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NOTE

Development of a novel flexible bone drill integrating hydraulic pressure wave technology

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Abstract
Orthopedic surgery relies on bone drills to create tunnels for fracture fixation, bone fusion, or tendon repair. Traditional rigid and straight bone drills often pose challenges in accessing the desired entry points without risking damage to the surrounding anatomical structures, especially in minimal invasive procedures. In this study, we explore the use of hydraulic pressure waves in a flexible bone design to facilitate bone drilling. The HydroFlex Drill includes a handle for generating a hydraulic pressure wave in the flexible, fluid-filled shaft to transmit an impulse to the hammer tip, enabling bone drilling. We evaluated seven different hammer tip shapes to determine their impact on drilling efficiency. Subsequently, the most promising tip was implemented in the HydroFlex Drill. The HydroFlex Drill Validation demonstrated the drill's ability to successfully transfer the impulse generated in the handle to the hammer tip, with the shaft in different curves. This combined with the drill's ability to create indentations in bone phantom material is a promising first step towards the development of a flexible or even steerable bone drill. With ongoing research to enhance the drilling efficiency, the HydroFlex Drill opens possibilities for a range of orthopedic surgical procedures where minimally invasive drilling is essential.

1. Introduction

1.1. Challenges in orthopedic surgery
Orthopedic surgery with its focus on the musculoskeletal system, confronts persistent challenges in procedures such as drilling through bone for fracture fixation, bone fusion, or tendon repair [1]. While conventional rigid and straight bone drills have proven user-friendly, reaching all desired locations with these drills poses challenges due to their limited maneuverability, especially in minimally invasive procedures. The introduction of flexible and steerable bone drills holds promise in overcoming these limitations, offering enhanced reachability in challenging areas, minimizing damage to surrounding tissue, and creating superior tunnels for fixation of tendons and bone anchors. As an example, steerable bone drills allow for the integration of curved tunnels and innovative bone anchors which has the potential to enhance the fixation strength of the currently used spinal bone anchors [2].

1.2. Steerable bone drills: state-of-the-art
Despite a variety of steerable bone drills presented in patent literature, there are currently no commercial bone drills available that allow real-time trajectory adjustment during surgery [3]. Although steerable bone drills are not commercially available, there are bone drills that allow for drilling of slightly more complex tunnels. These drills comprise a flexible drive shaft connected to a rotating drill tip creating a flexible drill that can be advanced through a curved guide [4], or, in case of a tubular drill, can be advanced over a pre-placed guide wire [5]. With the aid of a guide slightly curved or slightly angulated tunnels can be created. Several steerable bone drill designs are presented in scientific literature. These drills also comprise a flexible drive shaft that actuates a rotating drill tip that can also be angulated by the use of steering cables [6, 7]. Although the presented designs are promising the design of a steerable bone drill that uses an axially rotating drill tip to advance through the bone tissue presents a challenge as the required flexibility for creating a curved tunnel compromises the drill's buckling resistance needed to advance through hard materials like bone. Furthermore, heat generation during drilling can result in bone necrosis which may ultimately result in implant failure [8].

Although there is a lot of research describing the factors influencing heat generation, such as drill speed, drill diameter, drill design and the use of coolant, heat generation remains a problem when using an axially rotating bone drill [1, 8–11]. In the case of a steerable drill, the heat generation might even be a larger problem as heat generation is more severe when using a guide as the added friction between the rotating drill and the guide further increases the drills temperature [12]. Alternative drilling methods such as ultrasonic drilling or hammering offer potential advantages over rotating drilling as hammering generates less heat compared to traditional drilling, reducing the risk of bone necrosis [13]. However, the challenge lies in applying an impulse to bone tissue through a flexible shaft.

Addressing this challenge, Sakes *et al* [14] introduced a flexible catheter filled with a fluid capable of transferring an impulse with the aim to hammer through calcifications in blood vessels. The transfer of the impulse through the flexible catheter is achieved by utilization of a hydraulic pressure wave. A hydraulic pressure wave is a standing wave that comprises of high-pressure regions and low-pressure regions that can propagate through a fluid filled tube. While the catheter by Sakes *et al* has a smaller diameter (1.4 mm) than a bone drill (~4 mm) and calcifications in blood vessels differ in material properties from bone, the use of a hydraulic pressure wave holds promise in the design of a flexible bone drill. The use of a hydraulic pressure wave allows for the transfer of an impulse while facilitating the necessary bending for drilling curved tunnels without the risk of buckling.

