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K-wire Differentiation

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By

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ABSTRACT

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Kirschner Pins, known as K-wires, are smooth sharp stainless steel pins used in the field of orthopedics to stabilize bone fracture fragments in their correct position until they have fully healed. K-wires are most commonly used for comminuted metaphyseal fractures of the long bones, and fractures of smaller bones such as the phalanges. The wires are inserted into bone via a drill and the ends of the wire are bent and left outside of the body for easy removal once the bone has healed. The surgeon uses x-ray images to guide K-wire insertion, ensure proper internal alignment, and determine if any adjustments need to be made. The identical and 2D appearance of the K-wires on x-ray images presents orthopedic surgeons with a challenge of identifying, within the surgical site, the correct K-wires to adjust during surgery. This leads to unnecessary radiation exposure for the patient and longer procedures. We are designing a K-wire attachment to be used by the surgeon that gives each K-wire a unique appearance on the x-ray so that each wire can be identified from different imaging angles. Overall, our device will decrease the number of x-rays that need to be taken during surgery, thereby increasing the safety and efficiency of bone reconstruction surgeries. By creating a temporary attachment to be applied by the surgeon, both the number of x-rays and amount of time in surgery will be decreased.

Background

The field of orthopedic surgery is concerned with the restoration of form and function to the bones of the extremities and the spine [1]. A common injury orthopedic surgeons treat is fractures, as there are about 2 million of them in the United States every year. Furthermore, it's estimated that an individual in a developing country will experience at least two fractures within their lifetime [2].

There are many types of fractures, each classified based on the alignment of the fractured bone, how many pieces the bone breaks into, and whether the bone punctures the skin or not. The main categories of fractures are displaced, non-displaced, open, and closed [3]. Within the category of displaced fractures, we find comminuted fractures, which are when the bone breaks into multiple fragments. These fractures, seen in Figure 1, result from high-velocity impact injuries such as car accidents, explosive devices, or falls from a height [4].

Fig 1. Comminuted fracture of the elbow joint [5]

Unlike simple fractures that can heal either through immobilization or stabilization through a cast or sling, comminuted fractures- because they are multi-fragmented, often need to

be repaired through surgery. Depending on the location and number of pieces the bone breaks into, a combination of K-wires, pins, screws and plates may be used to repair the affected bone and stabilize it for proper healing. There are two types of surgical procedures used to fix comminuted fractures: open reduction internal fixations (ORIF) and open reduction external fixations (OREF). In reference to our capstone project, we will focus on ORIF’s, while specifically focusing on the hip as our case study for prototyping and testing. An open reduction fracture fix is when an incision needs to be made to access the bone, while the term “internal fixation” refers back to the surgical tools used within the patient's body to keep the bone in place [6].

Depending on the size of the bone fragments, and location of the fracture, Kirschner wires (K-wires) are often used for ORIF procedures [6]. The number of K-wires used for a procedure is dependent on the severity of the fracture and with more severe fractures requiring more K-wires. In procedures, it is important for the internal alignment of the K-wires within the body to be accurate, as misalignment of a K-wire can cause misalignment of the fracture fragments, resulting in improper bone healing. Furthermore, if a wire is accidently placed through a nerve or blood vessel, it could lead to paralysis or even death [7]. In order to avoid the consequences of improper K-wire placement, during and after surgery, x-ray images are taken of the surgical site, allowing the surgeon to see the internal alignment of the fracture. The x-ray, a 2D image, may reveal that an adjustment of a K-wire needs to be made; however, due to the 3D surgical view and the identical appearance of the K-wires on the x-ray image, it is difficult to determine which wire needs to be adjusted.

From speaking to multiple orthopedic surgeons and reading the account of a student who observed this issue in an operating room, we learned that different surgeons have individual methods of identifying K-wires on x-ray images. However, if the surgeon cannot determine which K-wire needs to be adjusted, they will move a wire, take an x-ray and look for the adjusted placement on the image. This trial and error with moving wires and taking x-rays is repeated until the surgeon is satisfied with the placement of all the wires. The trial and error of these procedures is costly because every minute spent in the operating room (O.R.) taking x-ray images, and exposing the patient and O.R. staff to excess radiation is costly- around $36, and potentially dangerous [8]. Our aim is to develop a product to increase the safety and efficiency of these procedures.

Current/Existing Technology

As mentioned earlier, orthopedic surgeons rely on informal methods to differentiate K-wires on x-rays. For instance, Dr. Silfa, a pediatric surgeon at the Military Hospital Dr. Ramón De Lara in the Dominican Republic, cuts K-wires to different lengths during elbow fracture open reduction and internal fixation (ORIF) procedures. Despite the success of this method, keeping track of the length of each K-wire can be challenging when the K-wires are constantly cut throughout the surgical procedure to prevent obstruction of the surgical site and manipulate or place other K-wires.

To innovate around this problem, we referred to prior technology that, despite not addressing K-wire differentiation on x-ray images, proposed innovative solutions that we could adapt to our application. The first device we looked at was Cook Medical's CXI Support Catheter [9]. Surrounded by a sheath of stainless steel, this catheter has platinum-iridium

radiopaque markers attached to it [Figure 2]. It is these markers that we focused on, as various markers could allow for the K-wire differentiation under x-ray imaging. However, a drawback of this design is that the markers are prone to dislodgement. In 2019, Cook Medical recalled its CrossCath due to a manufacturing error that caused some of its radiopaque markers to become loose, while others were too tight on the catheter, causing buckling [10]. The recall of this device later led us to include proper fixation of the marker or attachment on the K-wire as one of our functional requirements.

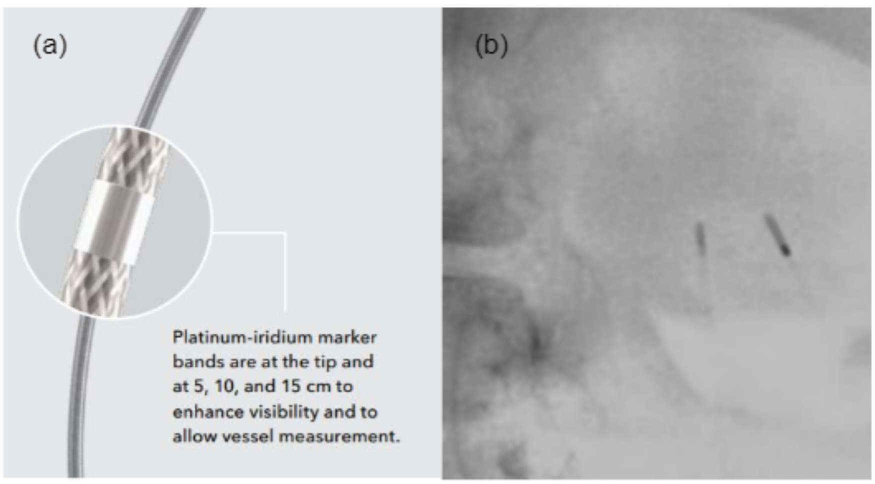


Fig 2. Section of Cook Medical's CXI Support Catheter [9]. (a) Shows the platinum-iridium markers placed on the stainless steel-covered catheter. (b) The markers appear as a black point under fluoroscopy.

