

# Experimental analysis of insertion torques and forces of threaded and press-fit acetabular cups by means of *ex vivo* and *in vivo* measurements

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*Purpose:* In THA a sufficient primary implant stability is the precondition for successful secondary stability. Industrial foams of different densities have been used for primary stability investigations. The aim of this study was to analyse and compare the insertion behaviour of threaded and press-fit cups *in vivo* and *ex vivo* using bone substitutes with various densities. *Methods:* Two threaded (Bicon Plus<sup>®</sup>, Trident<sup>®</sup> TC) and one press-fit cup (Trident PSL<sup>®</sup>) were inserted by orthopaedic surgeons (S1, S2) into 10, 20 and 31 pcf blocks, using modified surgical instruments allowing measurements of the insertion forces and torques. Furthermore, the insertion behaviour of two cups were analysed intraoperatively. *Results:* Torques for the threaded cups increased while bone substitute density increased. Maximum insertion torques were observed for S2 with 102 Nm for the Bicon Plus<sup>®</sup> in 20 pcf blocks and 77 Nm for the Trident<sup>®</sup> TC in 31 pcf blocks, which compares to the *in vivo* measurement (85 Nm). The average insertion forces for the press-fit cup varied from 5.2 to 6.8 kN (S1) and 7.2–11.5 kN (S2) *ex vivo*. Intraoperatively an average insertion force of 8.0 kN was determined. *Conclusions:* Implantation behaviour was influenced by acetabular cup design, bone substitute and experience of the surgeon. No specific density of bone substitute could be favoured for *ex vivo* investigations on the implantation behaviour of acetabular cups. The use synthetic bone blocks of high density (31 pcf) led to problems regarding cup orientation and seating. Therefore, bone substitutes used should be critically scrutinized in terms of the comparability to the *in vivo* situation.

*Key words:* insertion force, insertion torque, acetabular cup, press-fit, threaded, synthetic bone

## 1. Introduction

Every year, with an increasing tendency, more than one million primary THA surgeries are carried out worldwide [24]. In an effort to design bone-saving endoprostheses systems and increase their lifetime, a cementless acetabular cup design has been refined in the past.

Two different acetabular cup designs have been developed for cementless fixation: threaded and press-fit cups. The threaded cup design possesses a screw thread for primary fixation in the acetabular bone stock. Thread design and insertion torque can influ-

ence the primary stability of the acetabular cup [8], [13], [21]. Otherwise, press-fit acetabular cups are designed to be pressed into 1 to 4 mm under reamed cavities. Hence, initial fixation is obtained by the acetabular bone stock exerting a force on the equatorial rim of the hemispherical implant [6].

For both threaded and press-fit acetabular cups, high primary implant stability during surgery is required for ingrowth into the adjacent bone tissue, leading to secure secondary implant stability, i.e., osseous integration, which is the key factor for secondary implant stability in the bone-implant interface [7], [23]. Furthermore, the exact reaming of the cavity is essential to obtain sufficient primary implant stabil-

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ity for threaded and press-fit cups, because improper cavities jeopardise the initial implant stability [1], [13]. Furthermore, biocompatibility, adequate surface roughness and porosity as well as direct bone contact are essential for on-growth of bone cells [7]. Relative micromotions in the bone-implant interface must be below 30  $\mu\text{m}$  in order to gain sufficient osseous implant integration, while micromotions up to 150  $\mu\text{m}$  may lead to attachment by mature connective tissue ingrowth [19].

Several studies investigating the primary stability of acetabular cups have used different industrial foams such as polyurethane (PU), polyvinylchloride (PVC) or polymethacrylimide (PMI) of different densities as bone substitute materials for *ex vivo* studies, since these possess behaviour of homogeneous material in contrast to human acetabulum, consisting of cancellous and cortical bone [4], [5], [8], [10], [15], [16], [21], [22], [25]. There are studies comparing various synthetic bone models of different densities [4], [5], [16], [21], [25] as well as studies using only one type of bone substitute [8], [10], [15], [21], [22]. Furthermore, *in vivo* implantation behaviour has been investigated for threaded hip cups [20], but not for press-fit cups, although it has been investigated *ex vivo* using fresh cadaver pelvis [14].

