Master Thesis

Graduation Project

Design of a guidance device for minimally invasive hip prosthesis refixation

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Abstract

All around the world countries' populations are aging and with this increase of expected lifetimes there is additional need for medical interventions such as hip replacements. With many people outliving the lifetime of these implanted parts, revisions are sometimes necessary. In some hip prostheses, layers of fibrous tissue can grow and decrease the stability of the implant and cause a great deal of pain. Since open surgery is not an option for elderly patients, a minimally invasive approach is needed to remove the tissue and refixate the prosthesis.

A guidance device was designed particularly for this procedure because removing the tissue before cementing is a novel approach to the current method of only cementing. The engineering design process was implemented to develop practical ideas, from acquiring the requirements to establishing the functions that the device should perform to generating concepts based on those functions and mechanisms. Several concepts were created and evaluated resulting in an arc-shaped design being chosen. Preoperative planning is done with 2D CT images, and the surgeon maps out a path into the leg, which is translated to 3D using computer software. Due to the CT usage the guide must be constructed from plastic so imaging artifacts are not created.

An error analysis on the guidance trajectory was completed in case parts of the device moved out of position for any reason, including bending, loading, or angle missetting. The guide is still accurate up to 5° errors on the angle, equating to about a 1.5 mm bend from the fibrous tissue center.

After completing the design a similar looking arc guide was discovered called the Leksell stereotactic system which is used in neurosurgery to drill precisely into the brain. Although the two devices are similarly shaped, the requirements and functions are quite different, which are highlighted in the discussion. The design presented in this paper overcomes significant challenges with anchoring and stabilizing posed by poor patient bone quality and intraoperative CT use with which the Leksell system does not need to cope.

The designed guidance arc opens up the next step in hip refixation procedures. With the ability to guide new tools to remove the fibrous tissue and cement the area, the lifespan of the prosthesis and the quality of life of the patient will increase. It is the hope of the author that this design will be advanced further and eventually be tested and used in a clinical setting where it can help patients in need.

1 Introduction

Annually, there are approximately 1.5 million hip prostheses implanted worldwide. However, 10 years after implantation nearly 10% of hip prostheses become loosened and need reoperation [1,2] due to a variety of reasons. Additionally, it is widely predicted that there will be an increase in the number of hip prosthesis implantations done in the coming years in the Netherlands and around the world [3,4], and the number of reoperations has already increased nearly 20% since 1999 [1].

Loosening of hip prostheses can be divided into two main groups: septic loosening and aseptic loosening, with the latter accounting for 73.7% of first-time reoperations between the years 1979-2008 [1]. Although the rate of aseptic loosening has been in decline from 1999-2008 and septic loosening has seen a 10% increase over that same period [1], aseptic loosening is still more common and is the report's focus. Aseptic loosening can be caused by various factors including mechanical factors, material properties of the implant, and biological and host factors [5].

A fibrous tissue layer (Fig. 1) can form at the bone/implant interface, or additionally at the bone/cement interface if the hip implant had been cemented. This tissue layer usually results from a reaction to foreign body particles [6–9] leftover from the original implantation or over time as material wears from the hip implant. With time, the fibrous layer grows further and can lead to loosening and clinical failure of the hip prosthesis [8,10,11]. Moreover, prior to the failure of the prosthesis, the patient suffers a great deal of pain when placing weight on the loosened implant.

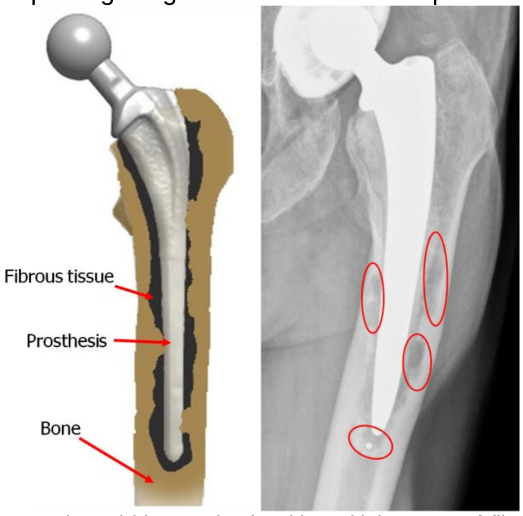

Fig. 1: Implanted hip prosthesis with multiple areas of fibrous tissue growth. L: Schematic of a hip prosthesis implanted in the femur with a surrounding layer of fibrous tissue. R: Radiograph of a hip implant with locations of fibrous tissue growth circled.

A patient requires revision surgery of the hip implant in order to remove the fibrous tissue and implant a new prosthesis. This surgery is an intensive process that requires a large incision (20–30 cm) [12,13] and general anesthesia for several hours; it results in a great amount of blood and bone loss [14] and possible trauma from the instrumentation needed for surgery. For many elderly patients who require such revision, their bodies are too frail to withstand the full procedure [14,15]. Thus, open surgery is not an option due to the increased chances of morbidity and mortality. Therefore, an alternative is needed so that elderly patients can undergo revision surgery.

Currently in the Leiden University Medical Center (LUMC), a minimally invasive procedure is used on elderly patients to re-fix loosened hip prostheses by injecting cement on top of the fibrous tissue growth. This method is a temporary fix due to the fact that the fibrous tissue is still present and can loosen the prosthesis again. It is desired to remove the fibrous tissue first and then inject cement over a clean interface. Through collaboration between the LUMC and Delft University of Technology, a special tool is currently under development which can remove the fibrous tissue. However, a path must be made through the leg to the fibrous tissue so that the special tool can be useful.

The aim of this project is to design an external guidance structure that allows the cannula and other tools to make an accurate and straight path into the leg. The following questions will be answered during this project: How can this device guide tools to reach various fibrous tissue locations in the leg? How can the guide be stabilized to provide a sturdy base for accurate guidance? How can the drill path length be minimized?

2 Requirements

In order for the designed guidance device to be clinically acceptable and usable by the surgeons, several design requirements are needed which are categorized into clinical and technical (Table 1).

2.1 Clinical

The first requirement is that the device must be adjustable to access the top (anterior) and sides (lateral and medial) of the leg while the patient is lying in the supine position (Fig. 2) because the fibrous tissue can be anywhere near the hip prosthesis and vital nerves and blood vessels must be avoided.

The second requirement states the cannula and other tools must enter between 20° and 45° with respect to the sagittal plane (Fig. 2, bottom). Due to the 8 mm turning radius of the fibrous tissue removal tool, and the fact that when the tool is in the tight space of the periprosthetic area, entering below 20° means the tool cannot manipulate itself properly around such sharp turns (Fig. 3). If it were to enter above 45°, the drill path would be too long and cause extra bone loss; the path becomes exponentially longer after 45° (Appendix D).

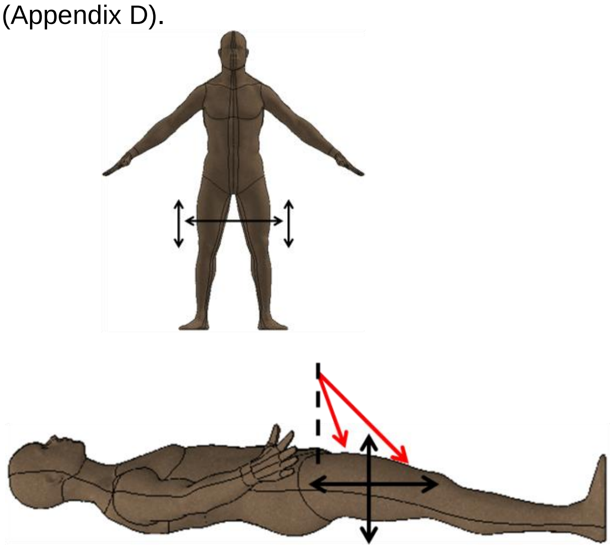

Fig. 2: Black arrows show the directions and areas that the guidance device must move in and red arrows (bottom) show the angle range of the guidance tube. Left arrow is lower limit (20°) and right arrow is upper limit (45°).