This study proposes the application of a hydraulic pressure wave to transfer an impulse through a flexible fluid-filled bone drill, thereby facilitating the development of the HydroFlex Drill. The HydroFlex Drill comprises a handle in which the pressure wave is generated that propagates through the flexible shaft. At the distal end, the pressure wave is transferred to the hammer tip where a hammer stroke, and thus impact, is generated onto the bone (figure 1).

1.3. Goal of this study

The goal of this study was to design and evaluate a flexible bone drill incorporating the use of a hydraulic pressure wave for the drilling of curved tunnels through bone. A concept design and prototype of the HydroFlex Drill was created and validated. The initial validation involved the evaluation of seven hammer tip shapes based on their penetration rate through bone. Subsequently, the optimal tip shape, determined through this evaluation, was integrated into the HydroFlex Drill prototype. The drill's performance was then assessed in both straight and curved configurations, providing valuable insights into its potential clinical application and broader implications for orthopedic surgery.

2. Hydro flex drill design

2.1. Concept design

The primary function of the handle is to allow the user to generate a hydraulic pressure wave. The handle incorporates a spring, which is tensioned by pulling the knob backwards (figure 2(A)). Upon loosening the knob, the spring releases and forces a mass forward striking an impulse delivery plunger at the proximal side of the flexible shaft. The generated impulse is transferred from the impulse delivery plunger located within the flexible, fluid-filled shaft to the fluid, minimizing losses due to wave reflection.

In the shaft, efficient transfer of the impulse from the handle to the hammer tip by a hydraulic pressure wave is crucial. Consequently, the shaft is designed as a radially incompressible hollow tube with a smooth inner surface to limit losses during impulse transfer. Additionally, the shaft's flexibility allows for potential future adaptation into a steerable drill. Besides the shaft design, the fluid medium used to transfer the impulse influences the efficiency of the impulse transfer [15]. As the drill is intended for clinical use and the risks related to leaking of the fluid must be minimised, saline solution would be preferred as fluid to transfer the impulse.

The momentum of the hydraulic pressure wave is effectively transferred to the bone material through the hammer tip. This tip comprises a pin fitting within the drill shaft, facilitating the transfer of the pressure wave's momentum to the surrounding bone. An internal spring within the hammer tip ensures its return to the initial position after each stroke, enabling repetitive hammering (figure 2(A)). The optimal tip shape to transfer the impulse to the bone material will be investigate. Only rotational symmetric tip shapes will be considered as rotational symmetric tip shapes have proven to be effective in the transfer of an impulse to brittle material [16].

2.2. Prototype

The assembled prototype, illustrated in figure 2(B), was manufactured using a combination of 3D printed parts (Envision TEC R5) and off-the-shelf components such as the spring in the handle (Ø: 24.4 mm, k: 0.78 N mm^{-1}) and the spring in the hammer tip (Amatec, Ø: 2.5 mm, k: 1.4 N mm^{-1}). The selected tube for the flexible drill shaft is a Nylon PA12 Tube (Advanced Fluid Solutions, UK, $Ø_{outer}$: 4 mm, $Ø_{inner}$: 2.5 mm, length: 40 mm). Although in clinical use saline would be preferred, in this prototype the shaft will be filled with water as the properties of saline and water are negligible [15]. To minimize leakage during the impulse transfer from the handle to the flexible shaft, the distal end of the handle and the hammer tip were precision-milled from stainless steel.

