Vibratory insertion of press-fit acetabular components requires less force than a single blow technique

a pilot study

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Aims

Periprosthetic fracture and implant loosening are two of the major reasons for revision surgery of cementless implants. Optimal implant fixation with minimal bone damage is challenging in this procedure. This pilot study investigates whether vibratory implant insertion is gentler compared to consecutive single blows for acetabular component implantation in a surrogate polyurethane (PU) model.

Methods

Acetabular components (cups) were implanted into 1 mm nominal under-sized cavities in PU foams (15 and 30 per cubic foot (PCF)) using a vibratory implant insertion device and an automated impaction device for single blows. The impaction force, remaining polar gap, and lever-out moment were measured and compared between the impaction methods.

Results

Impaction force was reduced by 89% and 53% for vibratory insertion in 15 and 30 PCF foams, respectively. Both methods positioned the component with polar gaps under 2 mm in 15 PCF foam. However, in 30 PCF foam, the vibratory insertion resulted in a clinically undesirable polar gap of over 2 mm. A higher lever-out moment was achieved with the consecutive single blow insertion by 42% in 15 PCF and 2.7 times higher in 30 PCF foam.

Conclusion

Vibratory implant insertion may lower periprosthetic fracture risk by reducing impaction forces, particularly in low-quality bone. Achieving implant seating using vibratory insertion requires adjustment of the nominal press-fit, especially in denser bone. Further preclinical testing on real bone tissue is necessary to assess whether its viscoelasticity in combination with an adjusted press-fit can compensate for the reduced primary stability after vibratory insertion observed in this study.

Article focus

- This pilot study evaluates a vibratory implantation method for acetabular component insertion in terms of impaction force and implant primary stability.

Key messages

- Vibratory implant insertion may reduce the risk of fractures due to excessive impaction forces by decreasing the impaction force.
- The implantation process, e.g. nominal press-fit, has to be adjusted to achieve

the benefits of vibratory implantation in terms of implant primary stability.

Strengths and limitations

- A vibratory implantation method with an impaction frequency of 60 Hz has been evaluated and compared to consecutive single blows for acetabular component implantation.
- This study used polyurethane foam as a bone model, which does not represent the viscoelastic characteristics of bone tissue.

Introduction

Total hip arthroplasty (THA) successfully improves the quality of life through pain relief and restoration of mobility function.[1] Cementless implants are most frequently used in THA using a press-fit technique. Using this method eliminates the need for bone cement, but requires forceful insertion of the implant to achieve primary stability as a prerequisite for good biological fixation over time, which relies on radial forces generated during implantation.[2,3]

Despite its success,[4] implant loosening and periprosthetic fractures (PPFs) are two of the major reasons for revision surgery.[5-8] On the acetabular side, only central medial wall fractures, which are recognizable on plain radiographs, may impair implant survival.[9] Occult undisplaced periprosthetic acetabular fractures are not infrequent, but usually remain undiagnosed since they tend to heal spontaneously without additional treatment.[10] Despite this fact, occult fractures are highly undesirable, and preventive measures such as modified impaction procedures should be developed. Intraoperative acetabular fractures can be related to the impaction process,[11-13] but are less common than femoral PPFs. Periprosthetic acetabular fractures have been attributed to either sclerotic unyielding acetabular bone, possibly predisposed to fracture, or age-related bone fragility due to osteoporosis,[14] and are associated with adverse outcomes.[15] The high force during a short blow of a mallet creates high radial forces in the bone cavity around the implant, which can lead to bone fractures, especially in poor-quality bones, such as bones affected by osteoporosis.[16,17] Therefore, the force for implant insertion should be kept as low as possible to lower the fracture risk.[18] The final component position is an important clinical factor. Insufficient implant seating can result in inadequate initial fixation and loosening.[6] Studies have indicated that polar gaps of less than 2 mm are associated with adequate primary stability.[19,20] The influence of implant and bone characteristics such as component design,[19-21] implant surface characteristics,[22] acetabular component stiffness,[23] bone density,[24,25] and the interface between bone and implant[2,26] on the initial implant stability have been investigated thoroughly. The impaction process has recently gained attention, such as different combinations of mass and velocity for impaction[27] or different energy levels.[28] Increasing the impaction frequency from 1 Hz to 6 Hz was shown to reduce the impaction force.[29] The application of vibrations has been demonstrated to be an advantageous approach in other fields: in the construction industry, vibratory pile driving is shown to be beneficial compared to impact driving in terms of reducing the required force for pile installation as well as the frictional force.[30] Therefore, this became a motivation to design this pilot study as the first step of an investigation to see whether vibratory implant insertion can help to achieve component seating in THA with lower impaction forces, by reducing the friction forces between the implant's rough surface and the bone cavity, which could reduce PPF risk and cause less damage to the bone cavity. In this study, polyurethane (PU) foam blocks with varying densities were used as bone surrogates, given their widespread use as bone substitutes in other studies.[27,28,31,32]