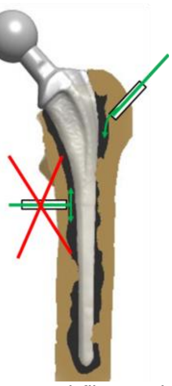

Fig. 3: Entering the femur and fibrous tissue layer below 20° (0°/perpendicular to bone surface in this example) as shown on the left is not possible because the tool cannot make turns at acute angles. The 45° entry at the top right allows the tool to make the turn with its 8 mm turning radius.

Table 1: Requirements

	Clinical Requirement	**Value**
1	Adjustability in space	3 planes
2	Cannula entry angle	20° - 45°
3	Un/Locking (joints)	Average each 5 seconds
4	Number of joints	≤ 7
5	Fixation method	On table or patient non-invasively
6	Legs in focus	1
7	Minimal artifact producing	Plastic or carbon fiber material
8	Number of cannulas to guide	1-3
	Technical Requirement	**Value**
9	Dimension footprint	500x700x500mm (HWL)
10	Minimum device width	225 mm
11	Minimum device height	200 mm
12	Stability	Withstand 40 kg forces
13	Cannula outer diameter	3-5mm
14	Accuracy	± 1.5 mm

From previous literature investigation into device fixation methods [16–21], it was determined that the most feasible option taking into consideration stabilization quality, space restrictions, and patient safety, is mounting on the CT table surface or non-invasively to the patient (fifth requirement).

The guidance device should focus on delivering tools to and fitting around a single leg at a time (requirement six). Not every patient has two hip implants, and if they do there is no guarantee both implants have fibrous tissue growth.

Because the guidance device is used concurrently with CT imaging, the seventh requirement states that the guide cannot contribute to imaging artifacts because artifacts can reduce the surgeon's accuracy. Therefore, non-metallic materials must be used in the device construction.

As requirement eight, since patients can have more than one location of fibrous tissue growth in a single leg, it is practical for the device to hold and guide up to three cannulas at the same time.

2.2 Technical

The ninth requirement is that the entire guidance device must stay within the boundaries of the procedure table and CT scanner, which has a standard bore diameter of 700 mm. Since the table enters the CT scanner, the height clearance is reduced to 500 mm, and because the guide only needs to cover the femur length, it does not need to exceed 500 mm in length.

Because women have larger thighs than men [22] and the thigh is the largest part of the leg, it is a conservative estimate to base the device on a large woman patient. At a 700 mm circumference [23], a 222 mm thigh diameter serves as a minimum that the guidance device must fit around (requirement ten).

The guidance structure must be able to withstand forces up to 40 kg (requirement twelve). Occasionally the surgeon may lean on the device or accidentally slip, and put pressure on it while delivering the cannula to the leg, so the device should be able to withstand half his body weight. If a drilling device is used, it will not create forces or moments greater than 25 N [17,24].

Due to the removal tool's planned 4 mm outer diameter, requirement thirteen states the guidance device must be able to handle cannulas and any tools used during the procedure up to a 5 mm outer diameter.

On average the fibrous tissue is a layer about 3 mm thick. The tool can be off center by about 1.5 mm, which is half the layer's thickness, and still be delivered accurately enough (requirement fourteen).

3 Device Design

During the guidance device design process, there were several aspects to keep in mind, including clinical requirements, human anatomy, and surgeon usability. Additionally, the guide needs to easily lock and unlock while providing stability for surgical tools. To satisfy the requirements the device needs to perform several functions which can be accomplished via an array of methods. The entire design process including morphological table with functionalities and solutions, concept generation, evaluation and all justifications for decisions are in Appendix A. The main points are discussed below.

3.1 Functions

Functions are device actions that satisfy a design requirement. Many mechanism ideas were generated which perform those functions (Appendix A, Table 1) however, only mechanisms that can be feasibly used or combined with other mechanisms were considered further (Appendix A, Table 2). The more important functions are stabilizing the base of the guide, delivering a cannula to the required parts of the leg, locking the guide in various angled positions, linking joints mechanically, and being able to guide multiple cannulas (of different size) at the same time.

If the guide cannot be stabilized then the quality of the guidance mechanism is compromised, no matter how well designed the mechanism is. Stabilization helps to prevent slips from occurring while inserting cannulas and prevents vibrations from affecting the planned trajectory. After the device is stabilized it must guide and deliver a cannula to all the required parts of the leg (Fig. 4). Once the desired angle and position is set on the guidance device, it must stay securely locked to provide stability during the procedure (Fig. 5).

The movements that are necessary for the guidance device to work and to be set in the correct position determines what types of joints are used to connect the parts together. If a directional change in a plane is needed then a hinge might be used. A ball and socket could be used if rotational movement is needed. Among other links are sliders and slots, gears, and universal joints.

Guiding more than one cannula at the same time would make the procedure run more quickly by allowing access to several fibrous tissue locations so that they can be cleaned before being all cemented. Therefore, the way to achieve this is through a combination of multiple guidance tubes and/or multiple bases. The simplest method and most adaptable to a variety of situations uses multiple bases each containing a single guidance tube. Each arc that is setup would be responsible for accessing a specific section of the femur so the chance of interference is reduced.

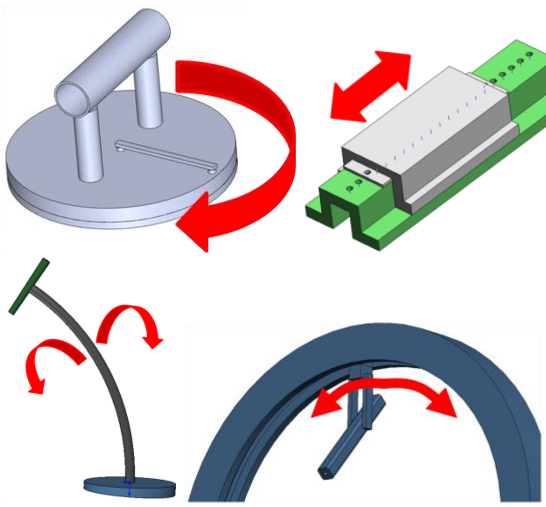

Fig. 4: Mechanisms for giving the guide access to various parts of the leg. Clockwise from top left: Stationary guide with rotating platform; a railing system which a guide is mounted on that slides along the length of the leg; a guide that is attached to an arc that spans the leg and revolves around it; and a flexible shaft like that of a desk lamp. Lastly a variation to all above mechanisms is to relocate the base by hand when needed.

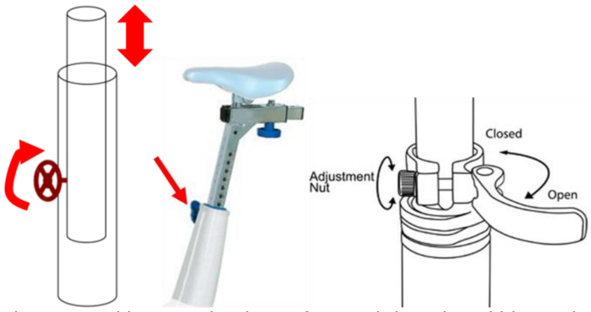

Fig. 5: Locking mechanisms featured in tube-within-a-tube system. From left to right: Pinch bolt or screws which press against the inner tube with force that keeps it in place; pull pins which lock a position by sitting in interval holes; and clamp which squeezes pieces together using friction to stay in place.