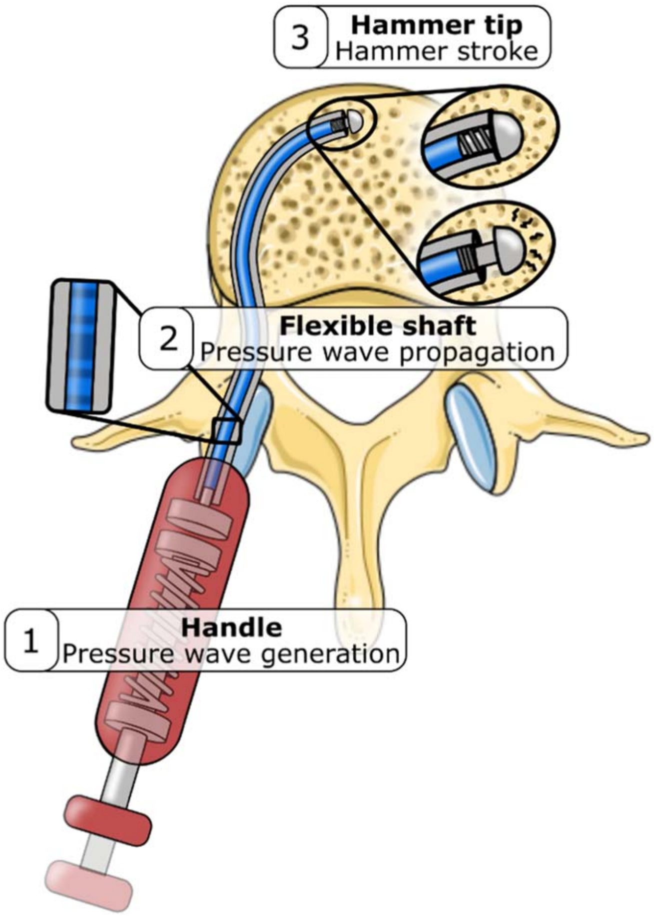

Figure 1. Proposed flexible bone drill with hydraulic pressure wave technology including (1) a handle where the pressure wave is generated, (2) a flexible shaft through which the pressure wave propagates and (3) a hammer tip that the hammer stroke on the surrounding bone. Illustration adapted from Servier Medical Art.

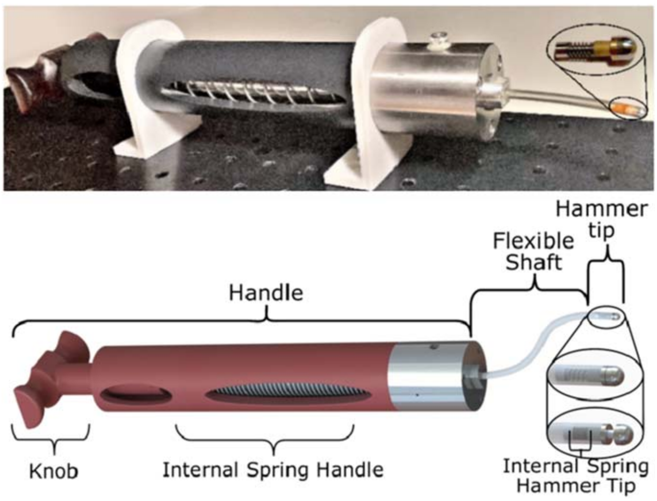

Figure 2. HydroFlex Drill prototype. (A) Model of the HydroFlex Drill including a handle to generate a hydraulic pressure wave that propagates through the flexible shaft where up on contact with the hammer tip, the hydraulic pressure wave is transferred via the hammer tip to the bone material. (B) Photo of the HydroFlex Drill prototype.

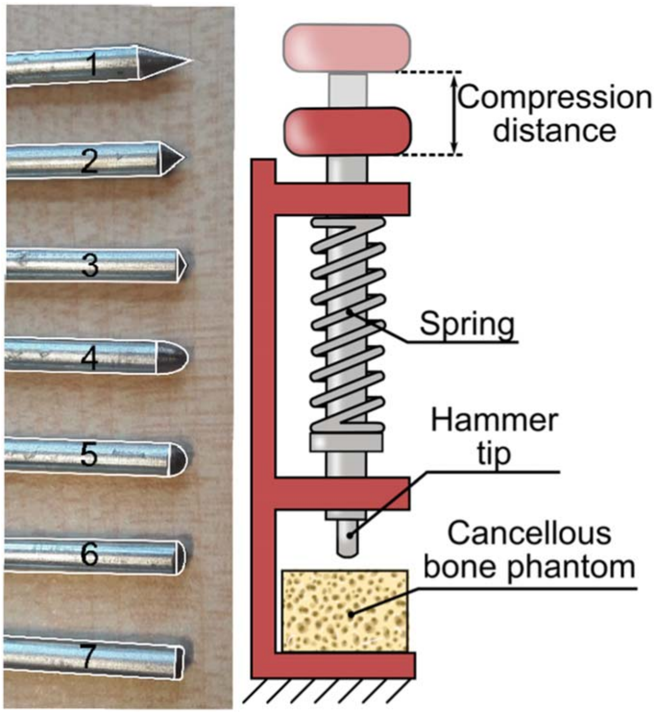

Figure 3. The effect of tip shape on performance. Left) Differently shaped hammer tips. Right) Experimental facility used in the Hammer Tip Shape Validation.