As we searched for materials that we could use for the attachment, we came across Kayiran and Kara's article titled "What to do for the exposed end of a K-wire?," where they presented various methods to cover the distal or free end of the K-wire and protect the patient from injury. The researchers followed a group of 36 patients aged between 3 and 75 many of whom suffered from a finger fracture [11]. In each patient case, the free end of the K-wire was covered using one or more of the following methods: bending, taping, using blood sampling tube caps [Figure 2], butterfly needles, needle hubs, and rubber gaskets.

Fig 3. Two K-wires were placed to fix the bone segments in the third metacarpal. Note that the free ends of the inferior K-wire were bent, while the free end of the superior K-wire was secured using a blood sampling tube cap [11].

In the second postoperative week, patients completed a questionnaire on the aesthetics of the method(s) used and assigned a comfort score to each. While the preferred method was taping, this article showed that we could use tools available in the O.R. to identify the K-wire and differentiate it from others, rather than cover the distal end of the K-wire to protect the patient from injury.

When considering tools in the O.R., we must be aware of the constraints that surgeons have during surgery, one of them being space availability. Throughout our prototyping process, we learned that K-wires themselves often obstruct the surgeon's line of sight during surgery, therefore, we began looking for ways that we could avoid exacerbating this problem by introducing an attachment. Through a patent search, we found a patent that addressed the problem of the K-wires obstructing the site of surgery by introducing a multi-component K-wire. As shown in Figure 4, this multi-component K-wire consists of a first K-wire component with a sharpened tip and an end that is "pivotally connected" to a second K-wire component via a pivot pin. In this case, the surgical tool includes a sleeve (130) that slides over the pin connecting the

two K-wire components to prevent pivoting of the two-wire components (110 and 120) when it is not desired [12].

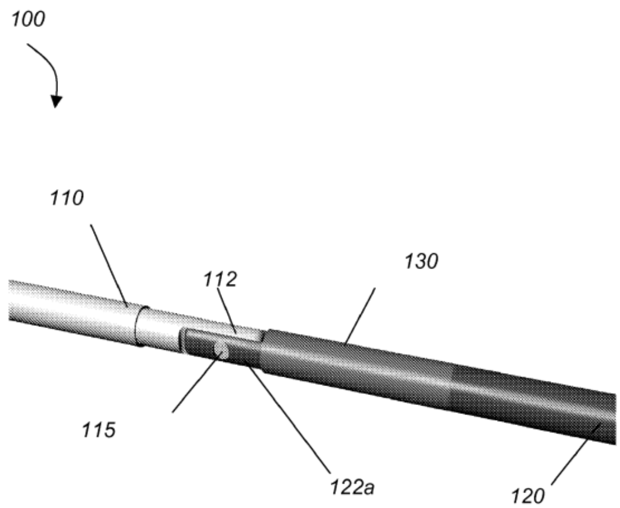


Fig 4. Perspective view of the multi-component K-wire (100). The first wire component (110) is connected to the second component (120) via a pivot pin (115) that goes through a hole in the end protrusion of the second component (122a). A sleeve (130) can be slid on the pivot pin to prevent pivoting of the two components [12].

During surgery, the multi-component K-wire (100) is inserted into the bone fragment with a pin-gun or high-speed drill. The K-wire can be removed from the line of sight by sliding a sleeve slid away from the pivoting area, such that the K-wire component (110) pivots away from the other wire component (120). Other locking mechanisms different from the pivot pin, such as a colet and a ring are also discussed in the patent. In the case of the colet, shown in Figure 5, the end of the second K-wire component is a sphere that engages with the collet (140) at the end of the first component (110).

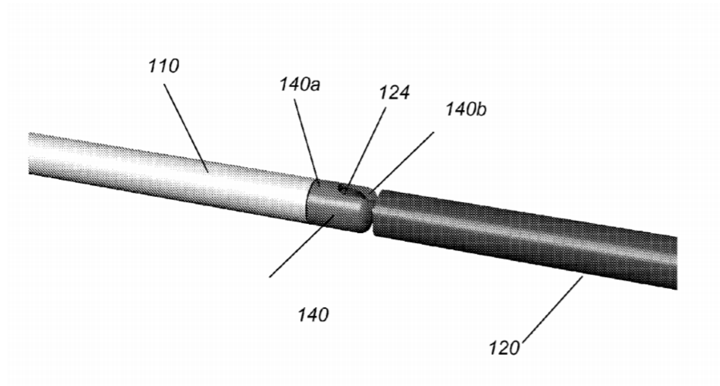


Fig 5. Multi-component K-wire with colet locking mechanism [12]. The first wire component (110) is pivotally connected to the second component (120) via a collet (140). The spherical end of the second component (124) inserts in the slot (140b) at the tubular end of the collet of the first component (140a).

The last locking mechanism is very similar to the previous one but the sphere (126) engages with a spherical groove formed within the second end of the first K-wire and the retention ring (150) prevents disengagement of the first and second K-wire components [Figure 6].

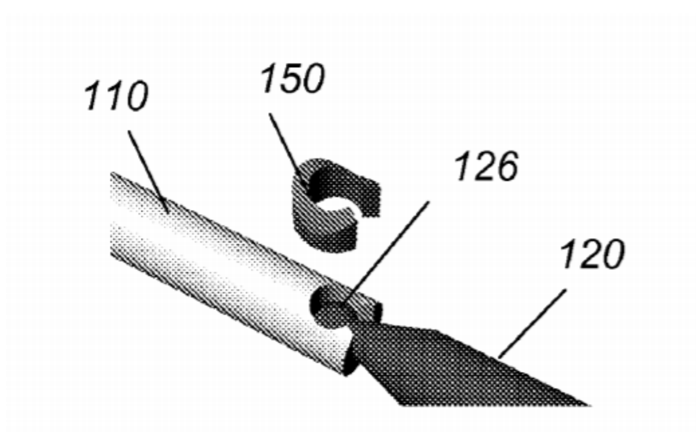


Fig 6. Multicomponent K-wire with ring locking mechanism [12]. The first wire component (100) connects to the second component (120) via a pivot sphere (126) at the end of the second component that fits in a slot at the end of the first component, where the connection is secured by a retention ring (150).