3.2 Conceptual design

The 3D computer-aided design (CAD) program SolidWorks (Dassault Systemes, France) was used to create the device designs. Several concepts were generated and evaluated and are in Appendix A along with variations on those concepts. The chosen design is the arc (Fig. 6) which spans the width of the patient's leg, giving the guide access to the anterior, lateral, and medial parts of the leg (Fig. 7) (Engineering drawings in Appendix E). With a diameter of 400 mm the arc will fit across even the largest of legs [23,25].

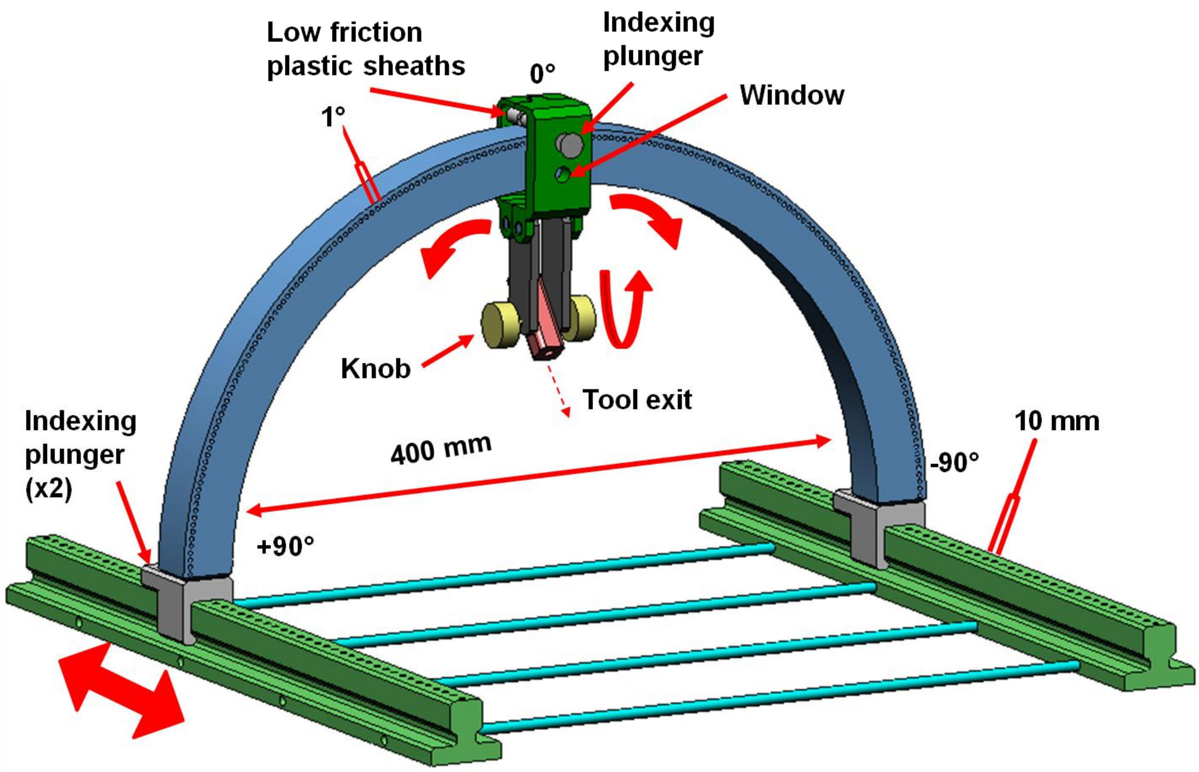

Fig. 6: Arc shaped design. Holes on the bottom rails are spaced every 10 mm that the sliders can lock into using an indexing plunger. Joining the rails together are horizontal rods which keep them aligned and parallel with each other. Under the bottom railing are vacuum cups. The arc face contains holes spaced 1° and the arc slider can lock into them with an indexing plunger. The arc slider contains bolts that are covered with plastic sheaths which act as contact points that slide along the arc surface. The possible movements of the arc slider (rolling around arc) and guidance tube (pitch adjustment) are shown with curved arrows and the rail sliders with a flat arrow.

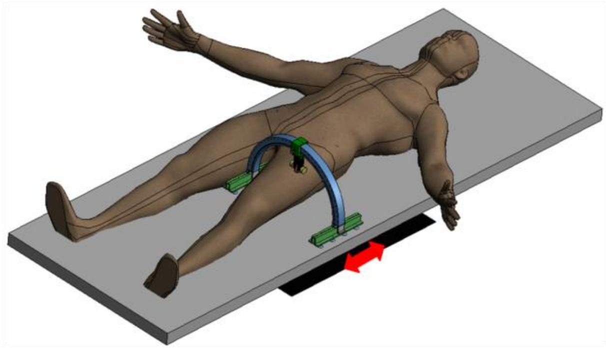

Fig. 7: The arc straddles the patient's left leg in the supine position and the slider can roll around the arc to access the anterior, medial, and lateral parts of the leg. Under the rails are the vacuum cups that hold the base to the table. The arc can slide along the length of the leg on the rails.

The arc can move along the length of the patient because of the railing system (Fig. 7). To keep the rails parallel to each other and the indexed numbers lined up in the same plane while setting up the arc, horizontal rods connect the railings. If the rails are not properly aligned the images on the CT will be distorted and produce an inaccurate guidance path. The arc, connected directly to the top rail sliders with two countersunk screws on each side, can access areas along the length of the leg using the rails. Vacuum cups under the rails provide enough force to keep the rails securely in place, even while locking and unlocking the indexing plungers. The guidance tube, where tools for the procedure are passed through, can roll around the arc to reach the leg sides and can also adjust its pitch for entering at different angles.

Located along the face of the arc are 179 - 2.6 mm diameter holes spaced every one degree that the slider block can be locked in at using an indexing plunger, and the window in the slider shows which angle is set. Once the indexing plunger is unlocked, it remains unlocked until it is locked again which makes it much easier to slide the block along the arc because the surgeon does not need to constantly hold open the plunger, freeing up a hand.

The slider contains three bolts covered by plastic sheaths which maintain surface contact with the arc. These sheaths, made from ultra-high-molecular-weight polyethylene, have a low friction coefficient meaning they are suitable for sliding, especially since the arc is also a low friction plastic. Hanging below the arc slider is the guidance tube, where it can rotate and change its pitch, altering the trajectory of the tool through the leg, and lock in position by the knobs on each side. The pitch angle is known as shown in Fig. 8.

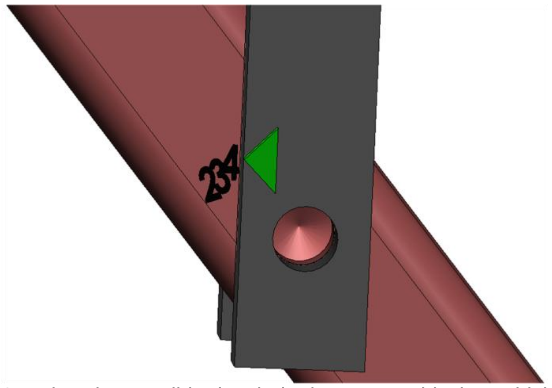

Fig. 8: Below the arc slider is a bolted connector block to which the guidance tube is mounted. The tube can adjust its pitch and then lock in place with the studded knobs. Surgical tools are passed through the center Ø5 mm hole of the tube and the side view of the tube shows how to measure pitch angle by lining up the numbers on the guidance tube with the arrow on the holder.