The aim of the present experimental study was to investigate the insertion behaviour of threaded and press-fit acetabular cups of total hip replacements using various synthetic bone densities *ex vivo*. Thereby, two different experienced orthopaedic surgeons inserted different acetabular cup designs manually, enabling the prediction of surgeon-related insertion behaviour. The experimental setup was designed such that it could be applied intraoperatively. Therefore, *in vivo* data were recorded and the results were compared to the data obtained during the *ex vivo* examination in order to analyse the implantation procedure and determine suitable bone substitute materials for *ex vivo* tests.

## 2. Materials and methods

### 2.1. *Ex vivo* torque and force measurements for cementless acetabular cups

Three different commercially available acetabular cups, two threaded and one press-fit, with an outer diameter of 57.8 mm, were used to investigate the torques and forces needed for implant insertion. The different cup designs are presented in Table 1. The *ex vivo* experiments were carried out using artificial bone substitute materials with three different densities, 10 pcf and 20 pcf (160  $\text{kg}/\text{m}^3$  and 320  $\text{kg}/\text{m}^3$ , polyurethane (PU) foam, Sawbones<sup>®</sup>, Malmö, Sweden), as well as 31 pcf (497  $\text{kg}/\text{m}^3$ , ep-Dur<sup>®</sup>, Emaform AG, Gantenschwil, Switzerland), which can be used to simulate the actual bone stock providing different bone densities instead of cadaveric specimens. The insertion torques and forces during an implantation into cadaveric specimens have been described in a previous study and were therefore not addressed in the present study [10]. The artificial bone substitute was cut into blocks of 110  $\times$  110  $\times$  79  $\text{mm}^3$  in size. A cavity was reamed into the centre of each block using the provided acetabular mill of the acetabular cups and a pillar drilling machine. The provided acetabular mills had an outer diameter of 56 mm and therefore led to a diametric under-reaming of 1.8 mm. An exception was made for the Bicon Plus<sup>®</sup> Standard cup, where the cavity was produced using a lathe (Typ E35, Voest-Alpine Steinel GmbH, Linz, Austria) according to the manufacturer's specifications.

For the experiments using both threaded acetabular cups, the prepared bone substitute blocks were slightly mounted into a fixture device at an angle of 45°, to ensure sufficient fixation while not deforming the circularity of the cavity. Threaded cups were in-

Table 1. Acetabular cups used for the *ex vivo* and introoperative investigations

Name	Manufacturer	Cup design	Surface Roughness (Ra/Rz) [ $\mu\text{m}$ ]
Bicon Plus <sup>®</sup> Standard	Endo Plus Orthopedics AG, Rotkreuz, Switzerland	bi-conical, threaded	3.8/22.9
Trident <sup>®</sup> TC	Stryker GmbH und Co. KG, Duisburg, Germany	hemispherical, threaded	5.8/35.4
Trident PSL <sup>®</sup>	Stryker GmbH und Co. KG, Duisburg, Germany	hemispherical, press-fit	22.9/100.4

serted using a custom-built torque sensor placed in-between the insertion instrument previously described, until a predefined cup overhang was reached with a horizontally aligned equatorial plane [10] (Fig. 1). The sensor was made of a torque shaft equipped with four strain gauges, each applied at an angle of  $45^\circ$  to the shaft axis, circuited to a full bridge. The advantage over commonly deployed torque wrenches is the possibility of recording the data continuously during the experiments. Both the insertion and removal torque were obtained for each acetabular cup and each synthetic bone material ( $n = 3$ ).