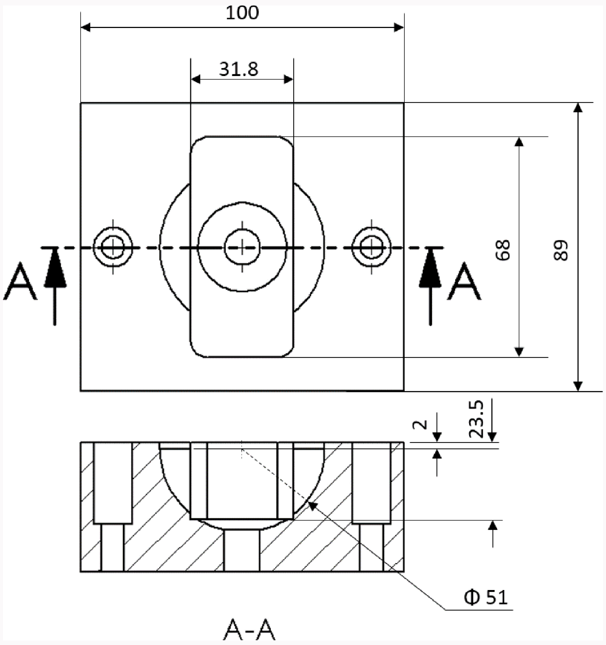

Fig. 1
Polyurethane foam block geometry (dimensions in mm).

Methods

Bone surrogates and acetabular component

PU foam blocks (SYNBONE, Switzerland) with densities of 15 and 30 pounds per cubic foot (PCF) with computer numerical control (CNC)-milled hemispherical cavities (diameter of 51 mm centred 2 mm below the top surface of the foam block; Figure 1) were used as bone surrogates. The cavity had two cut-outs creating a simplified acetabular anatomy model with similar component deformation as measured in cadaver experiments.[28,32] Press-fit acetabular components (cups) (Pinnacle, Sector hole, Gription Coating; DePuy Synthes, UK) with a nominal size of 52 mm were inserted into the cavities.

Component insertion process

A polar gap of 2 mm was used as the stop criterion for implant insertion in order to eliminate the effect of varying cup positions on primary stability for the comparison between the two implantation methods. The cup introducer was marked with a red line. Cavity depth was determined as the distance from the bottom of the cavity to the red line on the cup introducer using an under-sized cup to avoid damage to the reamed surface (Figure 2a). This cavity depth was marked on a guide rod with an indicator as reference point (Figure 2a). The indicator was then moved 2 mm upwards from the reference point to show the targeted position of

