

Vibratory and conventional impaction of acetabular components into porcine acetabula

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Aims

Sufficient primary implant stability with minimal bone damage is one of the challenges for uncemented implant fixation to prevent periprosthetic fractures and implant loosening. A pilot study on a non-viscoelastic material (polyurethane foam) showed a reduced impaction force when using vibratory implant insertion. This study assessed the effectiveness of vibratory implant insertion compared to an established implant insertion method in physiological viscoelastic bone from porcine hips.

Methods

Acetabular components were impacted line-to-line and into 1 mm nominal undersized cavities in porcine acetabula (n = 24 in total, n = 6 acetabula per group of study) using vibration (60 Hz) and 1 Hz (established) impaction methods. The impaction force, remaining polar gap, and lever-out moment were measured and compared between the impaction methods and different press-fits.

Results

The vibratory impaction method produced almost 40% lower impaction forces at both press-fit levels. However, complete seating at the nominal press-fit of 1 mm was not achieved, and primary stability was lower for the vibratory impaction for either press-fit.

Conclusion

Bone fracture risk due to high impaction forces could be reduced by vibrational implant insertion at the cost of a reduction in primary stability. The outcome of the vibratory impaction method in porcine bone was similar to a previous study using polyurethane foams, suggesting that the viscoelasticity of bone may not play a crucial role during press-fit implant impaction.

Article focus

- This study investigates the hypothesis that vibratory component impaction in porcine acetabula benefits from the viscoelastic properties of the bone.

Key messages

- The vibratory impaction device produced reduced impaction forces, mitigating reduced risk of bone fracture during implant insertion.
- However, the vibratory impaction device showed reduced implant stability compared to traditional methods.

Strengths and limitations

- Porcine samples were used to investigate whether bone viscoelasticity affects the implantation of uncemented implants. This approach is preferable to a recent study that used similar methods on a non-viscoelastic bone substitute.
- This study investigated conventional implant impaction with vibratory implantation insertion under fixed energy and frequency conditions, which does not fully reflect the clinical reality.

Introduction

Press-fit acetabular components are inserted into under-reamed bone cavities using mallet