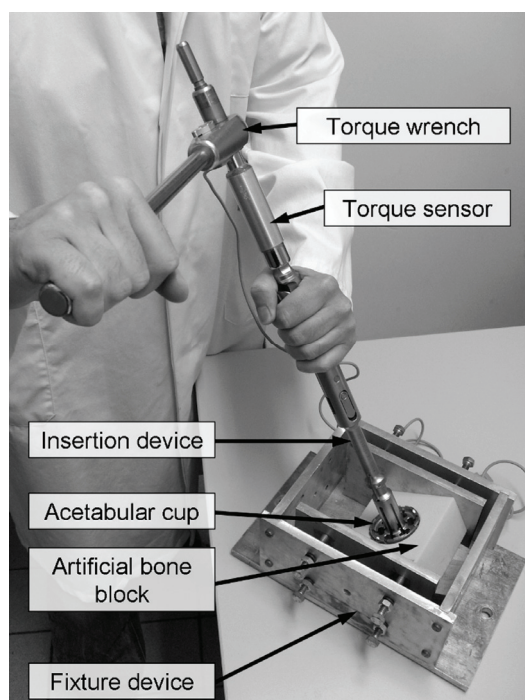


Fig. 1. Threaded cup (Trident® TC) insertion into a PU foam block at an angle of  $45^\circ$  using a modified surgical wrench equipped with a torque sensor (*ex vivo*)

Insertion force measurements were conducted using the press-fit Trident PSL® hip cup. The original impaction device was modified in such way that a piezoelectric force sensor (208C05, PCB Piezotronics®, New York, USA) could be mounted in-between the shaft (Fig. 2). Measuring the force directly transferred to the press-fit cup in the shaft of the insertion device is an advantageous enhancement compared to the impact mallet used in a previous study [10]. This allows the use of the original 1100 g surgical mallet for the experiments. All bone substitute test blocks were carefully mounted horizontally into the fixture device.

All experiments were conducted by a less experienced orthopaedic surgeon (S1) and a well experienced surgeon (S2) who carried out over 1000 THA surgeries, in order to resolve possible differences in

cup insertion behaviour depending on the experience of the orthopaedic surgeon.

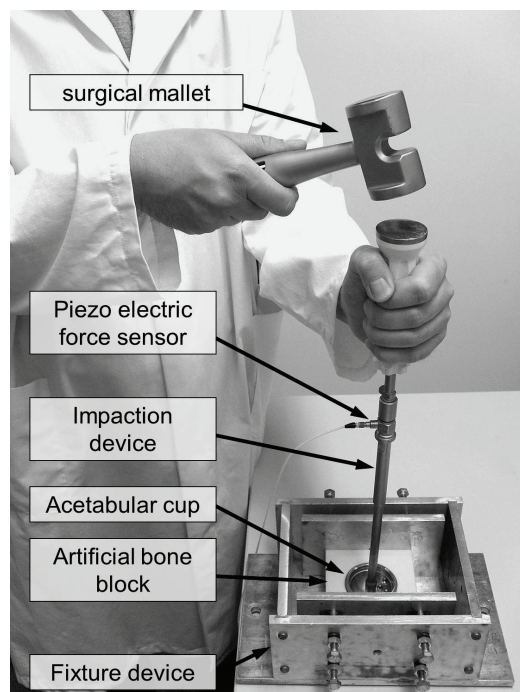


Fig. 2. Press-fit cup (Trident PSL®) insertion into a PU foam block using a modified surgical insertion instrument equipped with a force sensor for impaction measurements in a fixture device (*ex vivo*)

## 2.2. Intraoperative insertion torque and force measurements for cementless acetabular cups

The *in vivo* study was carried out using one threaded (Trident® TC) and one press-fit cup design (Trident PSL®) by the experienced surgeon S2 (Fig. 3). Patients



Fig. 3. Modified surgical insertion instrument used intraoperatively by the experienced surgeon (S2) to measure insertion forces and number of impacts

who agreed to participate in the study with an indication of primary osteoarthritis, a body mass index (BMI) less than 35 kg/m<sup>2</sup> and a bone density T-Score greater than -2.5 were considered for the intraoperative measurement of insertion torques and forces.