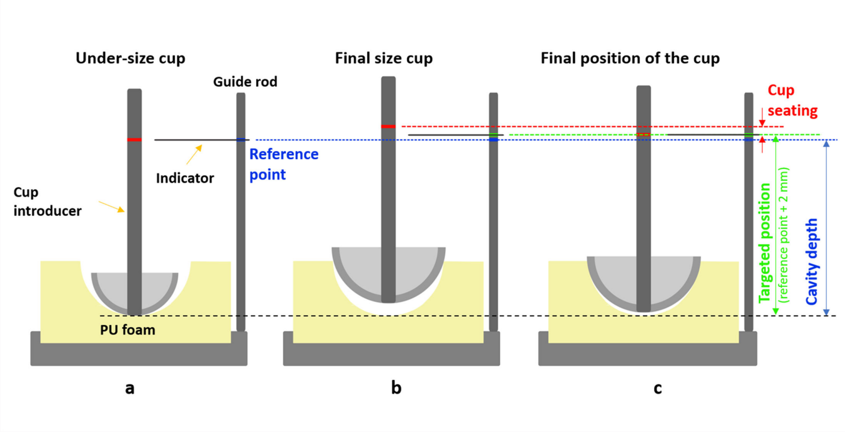

Fig. 2
Defining the final position of the cup. a) The depth of the CNC-milled cavity was referenced from a mark on the cup introducer (red) to an indicator on the guide rod (blue) without harming the reamed surface using an under-sized cup. b) The indicator was then moved 2 mm above the reference point on the guide rod to define the targeted cup position with a corresponding polar gap (green). c) Final position of the implanted acetabular cup. PU, polyurethane.

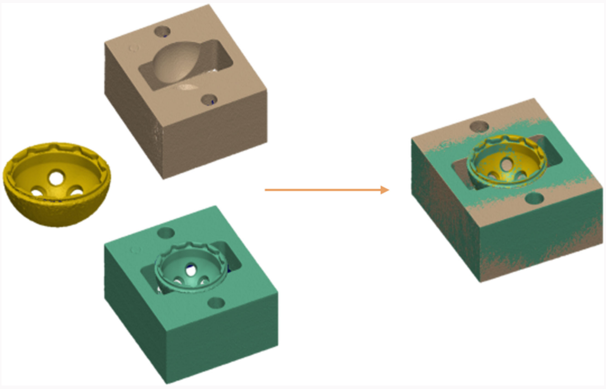

Fig. 3
The final polar gap was derived by superimposing pre-implantation 3D scans of the surrogate cavity and acetabular component to the post-implantation scan.

the seated cup. The final size cup was then mounted to the cup introducer (Figure 2b). Cup implantation was performed until the red mark on the implant introducer at least reached the indicator, and the desired position was attained without bounce back or further seating could not be achieved (Figure 2c). The exact value of the remaining polar gap after implantation was determined from a 3D laser scan (Handyscan 3D; Creaform, USA) by superimposing the scans of the implanted component together with the PU block on the scans of the acetabular component and the PU block acquired before implantation (PolyWorks|Inspector 2020; InnovMetric Software, Canada; Figure 3). The polar distance between two hemispheres fitted to the component outer surface, and the reamed PU block surface was then calculated and is referred to as polar gap.[19]

Two different battery-powered tools were used for acetabular component insertion. One was a commercially available and clinically used automated impaction device (KINCISE; DePuy Synthes, USA), which generates 3.5 J per blow and is triggered manually at 1 Hz using a metronome. The second was a vibratory implant insertion device with an impaction frequency of 60 Hz (Behzadi Medical Device LLC, USA).

Tests were performed with preloads of 100 and 200 N, simulating two force levels which might be applied by a surgeon to the device during the implantation (Figure 4). Components were implanted using a linear guidance in a load frame (Figure 4). Each combination of foam density, preload, and impaction device was investigated (n = 5 per group, n = 40 in total). Impaction force during the implantation process was measured using a force cell, which was fixed between the impaction device and the cup introducer (9333 A; Kistler, Germany; Figure 4). The force sensor was connected to an AD converter with a sampling frequency of 800 kHz (NI-9775 & LabVIEW; National Instruments, USA). The maximum force of every hit was determined (MATLAB R2020b; MathWorks, USA).

Primary stability

The lever-out moment to disengage the acetabular component from the cavity was determined as the representative value for the primary stability.[33] A force at 90° to the cup axis was applied quasi-statically under a displacement control procedure (0.05 mm/s) with a preload of 1 N until the force dropped to 70% of the maximum value (Z010; Zwick Roell, Germany). The lever-out moment was calculated as the product of the lever arm to the centre of the hemispherical cup and the maximum force (Figure 5).