3.3 Setting the device

There are two distinct motions to position the guidance tube (roll and pitch), assuming the arc is locked in place on the rails, and it is important to know how to correctly set those angles. Using the CT images, which are the same as currently used, the surgeon knows where to plan the path and entering angle to avoid blood vessels and nerves. Although the images are 2D slices, he can reconstruct the anatomy in 3D based on experience. The current procedure done by hand puts nearly no restrictions on the entering angle other than to avoid obstacles such as blood vessels and nerves, giving the surgeon flexibility, but because of the introduction of the fibrous tissue removal tool, the surgeon must enter the leg within the required angle range. Due to the geometry of the arc, the guidance tube follows a particular and fixed path.

A MATLAB (MathWorks, Natick, MA) model and analysis was performed in order to find the translation from the angles on 2D CT scans to adjusting the angles on the arc guide (Appendix B). The average human radii were used for modeling purposes only (50 mm and 110 mm for leg; 15 mm for femur) [26,27] although the exact measurements for a specific patient can be inputted during the actual planning phase of the procedure. Because of the arc geometry, and its center point staying concentric with the leg center point, the approach angles do not change with different leg diameters. To be consistent with the preoperative CT images, perspectives from the cross-section and side were used. Cases were performed with the fibrous tissue location set at the center and offset from the center of the leg to generate a guidance path to the tissue and determine the path angles. Adjusting the guidance tube angles is done in two ways with the roll angle, γ, corresponding to movement along the arc and β corresponding to the pitch angle (Fig. 9).

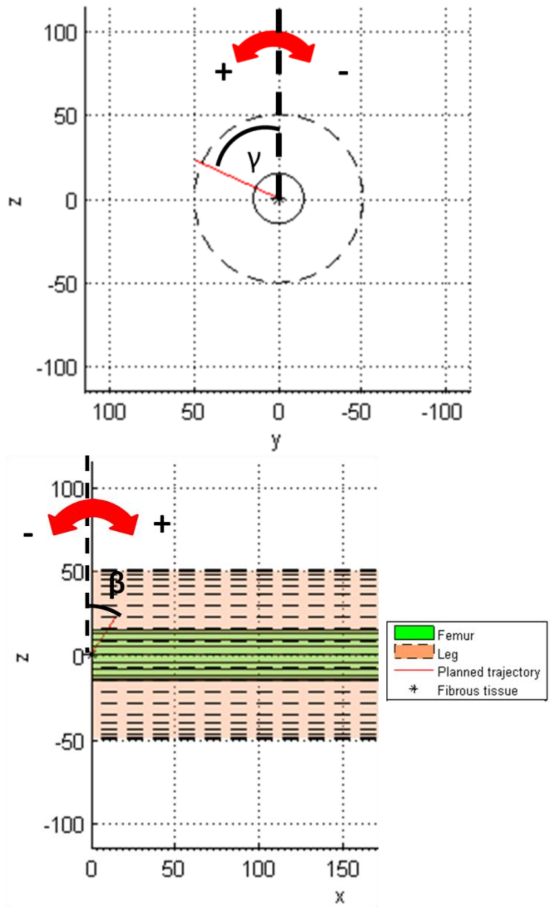

Fig. 9: Model with femur, leg, and planned guidance trajectory in cross-sectional view (top) and side view (bottom). The center point of the leg and arc is currently at the fibrous tissue location. The rotation angles about the arc axis are represented by γ, i.e. roll (top) and β, i.e. pitch (bottom). A positive γ is counter-clockwise (rotation about x-axis) while a positive β is clockwise (rotation about y-axis). The angles shown here in 2D can be transformed to 3D.

The basics of the SolidWorks model were recreated in the MATLAB model with the reference position and the rotated position (Appendix B, Fig. 1 and 2). The calculated angles and distances are different for each fibrous tissue location but all paths lead to the leg center. Using the fibrous tissue location as a starting point and another point along the planned trajectory and arc center, the 3D arc angle settings can be transformed from the 2D projections with Pythagorean relationships and rotation matrices (Appendix B). After the angles are determined the arc must be set at the correct Δx from the reference point.

3.4 Range of Motion of Device

One characteristic of the design geometry is that the guidance tube path must intersect the arc center and since the arc center is concentric with the femur center in the reference position, the guidance path is also in line with the femur center. However, it must be noted that although the model simplifies the leg and femur to be cylindrical, in reality they are not perfect shapes. The femur diameter decreases from the proximal end to the distal end, but importantly, the center does not significantly change its position. Likewise, the railings provide enough height so that the bottom of the arc is in line with the femur center. Taking that into consideration, and the fact that there is a prosthesis in the center of the femur, the guidance trajectory cannot cross the leg diagonally. Therefore, if fibrous tissue is present in the left side of the leg then the guidance tube should approach from the left side of the arc. Because the guidance tube is centered under the arc slider, the end of the arc slider will coincide with the railing slider at a roll angle of about 85°, so in the best case scenario for leg access, it is not possible to set the tube completely horizontal with respect to the leg (Fig. 10, top). For setting up the leg and guide so that access is maximized, the protocol should be followed (Appendix C). The procedure for using the device pre-operatively and intra-operatively is also laid out in Appendix C.

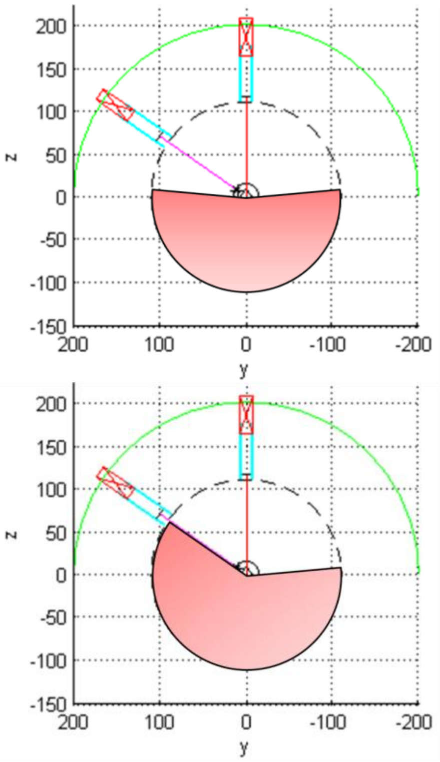

Fig. 10: Best case scenario (top) and true worst case scenario (bottom) of leg access with guidance trajectories. The shaded portion is where the trajectories cannot reach. The bottom of the arc coincides with the center line of the femur because the rails and rail slider elevate the arc above the table. The bottom half of the leg cannot be accessed due to the guidance tube always pointing toward the center, plus 5° on either side of the leg due to interference between the arc slider and the bottom rails. In the worst case scenario, the outside part of the leg still has the same restrictions as the best case scenario but the inside part of the leg is affected by the other leg and the length of the tools. When the pitch is shallow (20°) and the tools are more than 100 mm in length, the top 55° of the leg is accessible which results in an extra 30° restriction on the inside leg.

As the arc moves closer to the proximal femur the space between the legs reduces, potentially limiting tool trajectories. At angles above 55° on the arc while at the proximal end, the guidance tube can become trapped between the legs and tools longer than 100 mm may interfere with the other leg, resulting in a worst case scenario (Fig. 10, bottom). While the guidance tube should keep its angle range between 20° and 45° (requirements), it is possible to move the tube outside that range, although there are drawbacks (Fig. 11).