Problem statement

During bone reconstruction surgeries, the orthopedic surgeon uses x-ray imaging to guide K-wire insertion and ensure proper internal alignment of K-wires in the affected bone. However, the identical and 2D appearance of the K-wires on x-ray images presents surgeons with the challenge of identifying the correct K-wires to adjust, leading to more x-ray images, which lengthen the surgical procedure and expose the patient to unnecessary radiation. We are designing a K-wire attachment that gives each K-wire a unique appearance on the x-ray image, and increases the safety and efficiency of bone reconstruction surgeries.

Device - Customer Requirements

Prior to brainstorming concepts to solve this problem statement, we familiarize ourselves with researching ORIF procedures through academic studies and videos. Then, we spoke to our potential customer, Dr. Mulligan, an orthopedic surgeon at Albany Medical Center (AMC). From our conversation with Dr. Mulligan, we refined and finalized our customer requirements, shown in Table 1, and their corresponding customer importance ratings in addition to the section of the Quality Function Deployment (QFD) seen in Table 2 [A-1].

Table 1. The final customer requirements with corresponding customer importance. 10 indicates the most important while 1 represents the least important.

Customer Importance	Customers - orthopedic surgeons
10	Compatible with K-wires of different diameter (6-7.3 mm)
10	Option to vary shape
8	Little deflection of K-wire when attaching/ detaching
6	Easy to remove
5	Able to be sterilized
4	Straightforward to use
3	Not bulky: take up minimal space in field of view
2	Affordable

Device Functions

Our goal is to design a set of K-wire attachments that will be temporarily placed on the distal end of the K-wire, outside the patient's body, during surgery to help orthopedic surgeons with K-wire differentiation. The main function of our device is that it attaches onto K-wire outside a patient's body and also detaches from K-wire after the use of differentiating K-wires. We broke down the main function into the flow of information, material, and energy in and out of the device. This flowchart of the main function can be found in Figure 7 [A-2]. We further divided the main function into various sub-functions as shown in the function tree in Figure 8 [A-2].

To point out the most important sub-functions of the device, we considered "fixation," "force," and "differentiation" for the main three sub-functions of K-wire attachments. Fixation is needed for attaching the attachment to the K-wire firmly. This fixation prevents the attachment from sliding into the patient's body or off of the K-wire onto the operating room

floor. Moreover, the K-wire attachment should be compatible with various diameters and types of K-wires such as threaded, trocar, smooth, etc.

The second sub-function of our device relates to force, specifically, the amount of force the device enacts on the K-wire. When attaching and detaching the device to the K-wires during and after the surgery, force is applied. If a large force is applied when attaching the attachment to the K-wire portion outside the patient's body, this may lead the internal portion of the K-wire to move and affect adjacent nerves since the nerve system can be influenced by K-wire insertion [7, 13]. Consequently, we reflected on this information and determined a function of the device to be that a minimum force should be necessary to secure the attachment in order to maintain the alignment of the K-wire.

The ultimate goal of designing K-wire attachment is to help with differentiating K-wires on x-ray images, which is crucial to distinguish each K-wire from other K-wires. We reviewed various metals based on their densities. Regarding the uncertainty and unavailability of getting access to an x-ray machine to test metal densities, we considered varying shapes of attachments because different shapes of the attachments would appear differently on x-ray images in the anterior, posterior, oblique, and top views. While we considered various shapes, we also ensured that the attachment was small enough to prevent obstruction of the line of sight during surgery.

Design Specifications

According to the QFD in Table 1 [A-1], the top four design requirements are "compatible with different K-wire diameters," "minimal force maintains the alignment of K-

wire," "quick removal of a device from K-wire," and "attachment showing uniquely on x-ray." These requirements are hard to identify concrete and measurable criteria for risk assessments and prototypes because there is no competitive design to compare specifications to on the market. However, based on our background research and conversations with Dr. Mulligan, we hypothesize design specifications.

For the first requirement, "K-wire attachment should be compatible with various K-wire diameters," we specify it as "compatible with various K-wire diameters within 6 to 7 mm." Those are the range of K-wire diameters used in hip fixation procedures [14]. For the second and third requirements, "minimal force to maintain the internal alignment of K-wire," and "quick removal of a device from K-wire," we established the minimum numerical values; the force applied on the K-wire is less than 4.45 N with less than 45 seconds for removal time. Further numerical values of attachment and detachment time and force applied on K-wire to prevent changing the internal alignment of K-wire were calculated during prototyping and testing.

The last requirement is "attachment showing uniquely on x-ray." A word "unique" is not easy to define in terms of measurable numeric values. However, since this is the main design purpose of our device, we would use different metal materials and/or different shapes of the attachment to make it "unique" on x-ray images. Accordingly, we would vary dimensions (height and width) or sphere (inner and outer) diameters. For instance, the inner diameter that fits in the 6-7 mm diameter of K-wire would adjust to less than 7.5 mm and the outer diameter would be less than 20 mm. Moreover, we would observe and test our attachment in different angles, such as anterior, posterior, oblique and top planes, if it

appears "uniquely." Despite no numeric values to be concrete and measurable for the test, these help with a clear distinction between various K-wires, which is the central element of the design.

Documentation of the final design

The device design we are proposing consists of a set of three washers shapes, and bone wax, which together form a Kwasher. This device is designed to be applied after K-wires are inserted to the patient, and before x-rays are taken. The surgeon will insert the K-wire, apply the bone wax around the insertion site, and slide the washers onto the wire. The surgeon will then take the necessary x-rays, and compare the x-ray images to the wires outside the patient. With the addition of the washers, it will be clear which (if any) wires need to be moved. If a K-wire needs to be adjusted, the washer can be slid off, the bone wax removed and the wire can be adjusted. The surgeon can then reapply the bone wax and washer as they had initially. This process will be repeated until the surgeon is satisfied with the location of all the wires. A model of a Kwasher on a K-wire is shown below in Figure 9.

Our design consists of three washers with unique designs and thicknesses to provide the maximum amount of differentiation from various angles. In speaking with Dr. Mulligan, we learned that surgeons may insert two or three wires at a time, adjust the newly inserted wires until they are satisfied and then continue to add wires in sets of two or three [14]. Additionally, given the x-rays of hip-fixations that we have seen, it is unlikely there are more than four wires in a similar angle and location. By choosing to make three different shapes, the surgeon can differentiate between four wires (one with no attachment), without crowding the x-ray, nor purchasing excess attachments.

