	181.29	0.4994	26.15	51.39	54.39
SD	15.36	0.0105	0.46	0.27	0.50

	Peripheral Self Locking Cup Stryker 52mm		Hemispheric Cup Stryker 52mm	
	Seating Force [N]	Pull Out Force [N]	Seating Force [N]	Pull Out Force [N]
	5130.95	1268.26	4153.70	1039.35
	5571.45	1201.32	4169.00	1056.36
	4806.26	962.44	4529.49	1412.93
	4752.24	1161.83	3897.07	1082.12
	5955.11	1093.56	4341.48	1339.99
	7936.20	1910.59	5400.00	1619.89
	9186.42	1923.91	6860.30	2043.57
	6821.26	1528.17	6229.46	1912.21
	6423.59	1522.31	6942.81	2195.17
	7101.27	1666.53	5875.87	1827.59
Mean	6368.47	1423.89	5239.92	1552.92
SD	1435.04	338.43	1172.68	429.36

	Peripheral Self Locking Cup Stryker 52mm		Hemispheric Cup Stryker 52mm	
	Seating Force [N]	Lever Out [Nm]	Seating Force [N]	Lever Out [Nm]
	5764.81	21.34	6105.22	28.07
	8229.24	38.84	7208.73	28.76
	9752.53	41.70	7032.61	29.35
	9448.10	43.81	9200.55	38.10
	9696.27	42.41	6569.72	42.07
	9567.70	37.53	8054.05	43.84
	13756.00	48.08	6576.22	38.85
	7653.47	41.35	7967.48	42.19
	7826.50	40.04	8524.14	40.83
	11783.96	44.28	5646.87	37.35
Mean	9347.86	39.94	7288.56	36.94
SD	2235.69	7.18	1126.49	6.01