# Calibrated Drill Sleeve with Auto-Stop Device for Orthopedic Surgery

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*When using drills for internal fixation of fractured bones, the overlying soft tissue often is entangled in the drill bit. To overcome this issue, soft tissue protectors were invented to allow the drill bit to be delivered to the bone without directly contacting the soft tissue. After the drill bit passes through the bone, it has the potential to plunge into the soft tissue on the far side of the bone; this can endanger neurovascular structures. A third issue when using drills for internal fixation of fractured bones is the necessity to measure the depth of the hole drilled to allow for accurate screw length determination. This step takes additional time and can also endanger neurovascular structure on the far side of the bone. Our novel drill sleeve addresses all three of these issues in one device. It surrounds the entire drill bit serving as a standard soft tissue protector and the auto-stop device assists with the other two issues drilling faces. First, it prevents plunging through the far side of the bone, secondly, when the auto-stop device prevents progression of the drill, it allows a calibrated drill sleeve to give accurate hole measurement.*

*Keywords: plunging, auto-measuring, calibrated, dill sleeve, soft tissue*

## 1. Introduction

When a bone is severely fractured, a hard cast is often not enough to keep it in place throughout the healing process. For this reason, plates and screws must be employed to hold the bone in place during healing. To insert these screws in surgery, the surgeon drills into the bone with a surgical hand-held power drill. When drilling, the soft tissue in the incision site often becomes entangled in the drill bit. To overcome this problem, soft tissue protectors, also known as drill sleeves were invented to allow the drill bit to be delivered to the bone without becoming entangled in the surrounding soft tissue (1).

As a surgeon drills through a bone, they must be extremely careful not to plunge through the distal side of the bone into the soft tissue. When a surgeon plunges more than 2mm it causes trauma, excess bleeding, and neurological damage which leads to pain, scar formation, and additional healing times for the patient (2).

Another problem with this procedure is the fact the depth of the drilled hole must be measured after it is drilled. This process is currently done using a depth gauge. The drill bit and soft tissue protector are removed from the hole and the depth gauge's shaft is inserted into the hole in the bone. A small hook on the end of the shaft catches the distal side of the bone. The measuring mechanism is then slid down until it touches the entry point of the bone. The surgeon can then read the depth from the sliding ruler. This process is cumbersome and time consuming for the surgeon and leads to increased surgical times.

Once the depth of the hole has been measured, the surgeon chooses the correct size screw, which comes in 2mm increments. If the screw is too short, it can come loose, allowing the bone to move, resulting in improper healing. If the screw is too long, it could protrude out the distal surface of the bone and interfere with muscles and nerves causing the patient unnecessary pain, longer healing times, and scarring (1).

The objective of this work was to develop an instrument which could serve as a tissue protector, prevent plunging, and give an accurate depth measurement. Our self-measuring drill stop device utilizes a hydraulic stopping device to prevent excess plunging and a calibrated sliding mechanism to give accurate depth measurements. Since the device sits flush on the bone, it also serves as a standard soft tissue protector. If the device is utilized in orthopedic procedures, it will decrease both surgical time and recovery times, saving patients and hospitals millions of dollars each year.

# 2. Materials and Methods

## 2.1 Prototype Device

The original prototype was constructed in a 3-D printer through a layered additive process. The material used was acrylonitrile butadiene styrene (ABS), a ridged plastic that allowed for rapid prototyping. The drill bit is inserted through the hole at the top of the device and a small piece above the bearing comes in contact with the chuck of the drill. This piece is attached to the bearing so it spins when the drill's chuck is spinning, preventing damage to the slider with use over time. The slider is attached to the hydraulic plunger which sits inside the well in the base and is in a fully enclosed double O-ring system that keeps the viscous fluid internal at all times. When in use, the base sits directly on the bone which prevents the drill bit from becoming entangled in the soft tissue in the incision site. Therefore, the device also serves as a standard soft tissue protector (Figure 1). One way Duckbill valves (MiniValve) were also incorporated into the plunger to allow for easy retraction of the slider so the device can be quickly reset.

### 2.1.1 Plunge Reduction

The main concept behind the plunge prevention mechanism is a sliding hydraulic plunger. This plunger slowly slides into a well filled with a viscous fluid (glycerol). With normal drilling, the vertical velocity proceeds very slowly so the plunger moving through the viscous fluid is minimally affected. However, when plunging occurs, the drill bit moves at a higher vertical velocity, causing the slider and the attached plunger to push through the viscous fluid at a rapid pace. The viscous fluid then works to counteract this motion, greatly reducing the plunge depth.