Once the surgeon is satisfied with the location of the wires seen in the x-ray image, they can choose to remove the attachment, or cut off the excess wire with the Kwashers, and discard the Kwashers. Due to their small size, we intend for this to be a low cost, single use device.

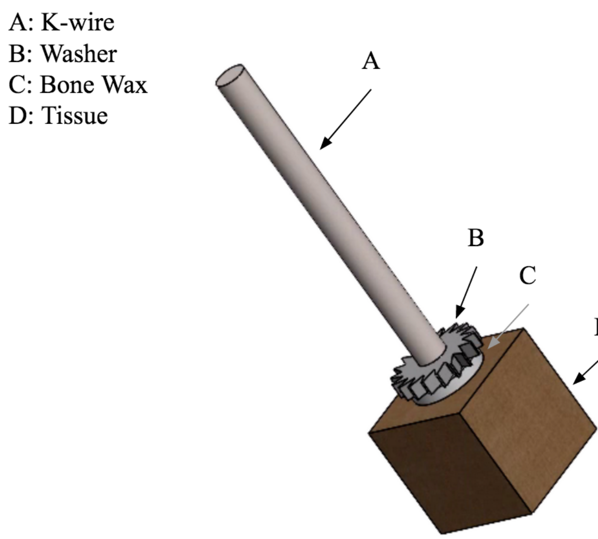
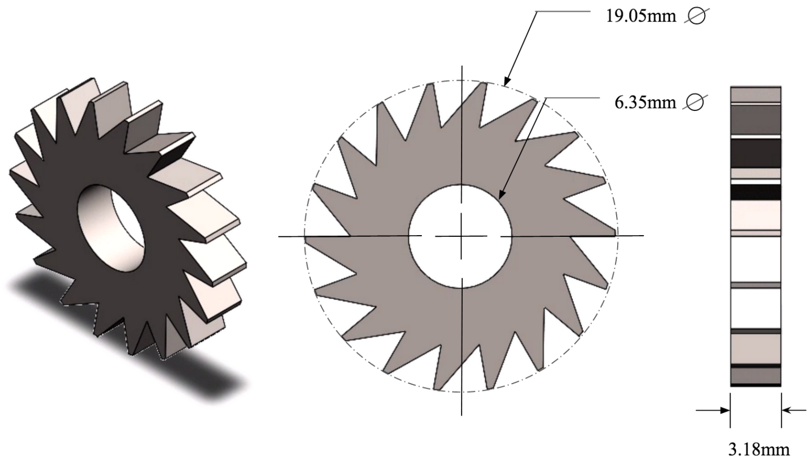


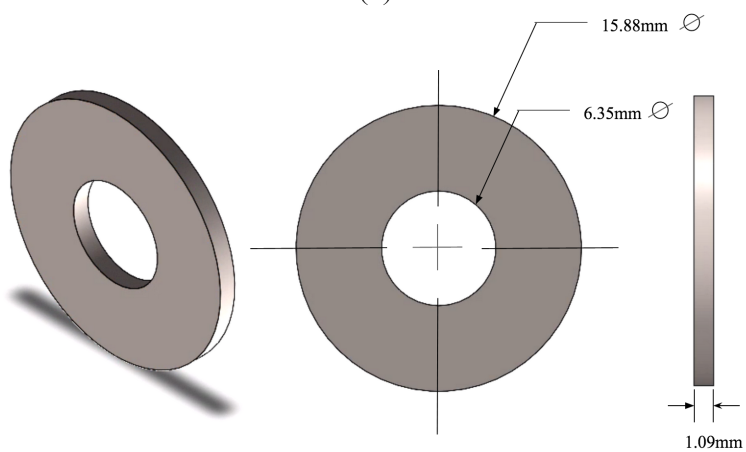
Fig 9. A model of the washers and sample bone wax can be seen on the K-wire against the patient's skin.

Washer Shapes

The differentiation in our design comes from the various washers we have made. The three washers we have chosen are a round flat washer, a gear, and a square washer. We choose these designs as they vary in shape in all directions, and allow the surgeon to quickly tell by touch which one they are holding. They also vary in height, allowing for differentiation from an anterior or posterior view. We wanted the design to be as simple and intuitive as possible to prevent any additional time in application of the attachment. When viewing the attachment from various angles. The same washers can be seen from various angles below in Figure 10.



(a)



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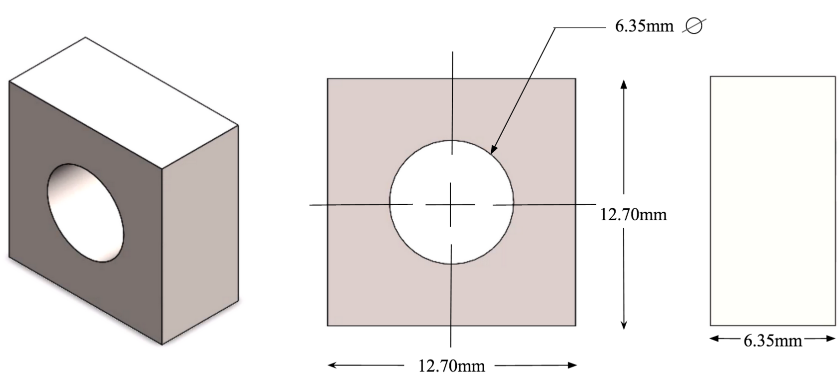

(c)

Fig 10. Three washer models, (a) the gear, with a manufacturer's drawing shown in Figure 11 [B-1] (b), flat washer, (c) square washer from isometric, front and right views. A set of washers such as these all have the same inner diameter for the same sizes of K-wires.

In addition to the horizontal morphology differences, we also varied the vertical morphology, or the height of the washers. These height differences add differentiation to additional angles of x-rays. This differentiation is important as without different heights, all of the washers would look nearly identical under an x-ray. We choose to keep the heights relatively small to decrease the likelihood of crowding on the x-ray image. The square washer is the tallest and measures 6.35mm in height, followed by the gear with a 3.175mm depth, adn finally the flat washer in the thinnest with a 1.092mm thickness. As shown in the images, these differences are visible, but are not large enough that the wires are obstructed.

Bone Wax

The bone wax is applied to the K-wire to prevent the washers from sliding into the patient's incision site, or off the wire and onto the floor. During discussions with Dr. Mulligan suggested using bone wax as our stopper as it is already present in the surgery suite [14]. Bone wax is a material used during surgery to stop bleeding from a bone [15]. The material is made primarily out of beeswax and is applied directly to the bone [15]. This material is sterile [16], and thus is compatible with surgery. Bone wax is our stopper of choice due to its sterilization ability and the surgeons are already familiar with the material, thus this was an ideal material for the function of keeping the washers on the wire.