3. Materials and methods

3.1. Experimental goal

Given the unconventional use of impulse hammering to drill through bone, a thorough investigation of this method is vital. The initial focus was on determining the optimal hammer tip shape for bone drilling, which will then be integrated into the HydroFlex Drill prototype. Subsequently, the drilling performance of this novel design was validated with the flexible shaft in various configuration. Two distinct experimented were preformed: (1) Hammer Tip Shape Validation, exploring the impact of different tip shapes on drilling performance, and (2) HydroFlex Drill Validation, assessing drilling performance of the HydroFlex Drill with its flexible shaft in straight and curved configurations using the identified optimal hammer tip.

3.2. Hammer tip shape validation

3.2.1. Experimental variables

The first independent variable in this study was the hammer tip shape. Seven rotational symmetric tip shapes (conical, hemispherical, and cylindrical), all with a 4 mm diameter, were developed and validated (figure 3 Left). The second independent variable was the compression distance of the spring, influencing the generated force used to hammer the tip into the bone phantom material. Two compression distances, 10 mm and 20 mm were evaluated resulting in a spring force of 7.8 N and 11.7 N being executed on the system, respectively. The dependent variable was the penetration rate [mm/stroke] through the cancellous bone phantom.

3.2.2. Experimental facility and protocol

The experimental setup, depicted schematically in figure 3 Right, comprised a hammer unit capable of generating impulses through a spring-loaded mechanism, similar to the one used in the handle of the HydroFlex drill. The impulse was generated by a spring (Ø: 24.4 mm, k: 0.78 N mm^{-1}) and transmitted through various hammer tips to the cancellous bone phantom (polyurethane foam). By adjusting the compression distance of the spring, the force used to hammer the drill tip could be varied.

The hammer tip was driven into the bone phantom material five times. If no visible penetration occurred, an additional five hammer strokes were performed. The penetration rate [mm/stroke] was determined by dividing the measured penetration depth by the number of a hammer strokes performed, allowing for a comprehensive evaluation of drilling efficiency. Each hammer tip was tested three times. The data analysis used to determine the mean penetration rate and the standard deviation was performed in MATLAB.

3.2.3. Experimental results

The penetration rates for the seven distinct hammer tip shapes and two different spring compression distances are illustrated in figure 4. Notably, an increase in spring compression corresponds to an increased penetration rate, aligning with expectations. The tip shape showed a limited effect on the penetration rate. However, it was

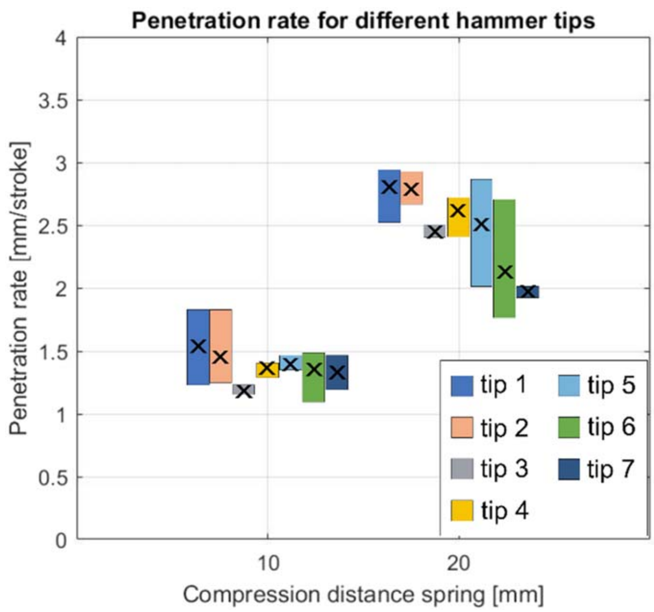

Figure 4. Penetration rate for different tip shapes and different compression distances of the impulse generating spring. The crosses indicate the mean value while the boxes indicate the standard deviation.