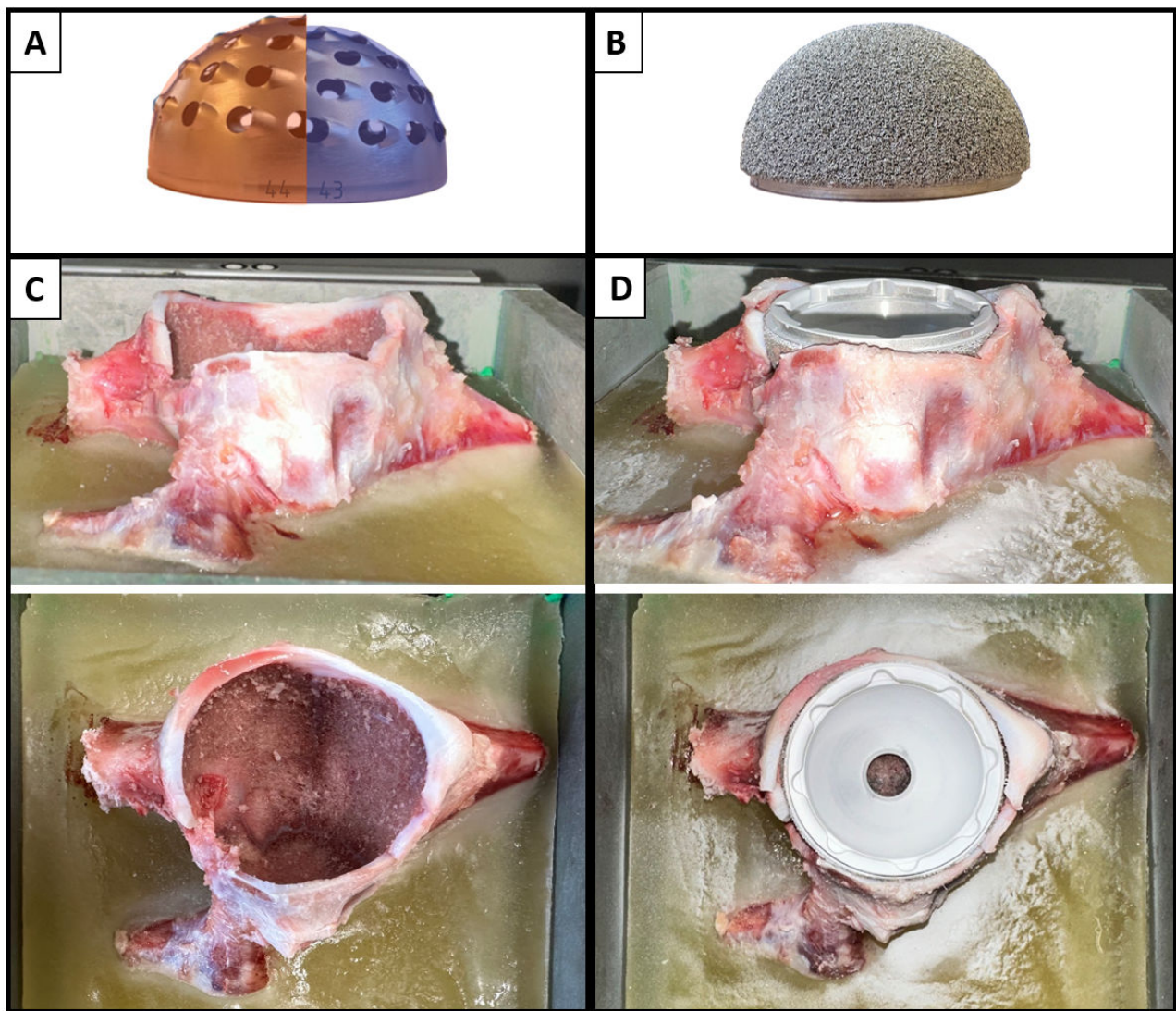


Fig. 1

a) Surgical reamers of 44 mm and 43 mm were the final reamers used to prepare the porcine acetabulum cavity for line-to-line and 1 mm nominal press-fit, respectively. b) The press-fit acetabular component used in the study. c) The potting position after reaming. d) After component implantation.

blows.¹ The discrepancy between the nominal diameter of the final reamer and the outer diameter of the acetabular component is considered to be the amount of press-fit. In the case of the line-to-line reaming, i.e. whereby the last reamer has the same nominal size as the implant, the amount of the actual press-fit is determined by the differences in the real diameter of the reamer and the reamed cavity, and the real outer diameter of the component, which can differ from the nominal diameters due to tolerances or coatings which are not considered for the size determination. The compression forces at the component's rim in combination with the contact area between implant and bone are essential for the initial stability of a press-fit component.² If sufficient fixation at the rim is achieved, polar gaps up to 2 mm are acceptable.³

Uncemented implant insertion can be accompanied by bone fractures,⁴ since the impaction process involves high amounts of force in a short period.⁵ It has been shown that nominal press-fits (NPFs) above 2 mm may exceed the yield stress of the bone and increase the fracture risk if full seating is

achieved.⁶ Certain bone conditions like osteoporosis can also increase the fracture risk due to the reduced bone quality.^{7,8} Additionally, some component designs, such as peripheral self-locking ones, are associated with higher implantation force, which can also cause an increased fracture risk even in high-quality bone.⁹ The goal of the implantation process is the placement of the implant into the prepared bone cavity, during which the insertion process plays an important role. The impaction technique varies between surgeons with regard to the velocity and mass of the mallet, as well as the number of blows.¹⁰ A combination of low-strike velocity with a high mallet mass may provide sufficient implant seating with a lower risk of component loosening. When high-velocity strikes are used, even with a low mallet mass, over-impaction can occur, which reduces the component stability.¹⁰ Automated impaction devices allow for the elimination of the variability between surgeons. It also gives us the possibility of studying implantation parameters (implantation force, impaction frequency, etc.) separately. It has been shown that