### 2.1.2 Locking Mechanism

A zip-tie locking system was incorporated into the design. This was done so after the surgeon has drilled through the bone and needs to read the depth of the hole, the distance does not change when he lifts the device to read the distance. This works because the locking device allows the slider to travel freely in a downward direction, but prevents the slider from traveling to the starting position without the surgeon first unlocking the device. This means the slider will be locked into the exact place the drill stopped, giving an accurate depth measurement.

### 2.1.3 Measurement Readout

A measuring mechanism was incorporated into the side of the well and the slider. On the side of the slider is a measurement system that includes a viewing window for depth and a traditional ruler marking system was added to the side of the base. The bottom edge of the inward points and the viewing square indicate the depth. This ruler system is calibrated to the drill bit so the exact measurement of the depth can be easily seen on the side of the device without the need for an additional measuring device.

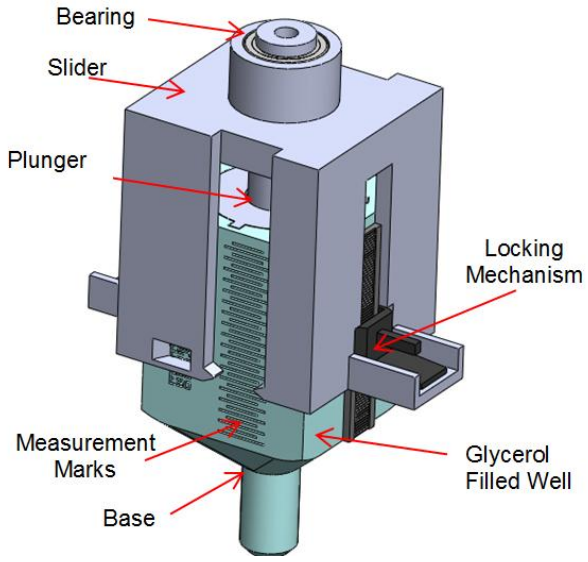


**Figure 1: ABS prototype.** SolidWorks drawing of the self-measuring drill stop device prototype made of ABS. The square design improved the overall strength of the device given the manufacturing process and material allowing for quick prototyping.

## 2.2 Final Device

The final device is made from stainless steel 304. This allows the device to be easily sterilized with an autoclave. It also permits the overall size of the device to be reduced, because the walls can be thinner and still retrain adequate strength. The overall shape of the device was also changed from a square prism to a cylinder due the ease of fabrication. Circular shapes are much easier to make by the use of a lathe and will cut down on manufacturing costs. Additionally, the circular

shape is less of a visual hindrance for the surgeon. Furthermore, the ruler system was revamped so the measurement numbers were in the middle of the ruler marks to help visibility. Finally, stabilizing spikes were added so the device does not spin during operation when bits of the drill grip onto the walls of the drill bit hole (Figure 2).

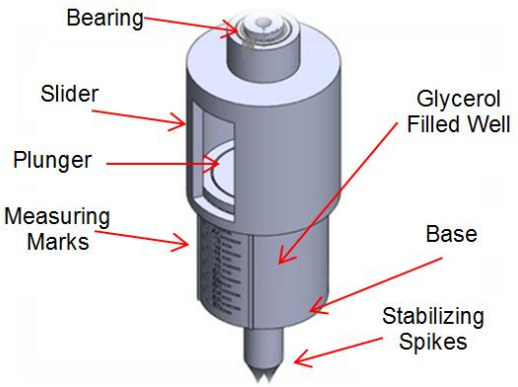


**Figure 2: Steel prototype.** SolidWorks drawing of the self-measuring drill stop device made of stainless steel 304.

### 2.2.1 Ergonomics

The device is designed to decrease visual hindrance during surgery. The stabilizing spikes decrease spinning induced by chuck rotation. The tip of the base ensures that the soft tissue is clear of the drill bit.

### 2.2.2 Manufacturability

The current redesign of the device reflects the best practices of steel manufacturing to reduce the cost of the device.

## 2.3 Testing Protocols

Three separate testing protocols were implemented during testing of the device. Each protocol was constructed to most accurately measure the experimental variable under investigation.