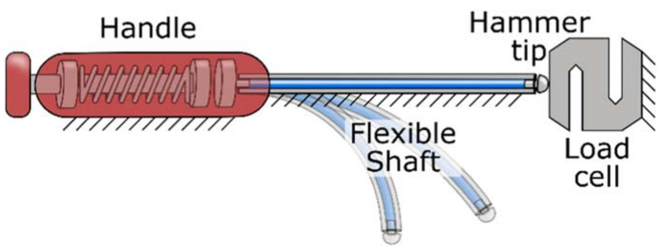

Figure 5. Experimental setup with the HydroFlex Drill with the flexible shaft in straight, 45° and 90° curve and a loadcell measuring the force.

found that the hammer tips with a flatter tip shape (6, 7) showed accumulation of densely packed bone at the tip, potentially impeding drilling efficiency over prolonged use. Furthermore, given the application of the drill in orthopaedic surgery, where safeguarding surrounding anatomy is crucial, the desirability of a sharp tip (1, 2, 3) is diminished due to the increased risk of damage to surrounding soft tissues such as nerves and blood vessels. Consequently, Hammer Tip 4 was selected for incorporation into the final design. This tip demonstrated a relatively high penetration rate with a small variability while featuring a blunt tip, thereby minimizing the likelihood of causing harm to surrounding tissues.

3.3. Hydro flex drill performance validation

3.3.1. Experimental variables

The independent variable of this experiment was the HydroFlex Drill shaft configuration (straight, 45° curve, 90° curve). The dependent variable was the generated maximum hammer force by the hammer tip to evaluate the drilling performance of the HydroFlex Drill.

3.3.2. Experimental facility and protocol

The experimental setup is illustrated in figure 5. The HydroFlex Drill handle was securely fixed, and the flexible shaft was positioned to reflect three configurations: (1) straight, (2) curved with a 45° angle, and 3) curved with a 90° angle. A compression distance of 40 mm of the spring within the handle was imposed, resulting in an input spring force of 31.2 N. The maximum generated output force by the hammer tip was measured using a load cell (PST, S-type, 150 kg). In each shaft configuration, 10 hammer tip strokes were measured using the force sensor. The measured output force ensures a comprehensive understanding of the HydroFlex Drill performance under varying shaft configurations. The data analysis used to generate a boxplot of the maximum hammer force was performed in MATLAB.

3.3.3. Experimental results

The outcomes of the HydroFlex Drill Validation are depicted in figure 6. The measured output force was 11.1 ± 1.3 N with the shaft in straight configuration, 5.7 ± 1.6 Ns with the shaft in a 45° curved configuration

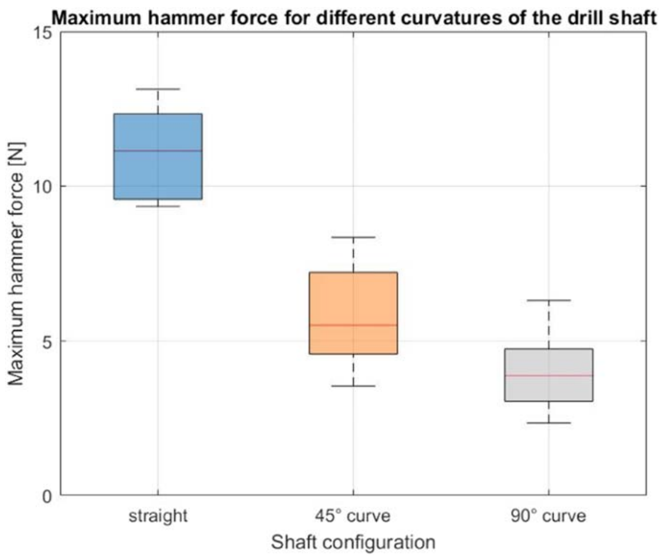

Figure 6. Boxplot indicating the measured impulse with the flexible drill shaft in a straight configuration and a 45° and 90° curve. The horizontal line indicates the median, the lower whisker indicates the lowest datapoint and the top whisker the highest datapoint. The box indicates the fist and third quartile.

and 4.1 ± 1.2 Ns with the shaft in a 90° curved configuration. It can be observed that the force transferred from the drill tip decreases when a stronger curve is introduced in the flexible shaft. These findings suggest that the presence of a curve in the flexible shaft has significant impact on the transferred impulse, with approximately a 60% decrease from straight to the 90° curved configuration.