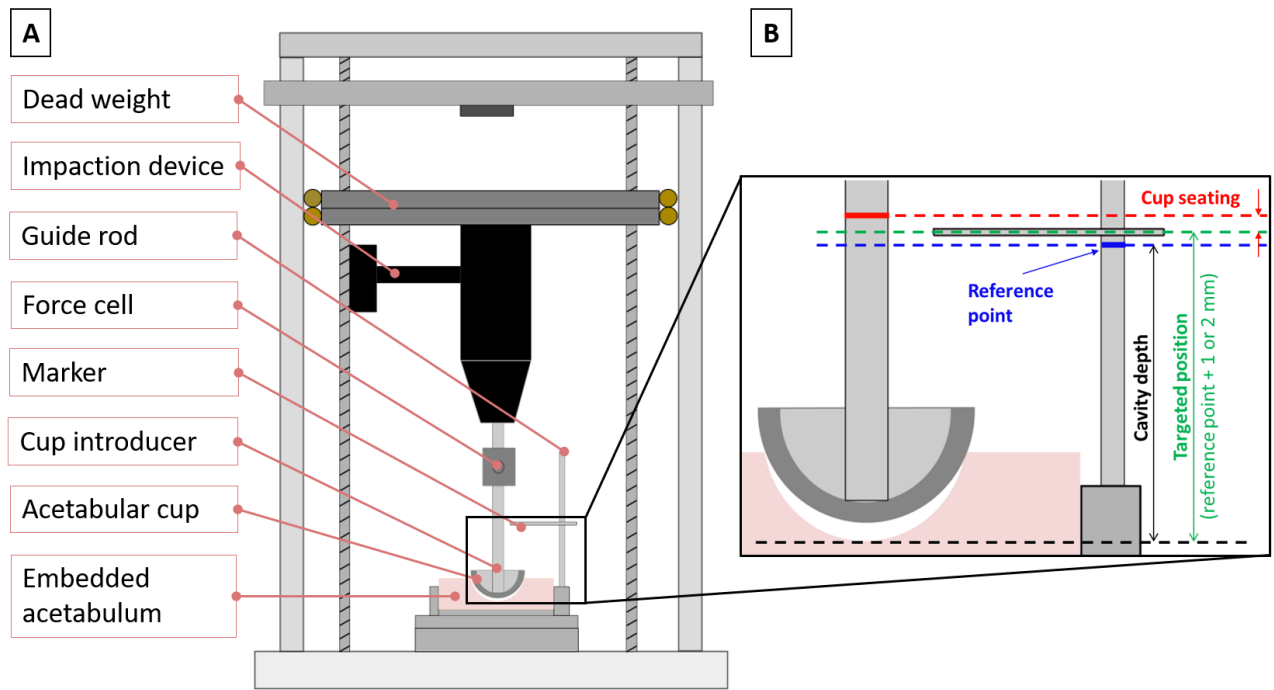


Fig. 2

a) Experiment setup. A dead weight (5 kg) was placed on the impaction device to apply a constant static force for all tests. b) Starting position for the component insertion (contact of the component with the reamed acetabulum). The reference line on the component introducer is marked on the guide rod, as are the targeted positions for the two press-fit conditions.

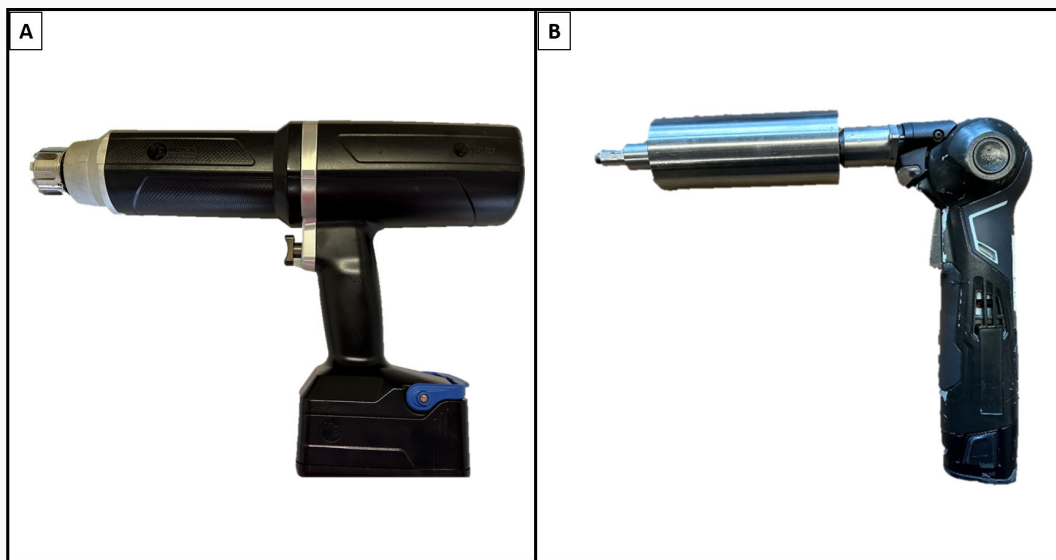


Fig. 3

a) Consecutive automated impaction device (established; KINCISE; DePuy Synthes, USA). b) Vibratory implant insertion device (prototype; Behzadi Medical Device, USA).

an impaction frequency of 6 Hz for acetabular component insertion with an automated impaction device requires less impaction force than for 1 Hz, while achieving the same primary stability, concluding that the viscoelasticity of bone may favour higher impaction frequencies.¹¹

In a previous pilot study on vibratory implant insertion in polyurethane (PU) foam, it was shown that the impaction force was lower for a 60 Hz vibratory impaction method compared to a 1 Hz.¹² However, the lever-out moment as an indication of primary stability was lower for the vibratory implant insertion group. It was hypothesized that this