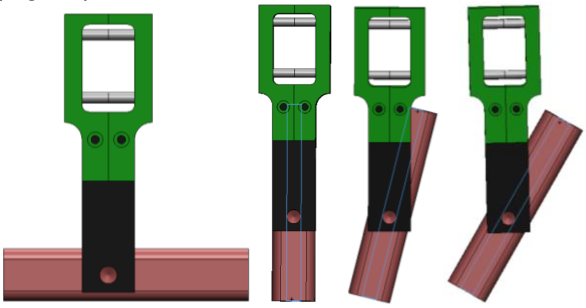

Fig. 11: Range of motion of the guidance tube. From left to right the guidance tube is set at 90°, 0°, less than 20°, and between the range 20° - 45°. At 90° tools can still enter the guidance tube but will not be at an angle to enter the leg. At 0° the guidance tube is blocked completely by the arc slider. Less than 20°, Ø5 mm tools will hit the backside of the arc slider. Between the 20° and 45° tools enter without problems and can enter the leg at appropriate angles and trajectories.

4 Mechanical Analysis

The exact placement of the cannula in the leg and where the fibrous tissue removal tool arrives can be affected by errors, small or large, and can be cumulative (Fig. 12). The fault tree (Appendix D) lists where each failure can occur on the device, whether it can happen during the procedure or before, and if the event is user related or inherent to the device. Knowing where the device can fail helps the user to avoid triggering those events. The failure modes and effects analysis (FMEA) summarizes the system faults and states methods or features that are available or integrated into the system to overcome pitfalls (Appendix D, Table 1 and 2).

Placement of the rails on the table with respect to the leg and femur position is the first and an important step because every piece of the device is connected from there and is affected. The initial rail position must be parallel to the patient's femur or else the target will not be reached. To make sure the target leg is parallel with the rails, the side of the table should be used as a reference (since it is straight and the leg has already been lined up with it preoperatively) and the positions should be confirmed with CT images.

Because the angles and distances are indexed on the arc, the calculations must be rounded to the nearest 1° for angles and nearest 10 mm for length along the leg. Another type of error comes from external forces placed on the guidance device, possibly resulting in twisting of the arc or the guidance tube bending off-center.

As with any machined product, tolerances can cause slight errors because there could be some movement between joints and holes. Error propagation and amplification could occur if there are gaps between sliding parts and joints.

4.1 Setting the device incorrectly

In the arc design it is more likely to have a user error while setting the pitch angle compared to setting the roll angle. This can be associated with the locking system in that the roll angle has individually indexed holes to lock into every one degree while the pitch angle is set over a continuously rotating system that must be locked by tightening a studded knob.

4.2 Matrix transformations to reality

Because matrix transformations are mathematical manipulations, it is possible that it results differently in reality than expected. The formula outputs rotation angles which need to be rounded to the nearest degree so that it can be set on the arc. Fig. 13 shows the difference between a calculated trajectory and the trajectory based on setting the arc rounded to the nearest 1° resulting in a negligible difference in all cases since the maximum possible rounding is 0.5° for each angle. In the end, both the calculated and rounded trajectories still intersect at the femur center because the arc geometry always points its guidance tube toward the center.

4.3 Device bending, deflection, and strength

Bending can occur in any direction around the connector joint. With the fibrous tissue spanning on average a 3 mm wide area (estimated as a sphere), the surgical tools, when aimed at the center of the tissue, can be off its target by 1.5 mm (length of radius) and still enter the tissue layer. As the path length increases or the target range is reduced, the allowable error on the guidance tube angle decreases (Appendix D). However, there are other factors to take into account such as the arc position and the direction of approach to the tissue (Appendix D).

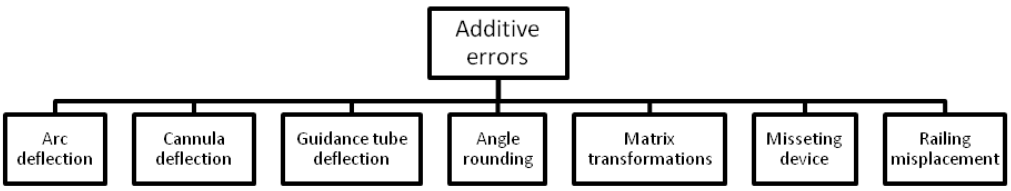

Fig. 12: A simplified overview of the major possibilities for accumulative errors in the guidance device. Each step although small and not significant by itself can create a noticeable error when all steps are added together.

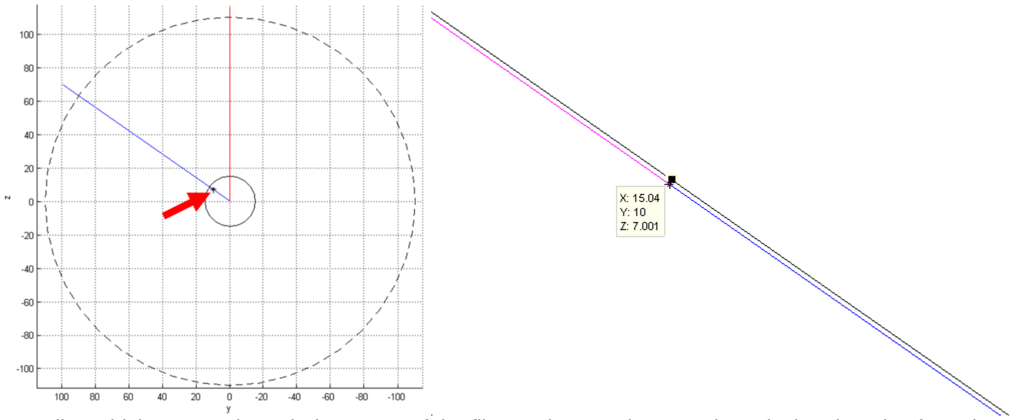

Fig. 13: Bottom line which passes through the center of the fibrous tissue point uses the calculated angles from the original rotation matrix (β=50.86°, γ=55.01°). The top line uses the rounded arc settings; in this case (β) the pitch angle is +0.14° and (γ) the roll angle is -0.01°. Both lines intersect the femur center [0,0,0] due to the center of arc principle, but the lines start from different locations with the bottom line at [150, 100, 70] and the top line at [150.2, 99.82, 69.88]. Fibrous tissue located at [15,10,7] and the new trajectory will pass at [15.04, 10, 7.001].

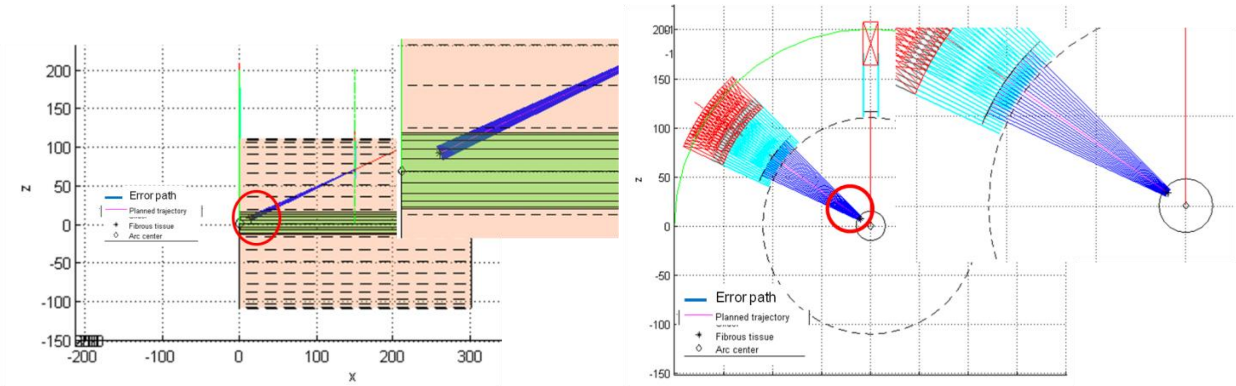

Fig. 14: Error in the pitch angle (left) and roll angle (right) of ±10° at 1° increments with fibrous tissue located at point (15; 10; 7) with a calculated pitch angle of 51° and a roll angle of 55°. The original trajectory can be seen in the middle of the blue error range. The pitch angle only affects the end point in the x-z directions and the roll angle only affects the end point in the y-z directions. An error in pitch angle is similar to bending at the connection joint while an error in roll angle is similar to setting the angle incorrectly as bending would not keep the trajectory pointed toward the center.