The study was approved by the Local Ethical Committee of the University of Rostock (Reg. No. HV-2008-06).

A total of 6 patients (5 female, 1 male) between the age of 53 and 82 years, with an average T-Score of  $0.7 \pm 1.4$  and BMI of  $25.9 \pm 5.4$  kg/m<sup>2</sup>, participated in the torque measurements using the Trident<sup>®</sup> TC. A further 6 patients (2 female, 4 male) aged 54 to 77 years, with an average T-Score of  $0.7 \pm 0.8$  and BMI of  $26.2 \pm 3.8$  kg/m<sup>2</sup>, took part in the force measurement investigations using the Trident PSL<sup>®</sup>. The acetabular cup sizes varied due to the individual requirements of the patients between 48 mm and 58 mm. It has to be mentioned that the cups contain a 1.8 mm peripheral press-fit built into the cup, e.g., a cup with the size 50 mm has an actual outer diameter of 51.8 mm resulting in an under-reaming of 1.8 mm. Furthermore, for both acetabular cup designs, the above-described specifically modified insertion devices were used intraoperatively. All assembly parts of the insertion devices, including the sensors, were sterilised prior to the surgery by hydrogen peroxide gas plasma (Sterrad<sup>®</sup> 100S, ASP<sup>®</sup>, Irvine, USA).

Based on the determined average insertion torques or forces for the obtained *ex vivo* and *in vivo* data, respectively, optimum synthetic bone substitute material should be derived. Significant differences between *ex vivo* and intraoperative data were interpreted as unsuitable artificial bone substitute material for experimental use.

### 2.3. Calculations and statistical methods

All data were stored and analysed using the SPSS statistical package 15.0 (SPSS Inc., Chicago, USA).

Descriptive statistics were computed for continuous and categorical variables [17]. The statistical evaluation included mean and standard deviations of continuous variables, frequencies, and relative frequencies of categorical factors. Comparisons within the groups were achieved using the Post Hoc test (LSD). All p-values resulted from two-sided statistical tests and values less than 0.05 were considered to be statistically significant.

## 3. Results

### 3.1. *Ex vivo* torque of threaded acetabular cups

The insertion and removal torques for both threaded acetabular cup designs are summarised in Tables 2 and 3. Generally, insertion and removal torques increased significantly while the density of the artificial bone substitute increased from 10 pcf to 20 pcf Sawbones<sup>®</sup> blocks for both threaded cups and surgeons ( $p \leq 0.003$ ). However, a further increase in insertion torque using 31 pcf ep-Dur<sup>®</sup> blocks could only be observed for the less experienced orthopaedic surgeon (S1) implanting the Trident<sup>®</sup> TC ( $p < 0.001$ ). In contrast, the insertion torque recorded using an artificial bone density of 31 pcf blocks and the Bicon Plus<sup>®</sup> cup significantly decreased ( $p = 0.035$ ) in the case of the well experienced surgeon (S2). Regarding the removal torque, a significant increase was observed for both surgeons using the Trident<sup>®</sup> TC ( $p \leq 0.031$ ) comparing 20 pcf with 31 pcf blocks. Furthermore, both surgeons had difficulties positioning both cup types properly using ep-Dur<sup>®</sup> foams, with tilted and not fully inserted implants being observed.

Acetabular cup design seems to significantly affect the maximum insertion torque depending on the experience level of the surgeon. The average maximum

Table 2. Average maximum torques and standard deviations obtained during insertion and removal from artificial bone blocks of varying densities using the Trident<sup>®</sup> TC threaded acetabular cup by two surgeons of different experience (S1 = less experienced, S2 = well experienced,  $n = 3$  for each configuration) and during *in vivo* implantation by the experienced surgeon ( $n = 6$ ). Insertion was achieved using a custom-built torque sensor placed in-between the insertion instrument