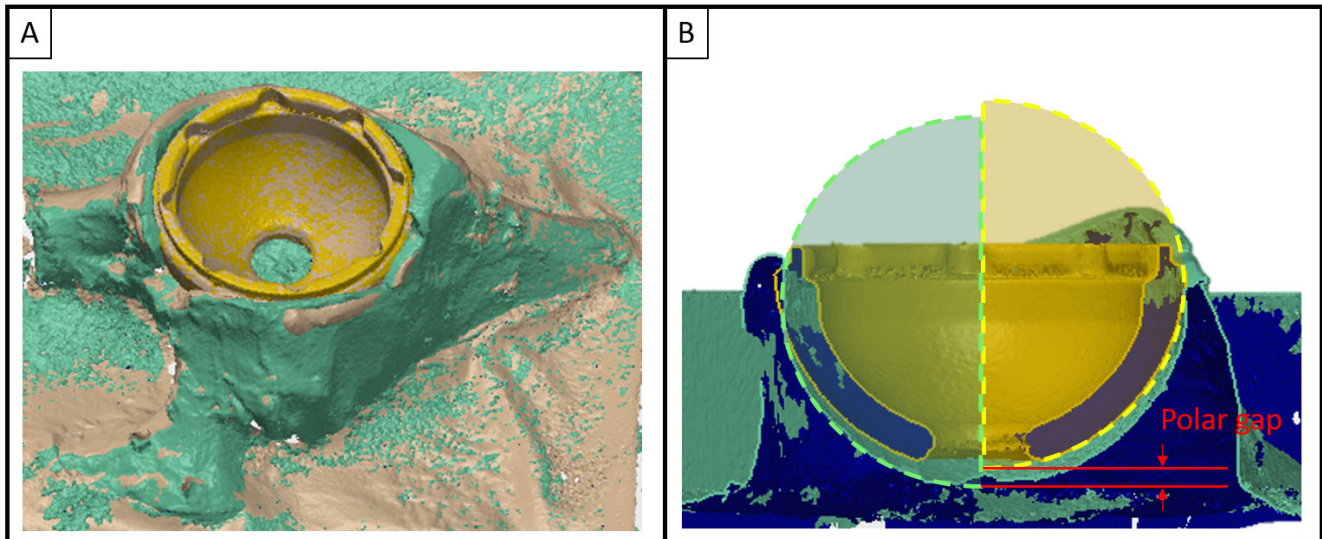


Fig. 4 Polar gap determination. a) Pre-scans of the component (yellow) and cavity (green) were superimposed to the post-scan of the implanted component (light brown). b) Spheres were fitted to the outer diameter of the component (yellow) and the cavity (green). The distance between the domes of the spheres was measured as the polar gap.

Table I. The mean diameter of the acetabular component was measured, including the coating. Values are presented as mm (SD).

44 mm acetabular component	Line-to-line (0 mm) NPF		1 mm NPF	
	44 mm reamer	Bone cavity	43 mm reamer	Bone cavity
44.13 (-)	43.36 (-)	43.52 (0.27)	42.09 (-)	42.53 (0.15)

NPF, nominal press-fit.

reduction might be due to the lack of viscoelastic characteristics in the PU foams. Moreover, vibratory implantation failed to achieve the targeted seating in high-density foams. Thus, a modification of the implantation process, e.g. the amount of NPF, was assumed to be beneficial when using this method.¹²

The purpose of this study was to evaluate whether vibratory implant insertion is capable of improving the implantation of acetabular components in a porcine bone model compared to an established method using a powered insertion tool. Two different nominal press-fits were tested. Impaction force, polar gap, and lever-out moments were compared between groups.

Methods

Bone specimen and acetabular component

Fresh-frozen porcine acetabula (24 in total, six bones per group) were defrosted at room temperature, and all of the soft-tissues were removed by surgical scalpel. Acetabula were embedded in a metal pot to keep the acetabulum surface perpendicular to the implantation axis (Technovit 4004; Kulzer, Germany). The bones were sprayed with phosphate-buffered saline (PBS) during the hardening process of the embedding material. Then, the acetabula were filled and covered with tissue papers soaked in PBS during embedding to keep the bone hydrated and prevent it from heating up excessively.

Table II. The outcome parameters for the two impaction methods.

Parameter	Line-to-line (0 mm) nominal press-fit			1 mm nominal press-fit		
	1 Hz	60 Hz	P-value†	1 Hz	60 Hz	P-value†
Mean impaction force, kN (SD)	20.45 (2.15)	12.71* (0.67)	0.016	21.91 (0.41)	13.30 (0.45)	< 0.001
Mean polar gap, mm (SD)	0.89 (0.38)	1.54 (0.64)	0.083	2.04 (0.18)	4.53* (1.61)	0.013
Mean lever-out moment, Nm (SD)	3.55 (0.32)	1.66* (0.36)	0.012	3.33 (1.73)	1.13 (0.23)	< 0.001

*Significant compared to the 1 Hz impaction ($p < 0.05$).

†Independent-samples *t*-test.