The error on the angle is due to bending of either the roll angle or the pitch angle. Bending in the roll angle direction causes the trajectory to aim off the arc center, different than only setting it incorrectly which maintains the lock on the center as the trajectory rotates about the arc. A bend in the pitch angle is similar to setting it incorrectly. A change of pitch only has an effect along the length of the leg and the height above the leg (Fig. 14, left) while the position across the width of the leg is unaffected. On the other hand, a change of roll angle affects the distance from the planned trajectory across the width and the height above the leg but not along the length (Fig. 14, right). If both angles are inaccurate in the same direction (both +5°), the error effect is magnified by a factor of about 1.5, although greater errors (e.g. both +10°) have larger magnification factors (Appendix D). If the errors are in opposing directions (one angle +5°, other angle -5°) the effect is compensatory and actually is better than only one inaccurate angle.

Also affecting the guidance tube position is the ability of the studded knob to hold tightly and with both knobs providing support, the guidance tube is able to balance itself, counteracting its momentum. Through the guidance tube, the cannula is inserted which can also bend during usage, with more bending exhibited with increasing cannula length. However, due to it being supported by muscles in the leg, there is a greater resistance to bending, up to 130 N (Appendix D).

From calculations and a SolidWorks simulation, it is shown that the arc is able to withstand the required 40 kg of force applied to it during normal use situations, defined as leaning over the arc during the procedure, disengaging the spring plungers, moving the arc along the rails, moving the arc slider along the arc, and inserting tools through the guidance tube (Appendix D). The fasteners used to join the parts together also provide enough strength and stability under the same loading case (Appendix D).

4.4 Total error

With all the sources of error counted, an overall error can be estimated. The arc can deflect 0.17 mm under a 400 N load, the indexing plunger on the arc slider can be off by 0.225 mm, the indexing plunger on the railing can be off by 0.24

Table 2: A material property comparison of carbon fiber composite, UHMWPE, and PEEK

	Carbon fiber	**UHMWPE**	**PEEK**
Elastic Modulus (GPa)	70 [28,29]	0.69 [30,31]	3.5 [32]
Shear Modulus (GPa)	5 (unidirectional, 0/90° to loading axis) – 47 (± 45° to loading axis) [29]	0.44 [33]	1.3 [34]
Mass Density (g/cm^3)	1.7 [29]	0.94 [35]	1.3 [34]
Ultimate tensile strength (MPa)	600 [28,29]	50 [35]	~100 [32,36]
Yield strength (MPa)	*	25 [35]	97 [34]
Friction coefficient	0.65 [37]	0.1 – 0.2[38]	0.35 – 0.5 [39]

* Carbon fiber yield strength depends on the composite used because normally carbon fiber does not yield [40]

mm, and the maximum rounding errors of 0.5° for each the roll and pitch angles results in the maximum distance from the tissue at 0.24 mm. These maximum inherent errors to the device when placed under maximal load totals 0.875 mm, allowing the cannula and guidance tube to bend up to 0.625 mm and still fall within the 1.5 mm range. If the force at the end of the guidance tube or cannula is at 11 N with no muscle support or at 54 N with muscle support, the tools will still reach their destination (Appendix D, Fig. 7D).

5 Material analysis

Constructing the guidance device from the proper materials is as important as the design itself. Since the device should minimally contribute to imaging artifacts, a large majority must be made of plastic. Where extra strength is needed, stainless steel or metal is used in some fasteners. Table 2 lists some properties of three of the discussed plastic materials below.

Carbon fiber composite is a strong and lightweight material that can be molded or machined into many shapes, while providing stability for a guidance procedure. The material can also be autoclaved so it is sterilizable. Since there are many proven applications of this material such as in airplanes, bicycles, vehicles, and other sport and consumer products, carbon fiber is very versatile. With a mass density of about 1.7 g/cm^3 (range: 1.4-1.9) depending on the exact composition, it is much lighter than steel but offers comparable strength to the metal. Carbon fiber is also a stiff material for a plastic composite with an elastic modulus of 70 GPa, comparing to steel (200 GPa) or aluminum (72 GPa). The downside is that carbon fiber does not yield under force; instead it catastrophically fails.

The numbers alone do not tell the whole picture of the quality and strength of carbon fiber composites. There are several orientations that the tubes can be arranged in to maximize strength, but the direction of the applied forces plays a role in the material's stability. The composite can withstand higher forces if the fibers are arranged multi-directionally including intermediate angles to the applied force instead of at just a single angle because unidirectional loading rarely occurs in real world situations [29].

Ultra-high-molecular-weight polyethylene (UHMWPE) is a traditionally used material in medical applications. It is possible for the material to be compression molded and also combined with carbon fiber in a mold. UHMWPE has a low friction coefficient and is more slippery than carbon fiber, so it is useful to have it as a surface coating to make the sliding parts move more easily. The pieces that require more friction to hold its position such as the guidance tube would best not use an UHMWPE coating. However, as UHMWPE is less strong compared to carbon fiber, it may reduce the overall strength of the composite. Beneficially though, the combination of carbon fiber and UHMWPE may give the material malleability and prevent some catastrophic failures.

Poly-ether-ether-ketone (PEEK) is another strong, sterilizable plastic material used often in medical and aerospace applications. It has a tensile strength of 100 MPa, a friction coefficient between 0.35-0.5 [39], and an elastic modulus of 3-4 GPa but can be increased much further by combining it with carbon fiber composites [36]. Because the guidance structure is small in size, thin-walled holes exist which need to stay strong under load so reinforced plastics such as PEEK and carbon fiber can handle such force. One downside to PEEK is its high cost, sometimes double the cost of traditional plastics [32,36], but with the size and different parts of the guidance device, it may not require much material.

Considering the costs and strength properties of the materials, carbon fiber is a good choice for the guidance device. It outperforms other plastics and is comparable to steel on a strength-to-weight ratio. The composite can be machined or molded to the arc shape and is stable enough to be used during the procedure. To supplement the composite's strength, PEEK can be included in the carbon fiber composite. The material should also be molded with UHMWPE to add extra abrasion resistance, flexibility, and sliding properties [41].

6 Discussion

During this project a medical device for hip prosthesis refixation has been designed that guides surgical tools at user specified angles. This device allows for the expansion on and improvement over the current procedure by giving a pathway for a new fibrous tissue removal tool to be used in the leg. Removing the fibrous tissue before cementing the prosthesis is an improvement over the current method of cementing on top of the fibrous tissue.