Statistical analysis

Statistical analysis with a Type I error level of 0.05 was performed using SPSS (version 26.0, IBM, USA). Independent-samples *t*-test was used to compare two groups for normally distributed data. Analysis of variance (ANOVA) was used to compare more than two normally distributed groups. The Bonferroni correction was used throughout. Data violating the normality distribution were analyzed using Mann-Whitney U testing to compare two groups, and Kruskal-Wallis testing combined with the Bonferroni post hoc test in comparisons among more than two groups. The power is specified for parametric tests not reaching significance ($p > 0.05$). Pearson correlation and Spearman's rho were used to investigate the

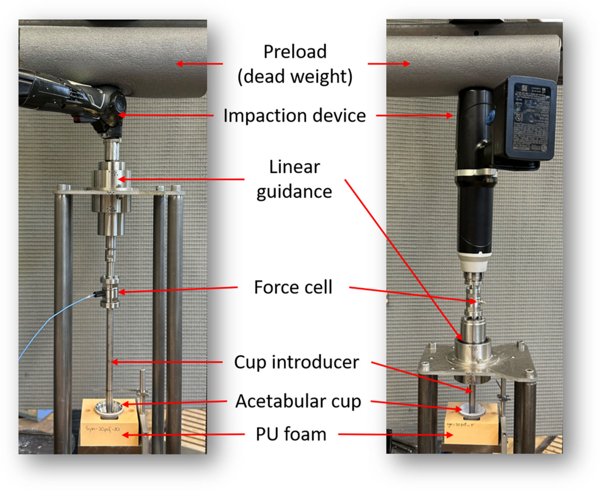

Fig. 4

Experimental setup. Left: vibratory acetabular cup insertion (60 Hz). Right: acetabular cup insertion by consecutive single blows (1 Hz). PU, polyurethane.

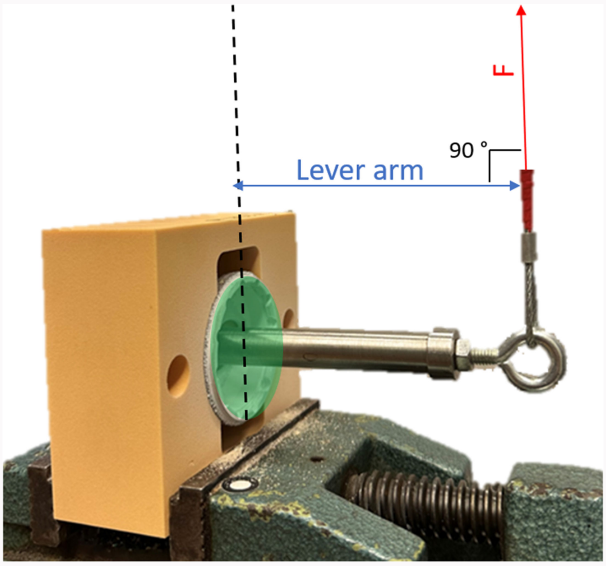

Fig. 5

Lever-out test. The lever arm was measured from the point of force application and the centre of the component.

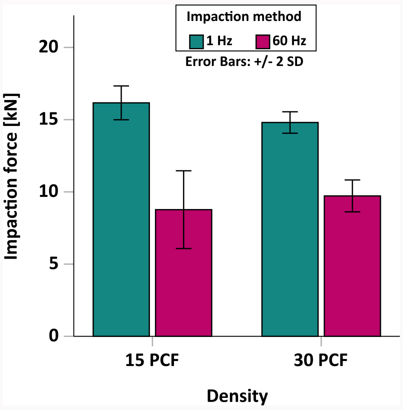

Fig. 6

Impaction forces (mean and standard deviation (SD)) during the acetabular component insertion for the two foam densities and impaction methods. PCF, per cubic foot.

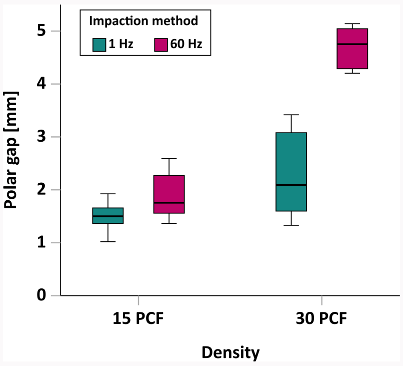

Fig. 7

Seated cup position analysis. Polar gaps less than 2 mm were attained in 15 per cubic foot (PCF) foam with both methods. In 30 PCF foam, the targeted position was not reached with the vibratory implant insertion (60 Hz).

correlation between polar gap and lever-out moment for normally and not normally distributed groups, respectively.