The acetabula were reamed using surgical reamers (Figure 1a) starting from a 39 mm reamer to the final size based on the nominal press-fit group. The reamer handle was fixed on a vertical drilling machine to ensure the same alignment to the implantation axis and that it was perpendicular to the acetabulum plane. The bone specimens were continuously sprayed with PBS to maintain bone hydration and its mechanical behaviour.¹³

A hemispherical press-fit acetabular component with a nominal diameter of 44 mm (Gription coating; Pinnacle 100 Series, DePuy Synthes, UK; Figure 1b) was inserted into porcine acetabulum cavities line-to-line (NPF 0 mm, $n = 12$; and NPF 1 mm, $n = 12$). The same acetabular component was used for all implantations since the deformations applied to the component during the implantation were fully elastic.¹⁴ The outer diameter of the acetabular component and the final reamers used (43 and 44 mm), as well as the reamed

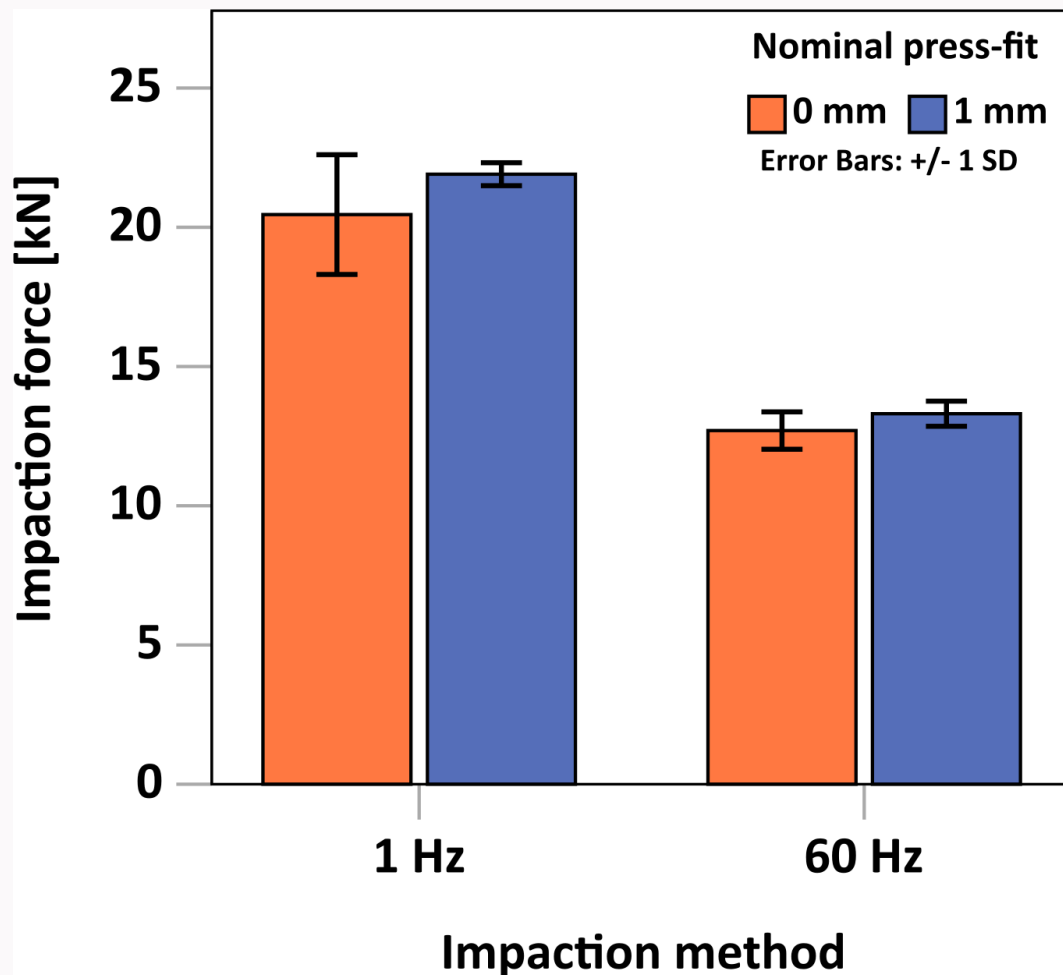


Fig. 5 Impactation force. Nominal press-fit did not significantly affect the impactation force (general linear model: $p = 0.382$).

bone cavities, were measured using 3D scans (Handyscan 3D, Creaform; Ametek, USA). The real press-fit was calculated as the difference between the outer diameter of the acetabular component and the cavity diameter.

Experiment design

To minimize the effect of component seating depth on implant primary stability for the comparison between the two different insertion methods, a polar gap between the dome of the component and the bottom of the bone cavity of 1 mm (line-to-line) or 2 mm (1 mm press-fit) for either impaction method was used as the stop criterion for implantation. These targeted positions were marked on a guide rod attached to the embedding pot (Figure 2a).¹² The component position during the implantation process was monitored by a reference line on the component introducer (red line; Figure 2b). The bottom of the reamed cavity was referenced by connecting an undersized component to the component introducer, positioning it at the bottom of the bone cavity without causing damage. The position of the reference line on the introducer was marked on the guide rod as the reference point (blue). The target marker on the guide rod was then fixed 1 or 2 mm (depending on the nominal press-fit) above the reference point to indicate the stop criterion for implantation. Implantation was stopped either when the reference line

reached the targeted marker or when further seating became impractical.