		Sawbones <sup>®</sup> 10 pcf	Sawbones <sup>®</sup> 20 pcf	ep-Dur <sup>®</sup> 31 pcf	intraoperative
Average max. insertion torque [Nm]	S1	19.6 ± 8.7	45.5 ± 2.9	76.1 ± 2.6	–
	S2	30.9 ± 1.1	72.8 ± 10.6	77.2 ± 15.6	84.9 ± 20.7
Average max. removal torque [Nm]	S1	7.6 ± 4.2	37.3 ± 4.9	71.0 ± 11.0	–
	S2	17.2 ± 7.3	65.7 ± 2.3	86.0 ± 19.0	–

Table 3. Average maximum torques and standard deviations obtained during insertion and removal from artificial bone blocks of varying densities using the Bicon Plus<sup>®</sup> threaded acetabular cup by two differently experienced surgeons (S1 = less experienced, S2 = well experienced,  $n = 3$  for each configuration). Insertion was achieved using a custom-built torque sensor placed in-between the insertion instrument

		Sawbones <sup>®</sup> 10 pcf	Sawbones <sup>®</sup> 20 pcf	ep-Dur <sup>®</sup> 31 pcf
Average max. insertion torque [Nm]	S1	35.6 ± 6.8	85.3 ± 4.8	88.2 ± 4.5
	S2	33.4 ± 14.8	101.8 ± 6.3	77.1 ± 3.5
Average max. removal torque [Nm]	S1	19.0 ± 11.2	56.7 ± 10.4	72.9 ± 16.1
	S2	25.5 ± 3.8	72.4 ± 8.3	67.5 ± 16.2

torque applied by the less experienced surgeon S1 was always significantly lower for the Trident<sup>®</sup> TC compared to the Bicon Plus<sup>®</sup> for all densities ( $p \leq 0.019$ ). In the case of S2, a dependence of the applied torque on the cup design does not seem as evident. A significantly lower average insertion torque using the Trident<sup>®</sup> TC compared to the Bicon Plus<sup>®</sup> cup was only exerted with 20 pcf blocks ( $p = 0.015$ ). The surgeons' level of experience did not strongly influence the insertion and removal torques. In the case of Bicon Plus<sup>®</sup>, only the insertion torque in 20 pcf blocks diverged significantly ( $p = 0.023$ ) depending on the surgeon and the insertion torque in 31 pcf blocks for the Trident<sup>®</sup> TC ( $p < 0.001$ ).

### 3.2. Ex vivo insertion force of press-fit acetabular cups

The experimental data of the average insertion forces recorded are presented in Table 4. Surgeon S1 inserted the Trident PSL<sup>®</sup> cup into all densities of the bone substitute blocks with a reasonably constant insertion force and number of impacts. The average insertion forces varied from 5.2 kN to 6.8 kN. A significant difference was only observed between the insertion force using the 10 pcf and 20 pcf bone substitute blocks ( $p = 0.049$ ), where the insertion force was significantly lower for 20 pcf.

The insertion forces measured for the well experienced surgeon S2 were significantly higher than those measured for S1 ( $p < 0.001$ ). In contrast to S1, S2 utilised diverse insertion forces increasing the force from 7.2 kN to 11.5 kN using 10 and 20 pcf blocks, respectively ( $p = 0.001$ ). However, a further increase in density of the artificial bone substitute material, i.e., the use of 31 pcf blocks, resulted in a significant decrease to 9.4 kN ( $p = 0.040$ ), which was still significantly higher than the force obtained for the 10 pcf bone substitute density ( $p = 0.036$ ). Furthermore, with the exception of the use of Sawbones<sup>®</sup> 20 pcf artificial bone substitute material, the number of impacts of S2 was significantly lower compared to S1 ( $p < 0.001$ ), but remained constant for all bone substitute densities. As for the threaded hip cups, using the denser ep-Dur<sup>®</sup> material as an artificial bone substitute resulted in improper cup positioning.