Testing the HydroFlex Drill on bone phantom material (SawBones) showed that the drill was able to create an indentation after repetitive hammering, thought the penetration rate was low compared to the penetration rate that was achieved in the Hammer Tip Shape Validation.

4. Discussion

This study marks a first exploration into the development of a steerable bone drill utilizing a hydraulic pressure wave to hammer through bone. The influence of tip shape on penetration rate was found to be limited, but concerns arise regarding the accumulation of densely packed bone when using blunt tips and the imposed risks to damage surrounding tissue when using sharp tips. It is therefore recommended to employ hemispherical tip shapes, which help prevent the issue of packing without causing harm to surrounding tissue.

In this study only rotational symmetric hammer tips were considered, however other tip shapes such as a diamond or trocar shape that is currently used in Kirschner-wires as these tip shapes are designed to propagate through bone.

Implementing this drill tip in the HydroFlex Drill prototype showed that it is possible to transfer high-force impulses with the flexible shaft both in straight and curved configurations. It was found that efficiency of impulse transfer decreases with shaft curvature, possibly due to changes in the cross section of the flexible shaft that result in more losses during the propagation of the hydraulic pressure wave. For efficient wave propagation the shaft must be both axial and radial stiffness while maintaining a low bending stiffness. Alternative shaft designs with incorporated braiding or a multi-layer construction could be investigated to minimise the energy loss when bending the shaft. Another source of energy loss could be the dissolved gas within the fluid which could be further minimised.

Validation of the HydroFlex Drill on bone phantom material showed clear decrease in efficiency compared to using a direct impact as was the case in the Hammer Tip Shape Validation. These losses in efficiency are attributed partly to leakage of the fluid resulting in small air bubbles in the shaft which can lower the efficiency considerately due their compressibility. Leakage could be limited through minimising play between the moving hammer tip and the tube or by integrating O-rings, however this is likely to increase the friction between the moving parts and as a result the efficiency will decrease. An alternative solution is to use the drill while ensuring the hammer tip is submerged in fluid such that the fluid that leaks during a hammer stroke will be replaced once the drill tip moves back to the initial position.

Another source of efficiency loss is caused by the energy dissipation by the compression spring in the hammer tip. To address this, future research could focus on redesigning the hammer tip to eliminate the need for a spring in the hammer tip, minimise leakage and integrating steering cables in the flexible shaft to allow for steering to control the drilling direction.

In a clinical setting, the HydroFlex Drill is intended to hammer repetitively in order to drill a tunnel through bone. The drilling speed of the HydroFlex Drill can be adapted by changing the generated input impulse as well as the hammer frequency in order to achieve conventional drilling speeds of 6.53 m min^{-1} [17]. A larger input impulse will result in a larger output impulse and thus a higher penetration rate, but this will also limit the control of the surgeon on the path and the drilling depth. Possibly an adaptable input impulse would allow a surgeon to change between faster and slower drilling. The drill speed can also be increased by increasing the hammer frequency, however it is important to ensure that the hydraulic pressure waves do not interact such that the efficiency does not increase.

The current HydroFlex Drill, utilizing a hydraulic pressure wave for bone drilling, exhibits promising initial results and represents a foundational step towards the realization of a steerable bone drill.

5. Conclusion

This study introduces the HydroFlex Drill with a flexible shaft (Ø: 4 mm, length: 40 mm) employing a hydraulic pressure wave for bone drilling. The HydroFlex Drill successfully transmitted impulses through the drill shaft in both straight and curved (45°, 90°) configurations. These findings underscore the potential of a hydraulic pressure wave in facilitating efficient bone drilling with a flexible shaft, marking a first step in the development of a steerable bone drill.

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Conflicts of interest statement

The authors declare no conflicts of interest.

Data availability statement

All data that support the findings of this study are included within the article (and any supplementary files).

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