Two battery-operated instruments were used for implantation.¹² Single impactations were applied using an established automated impaction device (KINCISE; DePuy Synthes, USA), which delivers 3.5 J of energy per stroke and was manually activated at a frequency of 1 Hz with the assistance of a metronome. Continuous impactations were exerted using a vibratory implant insertion device (Behzadi Medical Device, USA), with the impaction frequency set at 60 Hz (Figure 3).

The impaction force was measured at the top of the component introducer during the implantation using a force cell (9333 A; Kistler, Germany), and recorded with 800 kHz sampling frequency (NI-9775 & LabVIEW; National Instruments, USA). The impaction force peaks for each impact were determined for each corresponding sample (MATLAB R2020b; MathWorks, USA).

The final polar gap was determined using 3D scans (Handyscan 3D). Pre-implantation scans of the acetabular component and the reamed porcine acetabulum were superimposed on the post-implantation scan with the inserted component in the acetabulum. Spheres were fitted to the outer surface of the component and the bone cavity, and the polar gap was measured as the polar distance between these

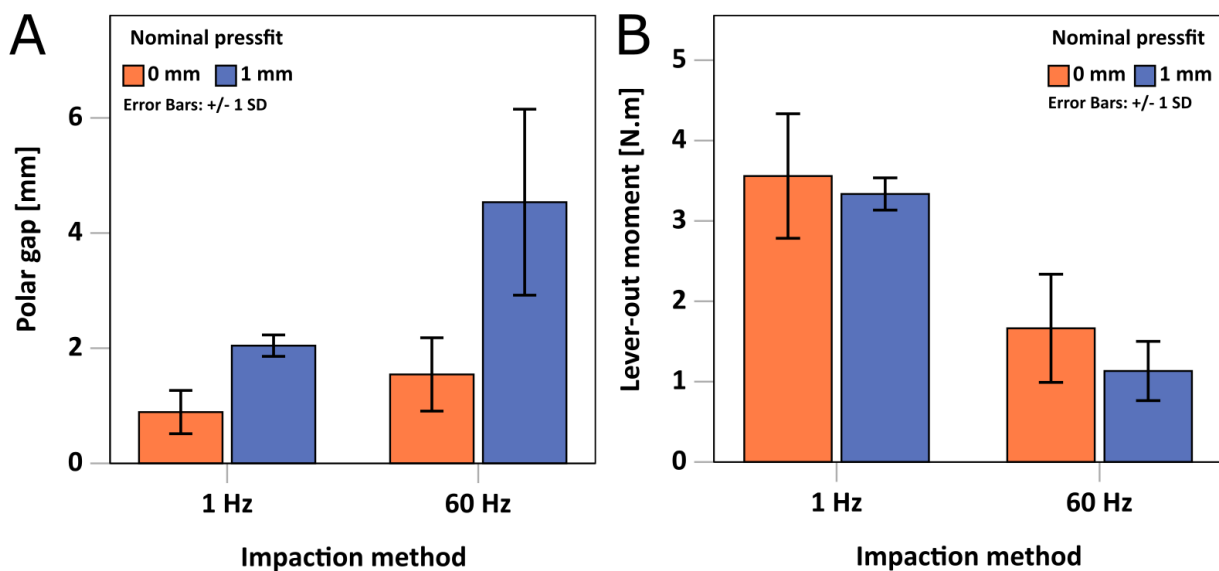


Fig. 6

a) Polar gap. The 60 Hz impaction method failed to insert the component to the targeted depth in a 1 mm nominal press-fit group. b) Lever-out moment. Nominal press-fit did not significantly affect the lever-out moment for both methods (1 Hz: $p > 0.999$, 60 Hz: $p = 0.520$, general linear model).

two spheres (PolyWorks|Inspector 2020; InnovMetric Software, Canada; Figure 4).

The lever-out test was used to quantify the acetabular component's primary stability.^{11,15-17} The component was levered-out by applying a force at 90° to the component axis quasistatically. This procedure was performed with a preload of 1 N under displacement control (0.05 mm/s; Z1010; Zwick Roell, Germany). The distance between the force application and the centre of the component was considered as the lever arm for the calculation of the lever-out moment.

Statistical analysis

Statistical analysis with a Type I error level of 0.05 was performed using SPSS v 26.0 (IBM, USA). Independent-samples *t*-test with a Bonferroni correction of α -value was used to compare the impaction force, polar gap, and lever-out moment between the different impaction methods. The general linear model (GLM) was used to investigate the effect of impaction method and NPF on impaction force, polar gap, and lever-out moment. One-sample *t*-test was used to verify whether the targeted polar gap was achieved for each NPF group. A multiple regression model was used depending on the polar gap, impaction force (defined as a dummy variable), and the interaction between them to investigate the correlation between the lever-out moment and polar gap.