Final Prototype

The final prototype of the Kwasher device is shown below in Figure 11. Shown in this image are the three washers in use, with the "bone wax" below them. In our models, we simulated bone wax with silicone due to material availability. The silicone was tacky, and the

washers adhered to the silicone, staying on the wire with silicone below the washer. This will have to be experimented with when using bone wax as the material properties may be different and additional bone wax above the washer may be needed to prevent sliding off the wire.

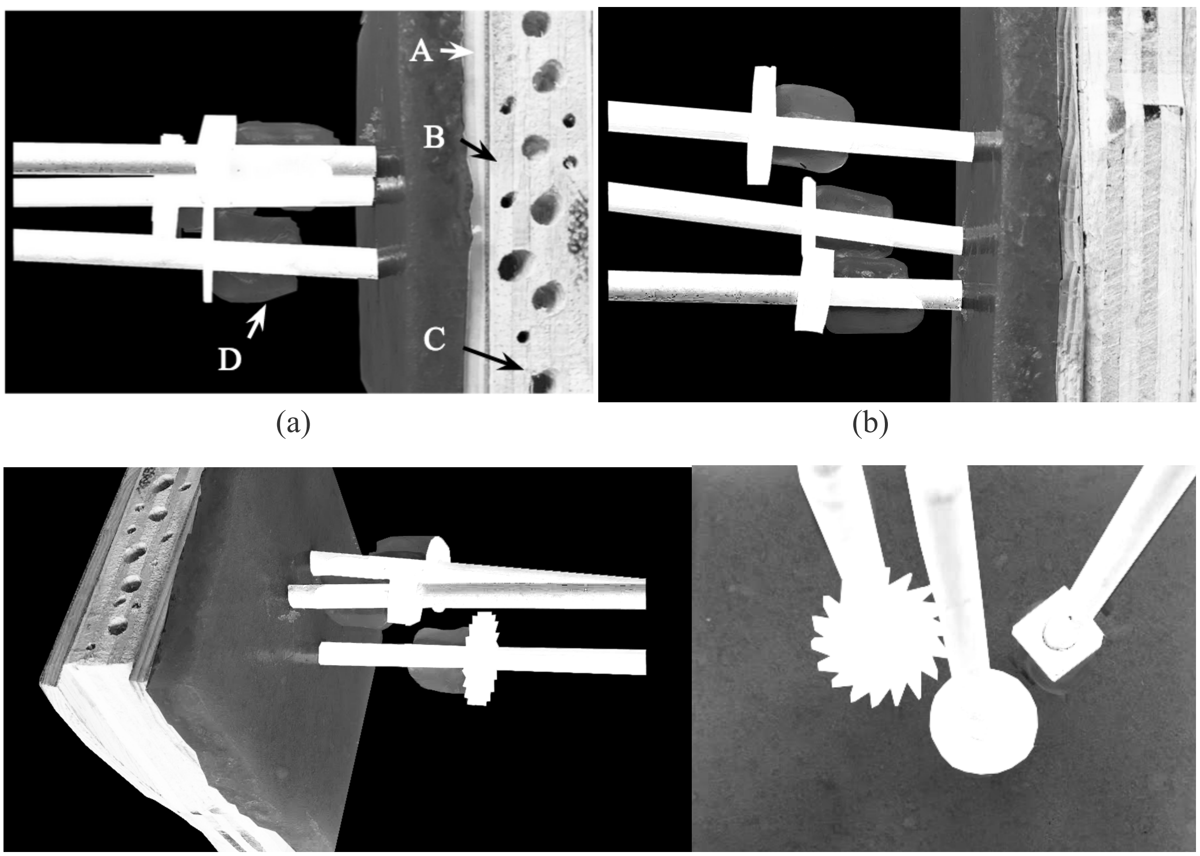

Fig 12. (a) Anterior, (b) posterior, (c) oblique, and (d) top view of Kwashers on K-wire. Wood represents bone, and the gelatin layer represents the skin layer.

When comparing the posterior and anterior views, it is evident that variance in height is needed, as this property is the primary differentiation present in these angles. This view demonstrates the right views shown above in the SolidWorks model in Figure 10.

Materials - Tissue Phantom

In order to create our prototype we modeled to the best of our ability a cross section of bone and skin where the wire is inserted. To best mimic the bone, we chose wood due to its similarity in stiffness to bone, as studied by [17]. A stiffer wood was used to represent the outer layer of bone (A), with a softer wood to represent spongy bone (B). To show the presence of spongy bone, small divots (C) were drilled into the wood. To best mimic the mechanical properties of human tissue a solution of gelatin and water (B) was mixed and then placed on top of the modeled bone to complete the phantom.

Materials - Stopper

In our prototype we used silicone earplugs due to their cost effectiveness and ease of availability, shown as (D) in Figure 12a. In surgical use this material would be bone wax, as it is able to be sterilized, and already present in the surgical suite.

Materials- Washers

For our washers, we utilized 3D printing, specifically Polylactic Acid, due to its low cost. If this device were to be used as intended, the washers would be made from implant grade stainless steel or of a material with a higher density. The scope of our project remained in the prototyping phase, thus it was not necessary for us to utilize steel for our testing. Additionally, we did not have access to an x-ray machine, thus 3D printing was sufficient for our testing. In order to best mimic how the Kwasher would show on x-ray images, the images were edited to the best approximation of an x-ray image.

Design Validation

The validation of our device was heavily dependent on the functional decomposition flowcharts in Figure 7 and 8 [A-2] and customer requirements [Table 1] we had predetermined and adjusted throughout our design process. The final Kwasher prototype allowed us to test multiple elements of our device, such as time it takes to attach and detach the device, the mechanical effects of adding the washers to the wires, and differentiability of the device.

To validate that the device was quick to attach and detach, we set a specification that the attachment and detachment process should individually take less than 45 seconds. Six time trials of the prototype were conducted during which one person representing the orthopedic surgeon attached and detached all three washers from the K-wires. Each individual trial time can be seen below in Table 3, and the average time to attach the washers was 38.55 seconds and to detach 36.26 seconds. It is important to consider these time values relative to the time it takes to obtain an x-ray image. According to an article written by the Fraunhofer Institute in Berlin, Germany, it takes about 15 minutes to position a C-arm x-ray machine, take images, and for them to develop [18]. Therefore it is imperative that the usage of our device does not add ample time to the normal procedure time.