### 3.3. Intraoperative insertion behaviour of the threaded Trident<sup>®</sup> TC and press-fit Trident PSL<sup>®</sup> acetabular cups

Tables 3 and 4 summarise the intraoperatively obtained insertion torques and forces respectively.

An average maximum insertion torque of 84.9 ± 20.7 Nm (range: 44.3–100.3 Nm) was obtained for

Table 4. Average insertion forces and number of impacts obtained during insertion of the Trident PSL<sup>®</sup> press-fit acetabular cup in artificial bone blocks of varying densities by two surgeons of different experience (S1 = less experienced, S2 = well experienced,  $n = 3$  for each configuration) and during in vivo implantation by the experienced surgeon ( $n = 6$ ). Insertion was achieved using a piezoelectric force sensor custom-built into the impaction instrument

		Sawbones <sup>®</sup> 10 pcf	Sawbones <sup>®</sup> 20 pcf	ep-Dur <sup>®</sup> 31 pcf	intraoperative
Average insertion force [kN]	S1	6.8 ± 1.5	5.2 ± 0.7	6.6 ± 1.1	–
	S2	7.2 ± 0.9	11.5 ± 1.2	9.4 ± 0.6	8.0 ± 1.3
Average no. of impacts	S1	7.0 ± 4.0	8.0 ± 0.0	6.0 ± 2.0	–
	S2	4.0 ± 1.0	5.0 ± 0.0	5.0 ± 0.0	17.3 ± 15.4

the threaded Trident<sup>®</sup> TC acetabular cup, which was significantly higher than the torque measured *ex vivo* using Sawbones<sup>®</sup> 10 pcf ( $p < 0.001$ ), but comparable to the magnitude reached using the denser bone substitute materials with densities of 20 pcf and 31 pcf blocks. The torque measured for the patient with the lowest measured bone density was comparable to the torque obtained for the 10 pcf bone substitute material.

For the press-fit cup Trident PSL<sup>®</sup>, an average insertion force of  $8.0 \pm 1.3$  kN (range: 6.4–9.7 kN) was assessed, which is of the same magnitude as forces obtained in the *ex vivo* measurements using bone substitute materials with densities of 10 pcf and 31 pcf. The average insertion force applied intraoperatively by S2 was significantly lower than the force exerted on the acetabular cups using Sawbones<sup>®</sup> 20 pcf ( $p = 0.001$ ). Regardless of similar insertion forces, the number of impacts needed to position the press-fit cup *in vivo* varies greatly from 7 to 46 (average:  $17.3 \pm 15.4$ ). These data show that numerous impacts can be applied intra-operatively. However, in four of the six cases, the number of impacts correlates to those in the *ex vivo* investigations using varying artificial bone substitute materials.

## 4. Discussion

In research and development of total hip replacements, it is common practice to use artificial bone substitute materials for *ex vivo* investigations of the insertion torques or forces for acetabular cups [4], [5], [8], [10], [15], [16], [21], [22], [25]. However, many studies concentrated on one density [8], [10], [15], [21], [22], making it difficult to define a suitable bone substitute model which correlates with the *in vivo* situation. Furthermore, cup insertion was achieved by a machine-controlled [4], [5], [8], [12], [15], [21], [22], [25] to ensure reproducible results. Nonetheless, in this study, a manual implant insertion was conducted in order to evaluate whether the insertion torques and forces measured *ex vivo* with established bone substitute models and intraoperatively are comparable. By using a custom-built torque and a piezoelectric force sensor placed within the specific surgical instruments data could be collected throughout the entire insertion processes digitally. This solution is advantageous over simple torque wrenches used in different studies, which only allow measurements of the maximum torque [10], [13], [21].