Results

The preload did not affect the impaction force (15 PCF: p = 0.916, power = 0.051; 30 PCF: p = 1.000; Table I) or the polar gap (15 PCF: p = 0.588, power = 0.082; 30 PCF: p = 1.000; Table I). Therefore, the data of different preloads were pooled for further analysis and are shown in Table II.

Impaction force

Impaction force (Figure 6) was 89% (p < 0.001, independent-samples *t*-test) and 53% (p < 0.001, independent-samples *t*-test) lower for the 60 Hz impaction method than for 1 Hz impaction in 15 and 30 PCF foams, respectively. The 1 Hz impaction method produced 10% higher forces in 15 PCF foam compared to 30 PCF (p < 0.001, independent-samples *t*-test), whereas the forces for 60 Hz impaction were similar in both density groups (p = 0.095, independent-samples *t*-test).

Cup position analysis

The targeted position was reached with both impaction methods in the 15 PCF foam (Table I). The remaining polar gap was 25% lower for the 1 Hz impaction method (p = 0.021, independent-samples *t*-test; Figure 7). In 30 PCF foam, the planned seated position could not be reached with the vibratory insertion but with the 1 Hz impaction (p < 0.001, Mann-Whitney U test; Figure 7).

Primary stability

The lever-out moment increased with foam density (p < 0.001, ANOVA) and decreased with impaction frequency (p < 0.001, ANOVA). 1 Hz impaction method resulted in higher primary stability by 42% in 15 PCF (p = 0.001, independent-samples *t*-test), and a 2.7-times higher stability in 30 PCF foam (p < 0.001, independent-samples *t*-test) (Figure 8a). The lever-out moment decreased with increasing polar gap (Figure 8), significantly for the 1 Hz impaction (15 PCF: p = 0.050, R^2 = 0.663; 30 PCF: p = 0.003, Pearson correlation; R^2 = 0.823) and

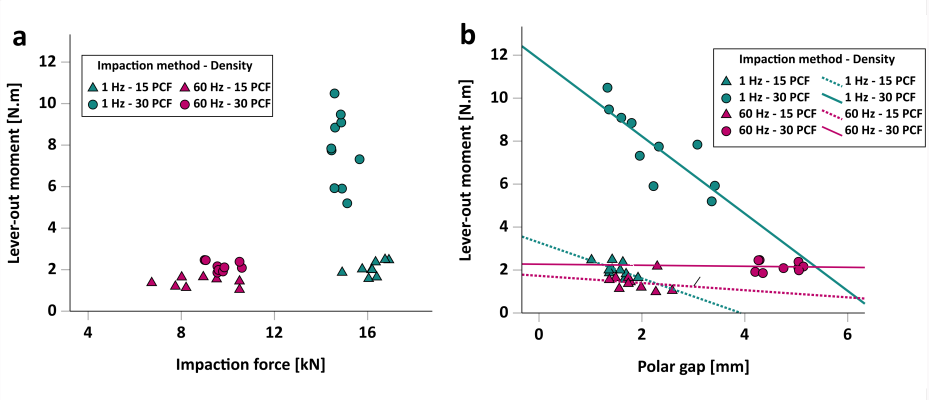

Fig. 8

Primary stability analysis. a) The lever-out moment was higher for 1 Hz compared to 60 Hz impaction by 42% in 15 per cubic foot (PCF) foam, and 2.7 times in 30 PCF foam. b) The lever-out moment decreased with increasing polar gap for all conditions.

Table I. Median impaction force for the different impaction methods under the different preloads.

Foam density	**15 PCF**				**30 PCF**			
Impaction method	1 Hz		60 Hz		1 Hz		60 Hz	
Preload (N)	100	200	100	200	100	200	100	200
Impaction force (kN) (IQR)	16.21 (15.19 to 16.78)	16.19 (15.97 to 16.54)	8.63 (6.98 to 10.25)	8.57 (8.06 to 10.11)	14.89 (14.58 to 15.38)	14.58 (14.44 to 14.85)	9.55 (9.02 to 9.57)	10.17 (9.80 to 10.57)

IQR, interquartile range; PCF, per cubic foot.