The design process resulted in four initial design concepts plus some variations on those concepts. In the end, the arc design was chosen as best due mainly to its ability to access all sides of the leg with ease, its locking system and stability, and its precision for setting angles. Because of the access provided by an arc, the surgeon does not need to move the base to another location since the railing system streamlines the arc positioning along the leg length. The simple and ergonomic locking system is effective in holding the moving parts in place because the plungers are embedded in the device and remain disengaged, making it easy to slide parts, until the plunger is locked again.

Fortunately, the guidance device is able to use the current CT system and software to plan trajectories into the leg, making the new device easy for the surgeon to adapt to and understand. Positioning the patient and keeping him stationary and supine on the table remains the same except for additionally orienting the arc guide with the table. Since it is not possible to attach the guide to the patient due to poor bone quality and reduced leg access, the rails need to be aligned by hand onto the table. Therefore, it is imperative to keep the patient aligned with the table, using reference markers if necessary. After a cannula has entered the leg, patient movement is not as big of a concern since the cannula will move with the patient. However, if there is more than one fibrous tissue location, movement will affect the outcome if the patient position is not corrected before guiding the next cannula.

Currently, these preoperative CT scans are done weeks or even months in advance. Because of this long lead time the position of the patient can be slightly changed from the initial scans to the procedure day, something that could affect guidance accuracy. Every effort needs to be made to replicate the same patient position on both the preoperative and operative day. One method for accomplishing this is to make a new scan on the procedure day and superimpose it over the old scan and adjust the patient to make the two images line up. A more exact approach but perhaps more difficult is to place markers on the table and record for each patient where on the table he lies during the scan and the patient can line up to those markers again on operation day.

After the guidance device was designed in detail, a similar looking arc-shaped guidance device (Fig. 15) was discovered later on [42–46]. It uses a center-of-arc principle to set its position and aim its trajectory toward the target. According to the company, it is able to achieve sub-millimeter accuracy. Preoperative images can be done so that the surgeon can plan his trajectory into the head, and the computer software transforms those images into coordinates to be set on the stereotactic frame. Although the arc shape is not unique to neurosurgery, there are advantages to the skull not present with the leg, and this is evident in the patent as it is specific to use on the head [46].

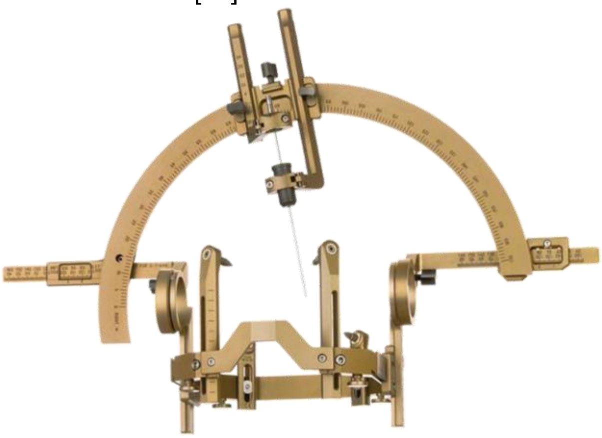

Fig. 15: Leksell stereotactic guidance device. The head mounted frame uses a center-of-arc method to guide tools to the target for biopsies and other procedures. The arc can adjust left and right to move its center point and the slider on top of the frame can enter at various angles around the arc. Obtained from [47].

The stereotactic frame is able to securely anchor itself into the skull using four self tapping screws, something not possible with hip refixation due to the low quality of the femur, which is why the hip refixation guidance device must be secured non-invasively or outside of the body. The head shape is different than the leg, which limits the device to being only above the leg and on the sides, also limited by the table surface. The head has open space on all sides meaning the whole arc frame can rotate about the head without interfering with the patient since the patient does not need to be lying on a table during that procedure because intra-operative imaging is not needed. The center-of-arc principle is based on putting the target in the center, which requires the arc structure to move in all directions, but there is simply not space around the leg to adopt such a method, so the arc center is instead always focused on the leg center. To transform between coordinate systems of imaging modalities and the guidance device, the Leksell system has a separate head mounted coordinate frame with markers that can be superimposed on the actual set-up. The stereotactic frame is not made for intra-operative imaging since it is metal, but for the hip refixation procedure, imaging during the procedure is a requirement. For neurosurgery, this stereotactic system works well because of the advantage of a strong skull to anchor into and the geometry of the head that has more space to move laterally and around. Unfortunately, there are more restrictions with the hip refixation procedure, such as bone weakness, imaging requirements, and table space.

Currently the procedure is done in a standard CT room, a non-sterile room. To compensate, the patient and table are covered in paper, leaving only the area around the femur uncovered. The arc design is dependent on fixating itself on the table with vacuum cups so the cups need to be placed under the paper to have good surface contact. The sterilization paper can still be used as it is now, but should be placed around the guide so that it does not block the view of the numbers on the railings. The arc can be already sterilized because its parts can be put in the autoclave or be onetime use. Sterilizing the arc may prove to be time consuming with all of the holes around the arc and on the rails. However, a large majority of the holes are non-threaded and through-holes meaning they have a lower chance of dirt being stuck.

Manufacturing the guidance device by machining the plastic into shape is a straightforward way to make the product, but alternatively, carbon fiber composite can be molded to shape. Constructing molds however is challenging in addition to the material injection process and the cooling process afterwards. Material injection rates and the material volume must be tightly controlled as well as the cooling rate so that it hardens properly and cracks and faults do not form in the product. If pieces of the device should be onetime use, then in the future it may be worth it to mold portions of the guide.

Future work includes producing a rapid prototyped scale model which will be used to demonstrate the device’s movements. Afterwards, the device will be machined in full size from plastic so it can be tested.

7 Conclusion

The questions posed in the introduction can be answered. The device does guide tools to reach various fibrous tissue locations by using an arc shape that can access all sides of the leg via a guidance tube, slider, and railings. By centering the arc with the leg center, the guidance tube is able to move to its position by transforming the preoperative image path angles in 2D to the path angles in 3D.

The guide is stabilized to the procedure table using vacuum cups. Horizontal rods hold the two railings together so they remain straight and parallel to each other while the guidance structure is being setup, assuring the rail sliders have a straight path to follow and are at the calculated distance from the fibrous tissue. The arc is fastened to the rail slider with enough strength to prevent too much deflection, and since the arc experiences loading during the procedure, the chosen material is strong enough to resist significant deflection.

Minimizing the guidance path length reduces error amplification during bending. More bone is compromised with longer path lengths since the angle of approach is more obtuse. The pitch angle, which is related to the path length, can be adjusted in tandem with the arc position along the railings, and as the pitch angle becomes steeper, the arc can move closer to the fibrous tissue, and vice versa. The surgeon has options when determining the guidance trajectory if the pitch angle and railing distance can be adjusted while still arriving at the target.

This project resulted in a medical device design for hip prosthesis refixation. Its purpose is to guide tools into the patient leg to remove fibrous tissue, to re-cement the prosthesis to give it more stability in the femur, and to reduce patient pain for many years into the future. The next goal is to have the guidance arc constructed so that it can be tested on cadavers and after that testing is finished, the guide will hopefully be used in real procedures, making an easier experience for the surgeon to complete refixations.