Results

The actual press-fits were larger than NPFs and amounted to 0.61 mm and 1.60 mm for the line-to-line and 1 mm NPF (SDs indicated in Table I).

The impaction force was significantly lower for the vibrational insertion method regardless of NPF ($p < 0.001$, general linear model; Figure 5). An impaction of 60 Hz

generated 38% and 39% lower forces compared to the 1 Hz impaction for the line-to-line and 1 mm NPF condition, respectively ($p = 0.016$ and $p < 0.001$, independent-samples *t*-test; Table II). Only a minor effect of NPF was observed among the applied impaction methods ($p = 0.382$, general linear model).

In the line-to-line NPF groups, the targeted polar gap was reached with both impaction methods (1 Hz: $p = 0.551$, 60 Hz: $p = 0.128$, one-sample *t*-test; Figure 6a). Only the 1 Hz impaction method achieved the targeted position for the 1 mm NPF condition ($p = 0.621$, one-sample *t*-test; Table II). The 60 Hz impaction resulted in polar gaps that were twice as high as intended ($p = 0.012$, one-sample *t*-test; Table II), which were significantly higher than the polar gaps for the 1 Hz impaction method ($p = 0.013$, independent-samples *t*-test; Table II).

Lever-out moments for the 60 Hz impaction method were 53% and 60% lower for line-to-line and 1 mm press-fit, respectively ($p = 0.012$ and $p < 0.001$, independent-samples *t*-test; Figure 6b). Regardless of the final component position, the lever-out moment did not significantly differ with different nominal press-fits for both impaction methods (1 Hz: $p > 0.999$, 60 Hz: $p = 0.520$, general linear model).

The multiple regression model showed that the polar gap and the impaction method determine the lever-out moment (adjusted $R^2 = 0.864$, $p < 0.001$; Figure 7). The lever-out moment increased with decreasing polar gap ($p = 0.007$). The 1 Hz impaction method resulted in a higher lever-out moment ($p < 0.001$) with no interaction ($p = 0.311$).

Discussion

A specific vibratory impaction method with the frequency of 60 Hz and a consecutive single stroke impaction method