Table 3: Kwasher attachment and detachment time trials

Trial	Time for attachment (sec)	Time for detachment (sec)
1	43.07	38.30
2	41.41	38.07
3	34.47	37.80
4	35.52	36.63

5	34.96	28.63
6	41.91	38.18
Average	**38.55**	**36.26**

A concern that we had about our device was that the force to attach the Kwasher could potentially cause the K-wire to lose internal fixation. In order to understand the force that the washers would enact on the K-wires, we measured the mass of each washer and silicone stoppers and converted that to the force values shown in Table 4. The force that each Kwasher would be enacting on each K-wire, would be 0.0393N using the Equation (1)

$$F = m * g \tag{1}$$

This force lies within our outlined specification that the force of attachment and detachment should be less than 4.45 N. In conjunction with the force of washer attachment, we also considered whether the attachment process caused any deflection to the position of the K-wire. We determined because of the low force of the kwasher on the K-wire, The wires would retain their fixation.

Table 4: Mass of each part of Kwasher design

Part	Mass (kg)
Gear Washer	0.001
Flat Washer	0.001
Square Washer	0.001

Silicone Stopper	0.003

The main validation of our device surrounded the main function of differentiability. Did the addition of our device allow for each K wire to be differentiated on an X-ray image? By taking pictures in the same anatomic view that an x-ray machine in the operating room would, and through photoshop, we were able to simulate an x-ray image and visualize how our attachments would appear if we were able to further manufacture and test them. In Figure 12, and number you can see the anterior/posterior plane view (a, b), the oblique view (c), the medial/lateral planes (d) respectively. From each of these views each washer appears differently thereby bestowing a unique appearance to each K-wire.

Ethical Considerations

Throughout the design process of this device, we evaluated several risks and ethical considerations for the end-user, the patient. Our device is designed to be paired with each individual K-wire, and eliminate the need for additional x-ray images of the patient to be taken. Patient exposure to radiation in the medical field has been and continues to be a point of ethical dilemma because although radiation from medical imaging may provide significant benefit to many patients, it may also confer a slight increase in the risk of a patient developing cancer [19]. By making it easier for surgeons to distinguish between K-wires on an x-ray image the need for multiple x-rays to be taken in order to ensure correct K-wire internal alignment is reduced. This device improves patient care and considers the ethics of medical imaging by reducing radiation exposure.

Although the Kwasher design is intuitive, with the action of sliding the washers onto the wire, there is a low risk for misuse, in the future stages of this design, an instruction manual would be included in the packaging in order to properly demonstrate how this device is meant to be used and the associated risks that accompany the use of the device. In addition, proper packaging to ensure sterility and proper labeling will be included in the manufacturing of this product.

The primary concern of our original design was the washers slipping into the patient’s incision at the site where the wire enters the patient’s body. Initially, we proposed using a malleable silicone to prevent the washers from sliding into the patient's body; however, after conversations with Dr. Mulligan and consideration of patient safety, we decided that in future iterations of the design, bone wax would be a better material in order to avoid the need to determine how the silicone would be sterilized. Furthermore, bone wax is a material already present in operating rooms therefore the surgical staff is familiar with its use and risks. Overall, there are no concerns of long term impact on the patient, because this device is not remaining with the patient once the surgery is completed. By not redesigning the K-wire itself, we considered the ethics of not needing to test if an alternate K-wire material would affect bone fixation or bone healing.

Anticipated Regulatory Pathways

After reviewing the definition of medical devices, we determined our attachment is classified as a medical device. Specifically, section two of 201(h) of the Food, Drug and Cosmetic act: “intended for use in the diagnosis of disease or other conditions, or in the cure,

mitigation, treatment, or prevention of disease, in man or other animals [20].” Our device is used in the treatment of fractures, during the stabilization process.

Analysis of Relevant Approved Device

Through extensive research throughout our background investigation and design brainstorming, we have not come across another attachment designed for K-wire differentiation. Thus, when looking for existing comparisons, we have chosen to examine the CXI support catheter with a radiopaque marker. The applicant was Cook Incorporated, 750 Daniels way, Bloomington, IN 47404 and the 510(k) number is K160884 with classification product code KRA. The FDA regulation number is 870.1210 and the review panel being “cardiovascular”, the catheter identification is as follows:

> “A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping [21].”

This device is a class II medical device, and its predicate is the CXI™ Support Catheter (K072724). The FDA documentation claims that because the predicate device (K072724) and the new device (K160884) are identical in intended use, technological characteristics, construction and operation, that the new support catheter is succinctly equivalent and only required 510(k) approval. The CXI support catheter is intended to be used, “in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use [22].” To ensure that the device met “applicable design and performance requirements and support a determination of substantial equivalence,” they conducted (unspecified) animal testing and it showed that the devices were

adequate or better than their predicates in terms of the following performance parameters: preparation, introduction, pushability, trackability, flexibility, torquability, withdrawal, and inspection after use [22].

Overall, there are several differences between our capstone project and the FDA cleared support catheter. Our device is not similar to the catheter in intended use, construction or operation. However, it is arguable that the Kwashers are similar to the CXI support catheter in technological characteristics. Documentation of the device from Cook Medical's website notes that the catheter has platinum iridium radiopaque markers [23]. To appear on the x-ray image, the Kwashers will also be constructed using a radiopaque material. In addition another similarity between the two devices is that the radiopaque markers on the catheter and the Kwasher are both attached to a device and should stay in place during the procedure. Because our device is not substantially equivalent to a predicate device we would need to go through clinical trials and the premarket approval process

Conclusions & Future Work

Initially, our Kwasher prototype was inaccurate. It included no representation of the surgical site and the dimensions of the washers and K-wires were too large. Similar to the current Kwasher design, our first prototype consisted of washers that were placed on the K-wires but instead of one washer per K-wire with a silicone earplug to keep the washer in place, three washers were placed on each K-wire.

As we transitioned to our second prototype, we decided to pursue a Kwasher design consisting of three shapes: a gear, a flat washer, and a saddle washer, all of which were fixed

on the K-wire using silicone earplugs as with the current prototype. However, two of the shapes we had 3D printed; the saddle washer and the flat washer, looked identical in the anterior view. Similarly, in the posterior view, the concave shape of the saddle washer was not readily visible and the saddle washer and the flat washer looked similar. To address this similarity, we substituted the saddle washer with a square washer of a height greater than both the gear and the flat washer. As we showed, this design proved to be differentiable in all the planes that x-ray images are taken during hip fixation surgeries.

Despite our success with the Kwasher, after speaking with Prof. Cortez, the Director of Engineering at Union College, we began considering using metal tape to differentiate the K-wires. The tape, shown in Figure 13, prevents obstruction of the line of sight and allows easy manipulation of the K-wires. The tape has two components: a radiolucent base that adheres to the K-wire and strands of a metal tape of higher density than stainless steel laid above it, in the patterns shown. In the future, this concept will be validated using the same tests that we used for the Kwasher.