One press-fit (Trident PSL<sup>®</sup>) and two different threaded (Bicon Plus<sup>®</sup> and Trident<sup>®</sup> TC) acetabular cups were investigated *ex vivo* regarding the insertion forces and torques, respectively, with blocks of bone substitute materials of varying densities (10 pcf, 20 pcf and 31 pcf) and corresponding cavities. Furthermore, intraoperative investigations using the threaded cup Trident<sup>®</sup> TC and the press-fit Trident PSL<sup>®</sup> cup were conducted. In order to carry out the *in vivo* measurements, sterilisation of the sensor-modified surgical instruments had to be assured. The Bicon Plus<sup>®</sup> was not implanted in our clinic, therefore, there are no *in vivo* measurements for this implant.

In general, intraoperative torque measurements showed considerably higher insertion torques in comparison to studies using formaldehyde-fixed human acetabular bone [10], [12]. The insertion torques assessed using the ep-Dur<sup>®</sup> (31 pcf) material correlate with those found in a previous study [10] using 30 pcf PU foam as well as to the intraoperatively measured torques. Insertion of the threaded Trident<sup>®</sup> TC acetabular cup *in vivo* also correlates with the results obtained using the 20 pcf blocks and to previous *in vivo* measurements by Refior et al. [20]. However, cup implantation using 31 pcf blocks was often insufficient, i.e., tilted and not fully inserted due to its high density, whereas cup positioning was satisfactory using the 20 pcf blocks. In conclusion, 20 pcf PU foam seems to be preferable to 31 pcf materials for *ex vivo* experiments. The insufficient setting of the cups in the 31 pcf blocks might be one reason for insertion torques being similar to those in 20 pcf blocks in the case of the Bicon Plus<sup>®</sup> cup. If the cup is inserted deeper into the PU foam, the contact area and therefore the friction in the interface between implant and cavity increase, resulting in higher insertion torques.

The use of 10 pcf PU foam resulted in the lowest cup insertion torques, which did not correspond to the average intraoperatively gained insertion torque. However, in the *in vivo* group, in the case of the total hip replacement patient with the lowest bone density (T-Score of  $-1.2$ ), a low insertion torque of similar magnitude to the insertion torques obtained using 10 pcf PU foam was measured. For experimental *ex vivo* investigations of acetabular cup behaviour simulating low bone density of the patient, 10 pcf PU foam may be the preferred choice. It has to be mentioned that the bone density of the patients were measured at the spine instead of the hip. Therefore, a low T-Score is not necessarily equivalent to a low bone density at the acetabulum [11]. Nevertheless, further torque measurements specifically aimed at patients with low

bone densities at the acetabulum are required to confirm this suggestion.

The insertion torque for the experienced surgeon (S2) did not vary much for each artificial bone substitute configuration regarding the two threaded acetabular cups tested. However, a difference in insertion torque magnitude was observed for the less experienced surgeon (S1) in direct comparison of the two threaded cups. With the exception of the ep-Dur<sup>®</sup> material, S1 generated a significantly lower insertion torque for the Trident<sup>®</sup> TC cup compared to the Bicon Plus<sup>®</sup> cup as well as in comparison to the experienced surgeon. The level of experience seems to influence the implantation behaviour of threaded acetabular cups. Moreover, the measurements showed that lower insertion torques can result in lower removal torque which may lead to a loss in primary stability against cup rotation and could increase micromotions of the acetabular cup.

For experimental purposes, press-fit cups are usually inserted by means of a testing machine, rather than manually [4], [5], [15], [21]. In fact, forces exerted during cup insertion by a surgeon have not been investigated *in vivo* previously, although the impact duration was measured in *ex vivo* experiments using reproducible mass falls [18] and an instrumented mallet on fresh cadaver pelvis [14]. Nevertheless, in this study, both *ex vivo* and *in vivo* insertion force measurements were conducted. The average measured force *ex vivo* for each bone substitute material tested was compared to the insertion forces applied *in vivo*. However, using all bone substitute densities, the number of impacts needed for cup insertion remained fairly constant, whereas the number of impacts varied greatly under surgical conditions depending on the individual patient requirements. As for the threaded cups, the use of ep-Dur<sup>®</sup> resulted in insufficient manual setting of the press-fit cups due to the high material density. Hence, it has to be mentioned that the use of dense materials, such as ep-Dur<sup>®</sup>, can be challenging for *ex vivo* experiments with press-fit cups and should be avoided even though that acetabular cups can be sufficiently seated in dense materials using a testing machine [4]. Moreover, with respect to our results, it is not evident whether 10 pcf or 20 pcf bone substitute material should be recommended for future experimental investigations.