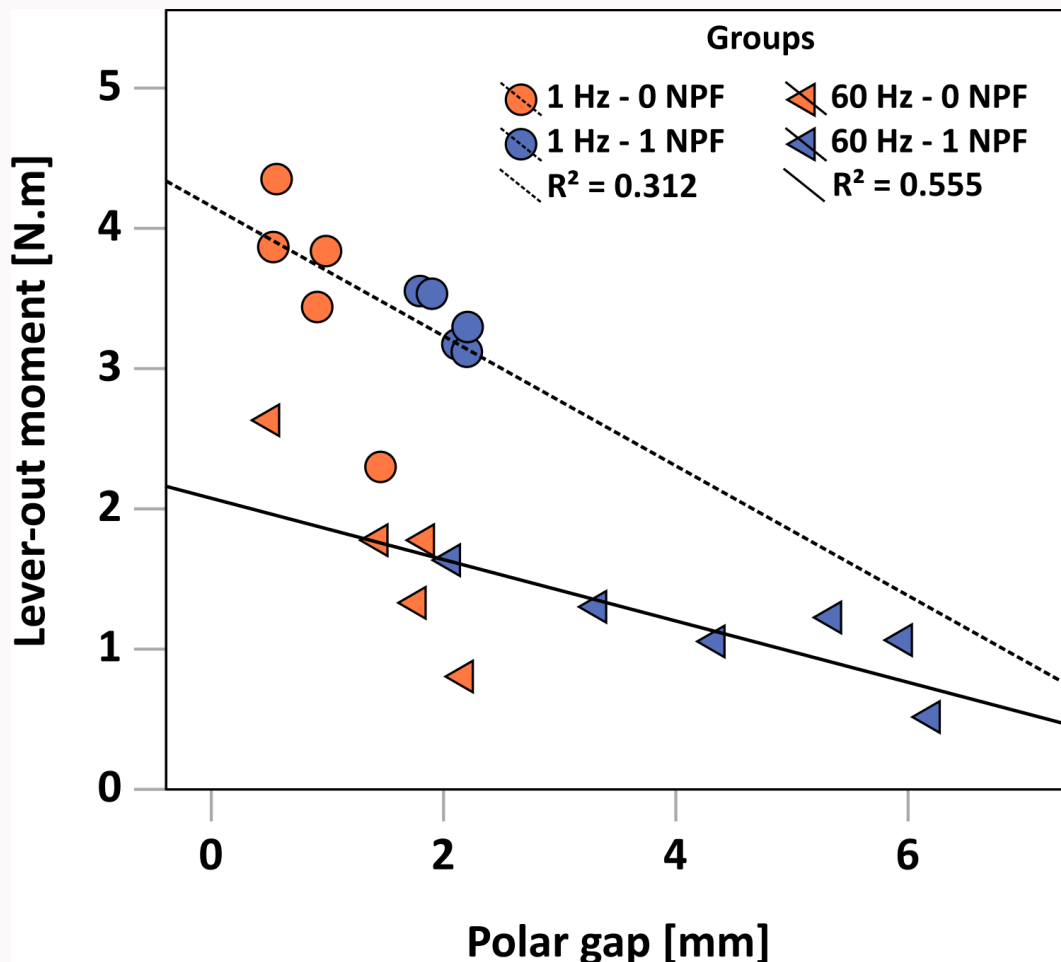


Fig. 7 The lever-out moment decreased with increasing polar gap for both impaction methods (adjusted $R^2 = 0.864$, $p < 0.001$). NPF, nominal press-fit.

with the frequency of 1 Hz were used for acetabular component insertion in porcine acetabula with two common NPFs. The aim was to investigate the potential benefits of vibratory implant insertion in terms of a reduction of impaction forces, while achieving sufficient implant primary stability in porcine bone.

This reduction in impaction force for the 60 Hz in the line-to-line press-fit group may contribute to a lower risk of periprosthetic fracture, which occasionally occurs during implantation.^{5,18,19} The lever-out moment as a representative of the implant's primary stability was lower for 60 Hz; even so, the desired seating position (polar gap of 1 mm) was reached. One previous study measured the friction moment acting on the acetabular component during walking between 2.25 Nm (SD 0.29) and 1.76 Nm (SD 0.83) after three and 12 months postoperatively, respectively,²⁰ which is close to the measured lever-out moment in the 60 Hz group.

In the 1 mm NPF groups, the impaction force was again lower for 60 Hz, but the acetabular component inserted by this method ended up with polar gaps not only higher than what was aimed, but also higher than the 1 Hz group. Polar gaps between 0.5 and 1.8 mm have been shown to be filled with bony structures within the first postoperative year,²¹ while the gaps over 2 mm carry a higher risk of early migration.²² Gaps above 4 mm, as in the present study, for the 60 Hz implantation with 1 mm press-fit, accompanied by an even

smaller lever-out moment as for the line-to-line condition with this impaction method, clearly indicates that a 1 mm press-fit is too much for the vibratory implantation method. Similar to 0 mm NPF, the lever-out moment was lower for 60 Hz.

The reduction in primary stability for the 60 Hz method compared to 1 Hz could be due to any interaction between the bone and the implant coating due to a higher number of strokes at 60 Hz. Micro-scale studies might be better suited to investigate processes at the bone-implant interface for different impaction methods and implant surfaces. A similar negative correlation between the polar gap and lever-out moment was also seen in another study in human bone.¹⁵

This study was limited to animal bones (porcine acetabula), which might not fully represent the characteristics of human bone, since they originate from young animals and are denser and stiffer compared to the bone of typically elderly patients undergoing THA. The effect of the patient's body is not considered in this study, since it has been shown not to have a significant effect on the implantation process due to the very short duration of each stroke during impaction.²³

Furthermore, the anatomical angles of the acetabulum were not considered during the implantation, as the bones were fixed perpendicular to the implantation axis. It must also be noted that the two implantation devices differ not only regarding their impaction frequencies but also the internal

mechanisms that create the impaction. This influenced the impaction forces and the resulting implantation outcome. The development of a device that allows adjustment of frequencies and forces independently is intended to investigate the potential of vibratory implant insertion systematically. This is also a requirement to allow a patient-specific adaptation of the implantation method and NPF. As a further limitation, it should be noted that solely adapting the NPF to the implantation method is insufficient to achieve a similar press-fit. A lower NPF for 60 Hz and a higher NPF for 1 Hz resulted in almost similar polar gaps, while the lever-out moment for 60 Hz was half that of 1 Hz. This finding indicates that other parameters of the implantation process (e.g. the implant characteristics) might have to be considered and adapted to the implantation method.

The comparison of the vibratory component insertion to the implantation with consecutive single blows in porcine bone specimens in this study resulted in quite similar results to a previous study in PU foam,¹² indicating that the impaction procedure of press-fit implants is instead an overcoming of the friction between the two different surfaces, not greatly influenced by the viscoelasticity of the surrounding bone material. This might be due to the short duration of each stroke in either method,²⁴ preventing the bone from fully exhibiting its viscoelastic behaviour.

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 M. Morlock: Conceptualization, Funding acquisition, Supervision, Writing – review & editing.

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ICMJE COI statement

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Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

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AI tools (Chat Gpt and DeepL) were used for some grammatical checking.

Ethical review statement

No human tissues were used for this study.

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