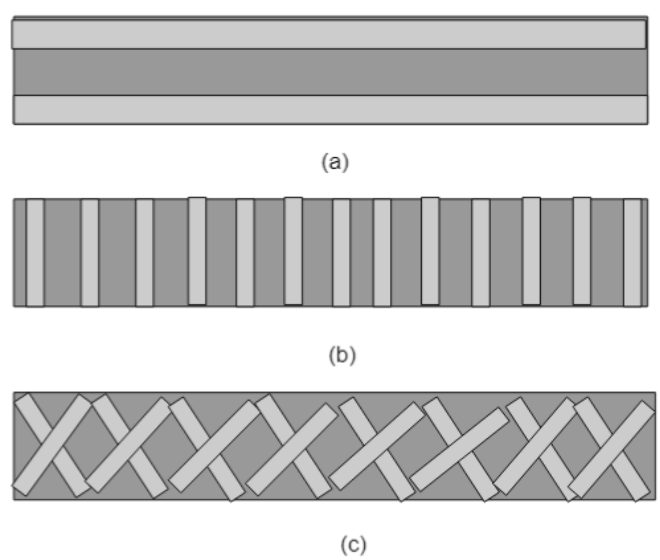

Fig 13. Sketch of the tape prototype. The radiolucent base that adheres to the K-wires is shown in the darker shade or gray, while the patterns on each design are in a lighter shade of gray. The following three patterns are shown: (a) horizontal stripes, (b) vertical stripes, (c) X's.

Overall, our Kwasher design is successful in adding differentiation to K-wires. Further development of the Kwasher would include utilizing the materials suggested in the design documentation and subjecting the design to an x-ray imaging test.

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Appendix A

Table 2: Overall Quality Function Deployment (QFD) table. This shows the strong (●), medium (○), weak (▽) or no relationships between the customer requirements and functional requirements. On the top roof, it also demonstrated positive (+), negative (-) or no correlation between functional requirements. Gray-colored boxes on the roof are showing the relationship between the same functional requirements and thus it is not important to consider the relationships. Based on the importance rating sums and relative weights, we ranked the priorities of our product.

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
(1) Compatible with various K-wire diameters								+
(2) Competitive cost with current products								
(3) Attachment shows uniquely on x-ray								
(4) Quick removal of device from K-wire						+		
(5) Reusable and durable					+			
(6) Minimal force to maintains the internal alignment of K-wire				+		+		
(7) Storage takes up minimal space		+					+	
(8) compatible with drilling process								+

	Customer Importance and Requirements	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
10	Compatible with different K-wire diameters (6 - 7.3 mm)	●	▽		●		●	○	▽
10	Option to vary shape	○	▽	●	○			○	▽
8	Little movement of K-wire when attaching/ detaching	○	▽	●	○			○	▽
6	Easy to remove	●		●	▽		●		
5	Able to be sterilized	○		●	●	○	●		○
4	Straightforward to use	●			○		●	○	●
3	Not bulky: take up minimal space in field of view				▽	●			
2	Affordable	○		▽	●		▽		
	Importance Rating Sum	222	38	229	223	72	220	87	38
	Relative Weight	19.7 %	3.4 %	20.3 %	19.8 %	6.4 %	19.5 %	7.7 %	3.4%
	Our Product	1	8	4	3	7	2	5	6

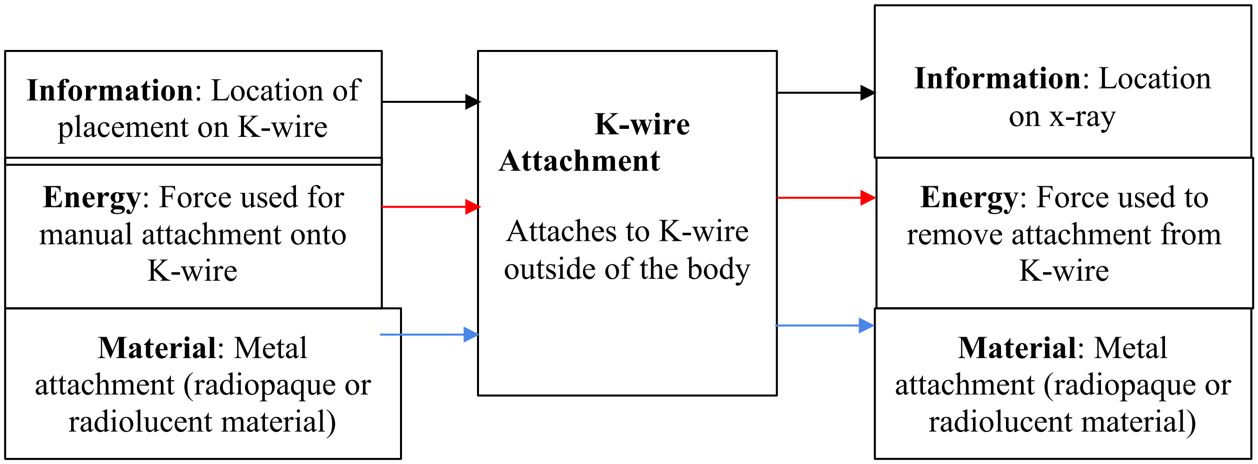

Fig 7. Overall functional decomposition for K-wire attachment. Flow chart showing the information, energy, and material inputs and respective outputs of the K-wire attachment. The overall function is detailed in the central box.