Table II. All parameters for the two impaction methods after pooling the different preloads.

	15 PCF		**30 PCF**	
Parameters	**1 Hz**	**60 Hz**	**1 Hz**	**60 Hz**
Mean number of blows (SD)	3 (1)	432 (155)	15 (3)	448 (215)
Mean impaction force, kN (SD)	16.16* (0.59)	8.77 (1.34)	14.8* (0.37)	9.72 (0.55)
Median polar gap, mm (IQR)	1.5† (1.36 to 1.66)	1.75 (1.54 to 2.27)	2.09* (1.54 to 3.15)	4.75 (4.27 to 5.04)
Mean lever-out moment, Nm (SD)	2.02† (0.32)	1.41 (0.36)	7.78* (1.73)	2.16 (0.23)

*Significant compared to 60 Hz impaction ($p < 0.001$).
†Significant compared to 60 Hz impaction ($p < 0.05$).
IQR, interquartile range; PCF, per cubic foot; SD, standard deviation.

slightly for the 60 Hz impaction (15 PCF: p = 0.609, Pearson Correlation; $R^2 = 0.185$; Spearman's rho, 30 PCF: p = 0.966, $R^2 = 0.017$) (Figure 8b).

Discussion

This study investigated whether vibratory implantation allows a gentler implant insertion while still achieving sufficient primary stability. One specific vibratory impaction with a frequency of 60 Hz was compared to a consecutive single impaction with a frequency of 1 Hz, which is comparable to the frequency that a surgeon may apply. PU foam models do not possess the viscoelasticity of bone tissue,[34] and also have different friction characteristics,[35] but they are commonly used as substitutes for bone due to their other mechanical characteristics, which closely resemble those of natural bone tissue.[27,28,33,36,37]

The desired seating depth in the 30 PCF foam model could not be reached with the vibratory implantation. This is due to the limited energy of the used device in combination with the amount of press-fit between the cup and the under-sized cavity in the high-density foam. A smaller nominal press-fit (e.g. line-to-line) could compensate for this obstacle. This needs further investigation using real bone specimens, which might provide a better understanding of the clinical applicability of vibratory implantation. The beneficial reduction of the impaction forces by the vibratory insertion was too large and prevented the cup from seating further. This highlights that the whole implantation process has to be modified if a gentler component implantation is the goal and not the impaction process alone. The press-fit magnitude, i.e. the amount of under-reaming, also needs to be adjusted, according to the density of the cavity material. In 15 PCF foam the intended depth was reached with both methods, but with clearly reduced forces for vibratory implant insertion, which could contribute to the desired decreased risk of fractures caused by excessive impaction forces.[38] The magnitude of the simultaneous undesired reduction in primary stability was clearly lower than the reduction in impaction forces (40% vs 89%, respectively). The reduction in primary stability at the similar final seating position in 15 PCF foam could be due to cavity over-reaming in the PU block by the rough implant surface when using the vibratory method, leading to a reduction in the effective press-fit between the cavity and the implant. As PU foam is more brittle than bone and does not carry any viscoelastic characteristics, this reduction might not occur in bone.

This study also considered the varying levels of force that surgeons might exert while operating the mentioned automated impaction devices. The different levels of preloading did not exhibit any discernible effect on impaction forces and component insertion depth. This could be an important step towards standardized implantation by providing similar impaction force magnitudes determined by the impaction device, and not by the surgeon.

Despite the limitations of the foam model, this study has demonstrated that vibratory insertion can reduce impaction forces, and potentially reduce the risk of intraoperative fractures. In this study this comes at the price of reduced primary stability, especially in the 30 PCF foam model, which is clinically not acceptable. The results demonstrate that the whole surgical process has to be adjusted in order to achieve the benefits of vibratory insertion. The next step will be a similar study in real bone investigating different amounts of nominal press-fit. The different friction characteristics and the viscoelasticity of bone are hypothesized to improve seating and primary stability for vibratory insertion if the appropriate press-fit is used.

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G. Huber: Conceptualization, Writing – review & editing.
K. Behzadi: Methodology, Resources, Writing – review & editing.
M. Morlock: Conceptualization, Supervision, Funding acquisition, Writing – review & editing.

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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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Ethical review statement

No human tissues were used for this study.

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