The relatively low number of patients for the intraoperative investigations and the deviations of the T-Scores, BMI and applied cup sizes are the limitations of our study. A larger number of patients would allow a more precise evaluation regarding insertion torque and force with respect to the bone stock qual-

ity, especially in less common cases. Furthermore, the uniform synthetic bone materials do not sufficiently depict the *in vivo* situation where reamed acetabular cavities comprise of cortical and cancellous bone [25]. Additionally, it has to be mentioned that the actual diameters of the milled cavities were neither measured *ex vivo* nor *in vivo*. In a previous investigation, the diameters of cavities drilled by the same two executive surgeons of the present study using the provided acetabular mills, were measured. We determined only minor deviations in the cavity diameters. Therefore, we suggested that the cavities can be reamed with high accuracy and only small deviations. Nevertheless, Amirouche et al. [3] showed a correlation between the amount of under-reaming and the insertion forces in a computational study, hence, the missing measurement of the actual diameter of the cavity is a limitation of the present study. Nevertheless, a correlation to the bone substitute blocks used in this study could be established. Natural deviations of the surgeon's implant behaviour were observed but the impact on the primary implant stability was not investigated. The influence of different individual insertion torques and forces on the primary implant stability could be investigated in further lever-out and pull-out tests. In the present study, whether threaded or press-fit acetabular cups are more beneficial with respect to the primary implant stability was not addressed. However, a recent study by Ellenrieder et al. [9] showed equivalent clinical outcomes and osseous integration, when a threaded cup was compared to a press-fit cup.

Differences between the two surgeons implanting the Trident PSL<sup>®</sup> press-fit cup were observed, whereby the less experienced surgeon (S1) applied slightly lower average impact forces compared to the well experienced surgeon (S2). Implantation of the press-fit cup in blocks of 10 pcf and 20 pcf PU foam was sufficient for both surgeons. With regard to possible fissures or fractures of the acetabular bone stock, a smaller insertion force could be the better choice if the resulting primary cup stability remains unchanged. Additionally, in further studies using the finite element analysis a primary stability depending on the press-fit and implant design can be solved numerically and hence predicted for different bone substitute materials [2], [25].

## 5. Conclusion

The results of the current study showed that the acetabular cup design and the experience of the orthopaedic surgeon may influence the implantation be-

behaviour *ex vivo* and *in vivo* regarding the insertion force, number of impacts and insertion torques, respectively. In the case of *ex vivo* investigations, the bone substitute material was shown to be a relevant influencing factor.

The synthetic bone blocks of high density (31 pcf) led to problems regarding cup orientation and complete seating in the *ex vivo* experiments, limiting their feasibility for *ex vivo* investigations, although the differences in the average insertion torques and forces were not significant compared to the *in vivo* measurements. Moreover, in the case of the 10 pcf bone substitute blocks, the determined differences between the average insertion torques measured *ex vivo* and *in vivo* were significant, whereas the insertion forces were not. Nevertheless, in the case of osteoarthritis patients with low bone density, the insertion torque was of similar magnitude compared to the *ex vivo* results for 10 pcf bone substitute blocks. This indicates that this material might be suitable to simulate osteoporotic bone. In the case of the 20 pcf blocks, the differences in the insertion torques were not significant, whereas the average insertion forces measured *ex vivo* and *in vivo* were significantly different. In our present study, none of the tested artificial bone substitutes could be favoured for *ex vivo* investigations on the implantation behaviour of acetabular cups, with respect to the densities, materials, shapes and dimensions used. However, in future investigations, the bone substitute materials available on the market should be scrutinised in terms of reproducibility of the *in vivo* situation.

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