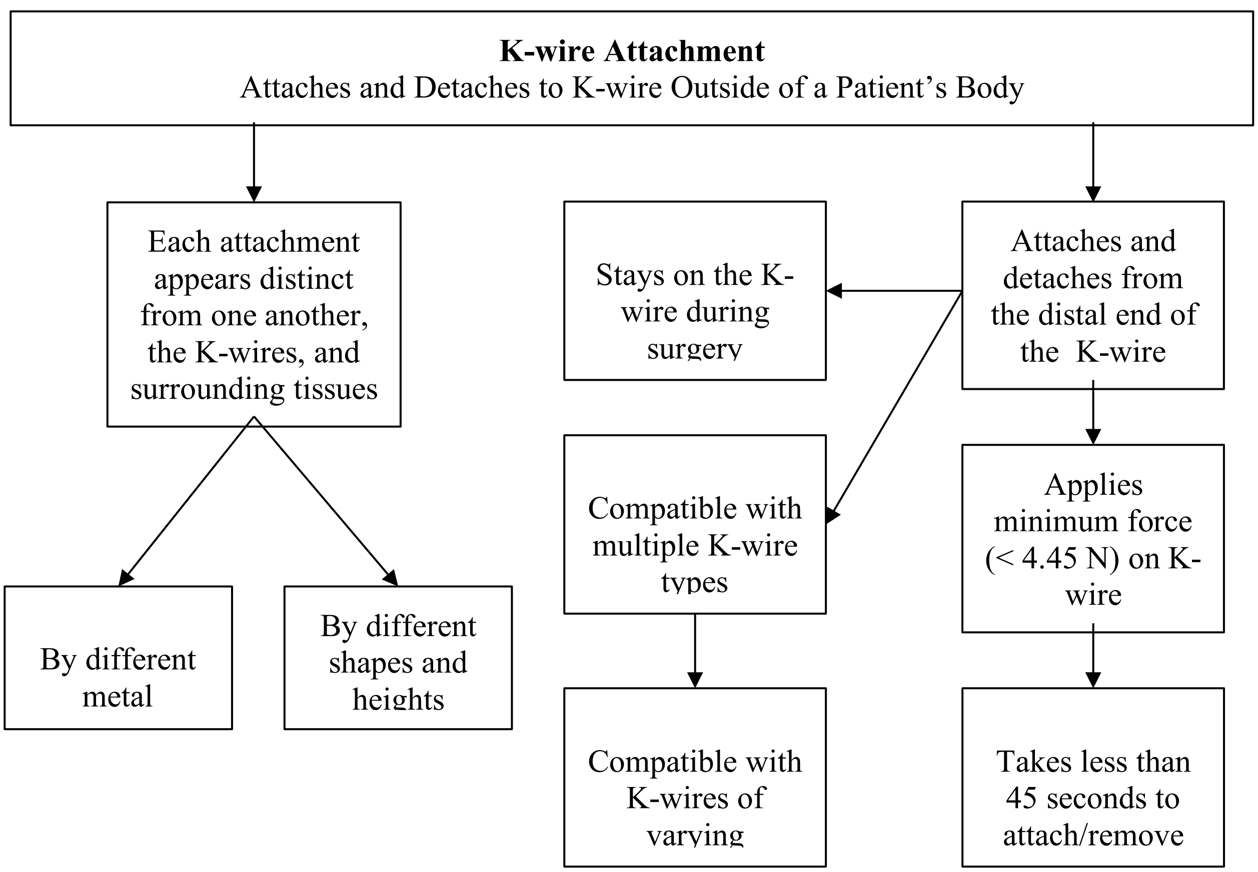

Fig 8. K-wire attachment functional decomposition. The main functions across the top are broken down into their respective subfunctions. The arrows indicate relationships between the functions and sub-functions.

Appendix B

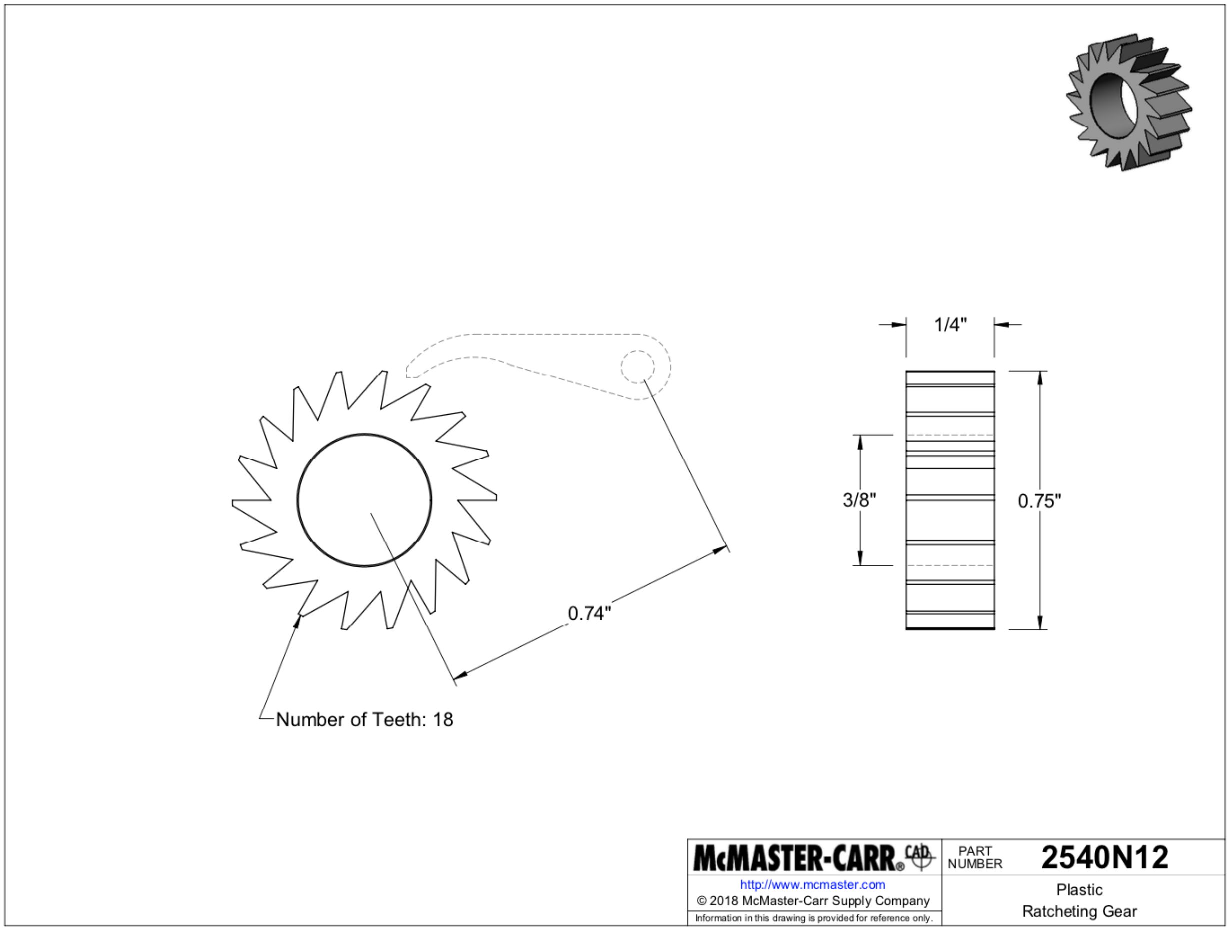

Fig 11. Manufacturer's drawing of the gear. The inner diameter and height were adjusted for our application to 6.35mm and 3.18mm, respectively.