Firstly, an initial test was required to prove the efficacy of the ABS design. Standard honey (~10,000 centipoise) was chosen as the hydraulic fluid (3). The testing setup consisted of an electronic, corded drill fitted with a 1/8" drill bit. A previous iteration of the ABS device was fitted to the drill bit; this setup was tested on an uncooked, bovine bone. The bone was left uncooked to keep the desired densities which would most accurately emulate human trials. As a soft tissue mimic, raw steak was used as a measurement medium behind the bone. A single user was given 10 trials: 5 with and 5 without the device present. Measurement of plunge was conducted by placing a measuring tool into the steak backdrop and measuring depth with digital calipers.

Secondly, a test was required to scientifically select a hydraulic fluid for the chamber of the device. The test included the following fluidal candidates: water (~0.982 centipoise), glycerol (~1400 centipoise), and corn syrup (~2500 centipoise) (4,5,6). This test used the current iteration of the ABS prototype fitted onto the same drill and drill bit as in previous testing. Certain testing changes were made to more accurately account for variability present in prior testing. For instance, practice drilling was performed before any measurements were taken. This was done in hopes of reducing user calibration to the "feel" of plunging which may have skewed results. Also, a rotation of blinded users was implemented for the most accurate results. Each fluid was given 10 trails. Additionally, a higher resolution testing medium was required. The medium chosen for this test was standard diameter computer paper. While this medium certainly does not represent soft tissue, it does give extremely accurate plunge measurements. This test attempts to account for the hydraulic fluid differential, therefore accuracy is the preferential property. For this test, plunge depth was assigned as the number of sheets the drill penetrated (e.g. a trial which punctured 11 sheets of paper is given a score of 11).

Thirdly, a test was conducted to most accurately replicate a surgical setting. Since the hydraulic fluid had been established, the exact plunge reduction of the device in a real testing situation became the metric of interest. To achieve this testing standard, the measurement medium was changed to a gelatin matrix. The matrix was constructed from standard Knox gelatin, derived from animal sources. The material has a density of 0.34g/mL and is clear to allow for a visual of the plunge reduction. Three separate sets of trials were performed: drilling without device, drilling with an empty device, and drilling with the optimal hydraulic fluid loaded into the device. Each of the categories received 10 trials. Standard procedures established earlier were all replicated in this test. The measurements were taken via the prong extension of a digital caliper.

**Table 1:** A table summarizing the testing protocols.

| Test | Drill bit | # Trials | Measurement Medium |
|---|---|---|---|
| #1 | 1/8" | 10 | Raw steak |
| #2 | 1/8" | 30 | Paper |
| #3 | 1/8" | 30 | Gelatin matrix |

## 3.0 Results

The results from each of the testing sessions drove the research and development of the device towards its current, capable iteration.

The initial test for device efficacy included 10 total trials. The average with no assistance is 12.6 mm, and the average plunge with the device is 3.6 mm. These figures show a substantial reduction in plunge after the device had been added to the experimental setup. Moreover, the device trials showed a significantly lower intra-categorical variance (standard deviation = .547 mm) than trials in which no assistance was provided (standard deviation = 2.302 mm) (Figure 3).

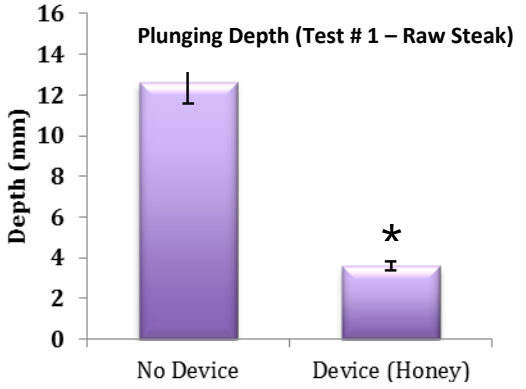


**Figure 3: The results of Test #1.** A significant difference can be seen with introduction of the assistive device (p=.001).

The second test included a total of 30 trials, 10 for each hydraulic fluid candidate. The fluids were assigned depth scores proportional to the number of sheets penetrated and normalized to the highest value. Water produced an average penetrance score of 13.00, glycerol 7.83, and corn syrup 7.00. The device has a notably lower penetrance score when loaded with a viscous fluid. Also, the thicker fluids act to reduce the variation of plunge depth across trials. The standard deviation of the water test is 5.10, while each of the viscous fluids exhibited standard deviations below 4 (glycerol = 3.65, corn syrup = 3.52).

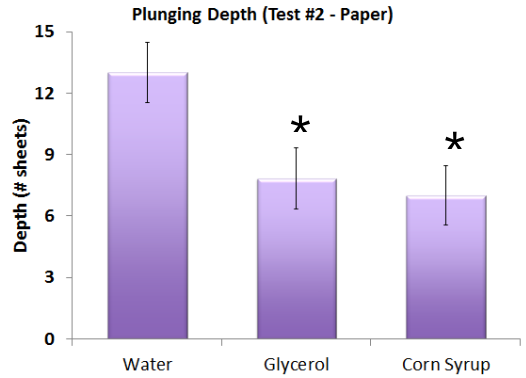


**Figure 4: The results of Test #2.** A significant difference can be seen between the plunge depths of glycerol and water (p = .01) and corn syrup and water (p = .007).

The final test included a total of 30 trials: 10 trails without the device, 10 trials with an empty device, and 10 trials with a device loaded with glycerol. Due to the fact gelatin is a proper imitation of soft tissue, no penetrance scores were assigned for this test. Instead, measurements were given directly in millimeters to convey the pertinence of these results to a proper surgical setting. The average plunge depth is 18.60 mm without the device, 22.50mm with an empty device, and 4.42 mm with a glycerol filled device. Similarly to the previous tests, introduction of the device had a marked decrease in the variance of the trials (no device = 7.10 mm, empty device = 1.70 mm, loaded device = 1.48 mm).

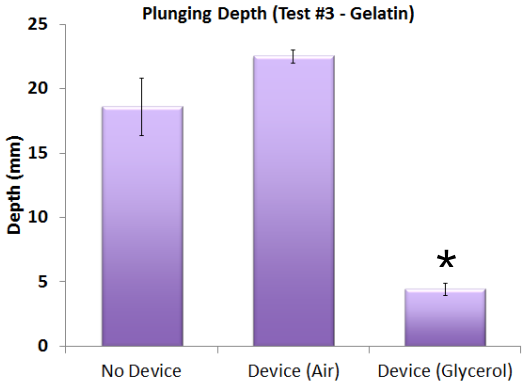


**Figure 5: The results of Test#3.** A significant difference can be seen between the plunge depths of the loaded device and no device ($p = 5 \times 10^{-5}$) and an empty device ($p=1.15 \times 10^{-15}$).

## 4.0 Discussion

The testing shown has driven the design of the device to its current, functional iteration. The testing clearly indicates the ABS prototype worked as predicted with the materials chosen. Test #1 proved the original ABS prototype worked, which provided us with the means to create newer versions of the device with novel features, such as the locking mechanism.

The fluid testing (Test #2) showed the expected impacts of a viscous fluid on the device. Further, it helped define the viscosity range over which this impact occurred. Glycerol (viscosity = 1200 cP) and corn syrup (viscosity = 2500 cP) each displayed a significant reduction in plunge over water. However, the glycerol and corn syrup trials were not significant when compared to each other. This proved that the benefits of adding a viscous liquid to the setup are achieved at a viscosity of more than or equal to 1200 centipoise. For these reasons, glycerol was chosen as the optimal hydraulic fluid, despite being less viscous than the alternative. Glycerol simply showed that it is adequately viscous for the application.

Additionally, glycerol has the added benefit of being a natural metabolite in the human body (7). This will be of use if there are any emergency instances of fluid spillage with the final design.

Test #3 helped characterize the exact reduction in plunging that could be expected after application of the device. Additionally, this testing showed the client's intuition regarding the device obstruction of the plunge "feel" to be correct (8). Namely, the device showed an increase in plunge depth with an empty device over no device at all. This implies that the device, acting as an added layer between the surgeon and the bone, disrupts some of the feel necessary to know when the bone is about to give way. However, this finding in no way hampers the efficacy of the device. When the device is used as intended (with glycerol), the plunge depth reduces to optimal levels. Therefore, the effect of the device is to prevent the user's ability to perceive imminent plunge, not the user's ability to detect if plunge has already occurred. The added hydraulic fluid causes such a drastic drop in the velocity of the drill post-plunge, it can be considered an indispensable tool for minimizing soft tissue damage.

## 5.0 Conclusion

The self-measuring drill stop device described above reduces plunging depth by over four fold when tested by amateurs. Trained professionals will most likely see similar results, although further testing is needed to conclude this. Through fluid characterization, an optimal, bio-inert, viscous fluid (glycerol) was selected for the final design and the locking mechanism of the devices guarantees an accurate hole measurement within 0.5 mm. Once the stainless steel prototype is constructed further testing will be conducted to determine the plunging depth of orthopedic surgeons and compare the measuring mechanism to the status quo of the depth gauge in both accuracy and timing. Safety concerning the closed-system of the hydraulic fluid along with autoclavability of the hydraulic fluid will also be addressed in the future when the final prototype is constructed.

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