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Appendix A: Device design process

Table 1A: Morphological table of the functions for the guidance device design

Functionality	Solutions								
Stabilizing the guide's base platform	Suction cup to table; adhesives	Clamp to side of table	Clamp around patient leg; tie around; Velcro	Mounting to rails; rails attached on table	Mounting to ceiling	Mounted / stationed on floor	Under the weight of the patient		
Delivering cannula to lateral, anterior, and medial parts of leg	Stationary guide with rotating base	Guide mounted on rail system (slide system) that runs the length of the leg	Guide mounted on (flexible) arm [similar to a desk lamp]	Guide that has its base relocated by hand each time [access different parts of leg]	Guide attached to ceiling with (flexible) arm	Guide attached to arc that revolves around leg	Stationary guide that can adjust height/pitch		
Locking the guide in (angled) position	Pinch bolt; screws	Pin that locks into interval holes	Quick release clamp, other clamp	Air pressure	Friction, squeezing;	Springs and static balancing	Lock and key; wafer tumbler	Magnetic lock	Clamp with grooved teeth pattern
Linking joints mechanically	Hinge; swinging hinge	Ball and socket	Bearings	Slider, slotted length	Cam and follower; rack and pinion; gears	Universal joint	Cylindrical joint	Planar joint	
Guiding multiple cannulas	Multiple guide tubes on single base	Single guide tube on multiple bases	Multiple guide tubes on multiple bases						
Guiding varied diameter cannulas	Modular guide tube inner diameter sizes	Adjustable inner diameter on guide tube	Separate full base structures						
Not interfering with leg surface	Modular guide tube total length	Slotted guide tube which can slide toward and away from leg	Having multiple starting positions for the guide which can reach same end point in leg						
Measuring angle and position of guide	Numbers written at intervals	Tick marks to indicate measures (in small places)	Electronic readout	Level tool, accelerometer (gravimeter)					
Adjusting position of guidance tube in (3) planes*	Linear movement along length of leg (x-axis only)	Circumferential movement over width of leg (y-axis only)	Pitch adjustment into leg (z-axis only)	Rotational movement	Hinged motion; swinging	Combined rotational and pitch movement	Gimbal		

Table 2A: Reduced morphological table with decisions for implementing possible design solutions. Color code: Red = No, Orange = Possible, White = Yes

Functionality	**Solutions**								
Stabilizing the guide's base platform	Suction cup to table; adhesives	Clamp to side of table	Clamp around patient leg; tie around; Velcro	Mounting to rails; rails attached on table	Mounting to ceiling	Mounted / stationed on floor	Under the weight of the patient		
Delivering cannula to lateral, anterior, and medial parts of leg	Stationary guide with rotating base	Guide mounted on rail system (slide system) that runs the length of the leg	Guide mounted on (flexible) arm [similar to a desk lamp]	Guide that has its base relocated by hand each time [access different parts of leg]	Guide attached to ceiling with (flexible) arm	Guide attached to arc that revolves around leg	Stationary guide that can adjust height/pitch		
Locking the guide in (angled) position	Pinch bolt; screws	Pin that locks into interval holes	Quick release clamp, other clamp	Air pressure	Friction, squeezing;	Springs and static balancing	Lock and key; wafer tumbler	Magnetic lock	Clamp with grooved teeth pattern
Linking joints mechanically	Hinge; swinging hinge	Ball and socket	Bearings	Slider, slotted length	Cam and follower; rack and pinion; gears	Universal joint	Cylindrical joint	Planar joint	
Guiding multiple cannulas	Multiple guide tubes on single base	Single guide tube on multiple bases	Multiple guide tubes on multiple bases						
Guiding varied diameter cannulas	Modular guide tube inner diameter sizes	Adjustable inner diameter on guide tube	Separate full base structures						
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Measuring angle and position of guide	Numbers written at intervals	Tick marks to indicate measures (in small places)	Electronic readout	Level tool, accelerometer (gravimeter)					
Adjusting position of guidance tube in (3) planes*	Linear movement along length of leg (x-axis only)	Circumferential movement over width of leg (y-axis only)	Pitch adjustment into leg (z-axis only)	Rotational movement	Hinged motion; swinging	Combined rotational and pitch movement	Gimbal		

Morphological table decisions and justifications

Row 1, stabilizing the guide's base platform:
Suction cup to table; adhesives → strong hold; remains on table; good location for base; potential for damaging table; maintains orientation with CT and patient [YES]
Clamp to side of table → stable; maintains constant position relative to table; would interfere with CT imaging [MAYBE, partial use]
Clamp around patient leg; tie around; Velcro → maintains constant position relative to patient; may cause discomfort for patient; may not be stable if patient moves; maybe difficult to stabilize/anchor system; chance of blocking access to part of leg to be treated [MAYBE]
Mounting to rails; rails attached on table → need to combine with adhesives to stick rails on table; maintains orientation with CT and patient [YES]
Mounting to ceiling → requires modification of surgical room; difficult to combine with CT; unlikely to fit inside scanner [NO]
Mounted / stationed on floor → easily moveable; flexible to position and store; difficult to combine with CT [NO]
Under the weight of the patient → simple method of stabilizing; may not be fully reliable [MAYBE]

Row 2, delivering cannula to lateral (outer), anterior (top), and medial (inner) parts of leg:
Stationary guide with rotating base → limited to only one side of leg unless combined with more bases; could be combined with additional method may be cumbersome with multiple separate rotating bases [YES]
Guide mounted on rail system (slide system) that runs the length of the leg → limited to one side of leg unless combined with another rail; rail system oriented on ceiling can access multiple parts of leg [YES]
Guide mounted on (flexible) arm [similar to a desk lamp] → provides good access to parts of leg; depends on stability and lockability [MAYBE]
Guide that has its base relocated by hand each time [access different parts of leg] → not practical; takes too much time to adjust; may be inaccurate; cumbersome to do during surgery, unless several bases are set up prior to the start [MAYBE]
Guide attached to ceiling with (flexible) arm → not enough space in operating room; need to modify internal fixtures in operating room; does not maintain constant positioning with patient if he is moved into CT [NO]
Guide attached to arc that revolves around leg → provides good access to all sides of leg; easy to move around leg [YES]
Stationary guide that can adjust height/pitch → provides access to 2 sides of leg, but not 3rd; would require an additional base or be combined with additional method [YES]

Row 3, locking the guide in (angled) position:
Pinch bolt; screws → easy to use and is a simple mechanism; requires mechanical strength to engage; can be used as a "continuous" lock; does not prevent rotational motion [YES, circumstances]
Pin that locks into interval holes → good for linear motion; good for determining increment values; would not stop rotation [YES, circumstances]
Quick release clamp, other clamp → easy to use; requires mechanical strength to engage; can be used as a "continuous" lock [YES]
Air pressure → good, strong locking system; would require system of tubes to supply air; easy to activate with button [MAYBE]
Friction, squeezing → easy to use; reliability needs confirming; may cause unknown damage if too much friction is applied [YES]
Springs and static balancing → difficult to get perfect balance; movements may counter the balance and destabilize the lock [NO]
Lock and key; wafer tumbler → would prevent rotational motion; lock and key is cumbersome to use with separate small parts [MAYBE]
Magnetic lock → strong lock; may interfere with imaging quality; reduces possibility of using device with MRI [NO]
Clamp with grooved teeth pattern → strong; may need extra hands/help to tighten this type of lock; may not offer large benefit over simple friction [MAYBE]

Row 4, linking joints mechanically:
Hinge; swinging hinge → good for 90° movement; swinging hinge allows 180° motion; one degree of freedom [YES]
Ball and socket → good for 360° movement and leg access; offers rotation and pitch adjustment; three degrees of freedom [YES]

Bearings → can permit motion in various directions; hinge, linear, spherical, axial; makes movement smoother; may not be a necessary addition [MAYBE]
Slider, slotted length → good for adjusting linear components; one degree of freedom [YES]
Cam and follower; rack and pinion; gears → translates rotational motion to linear motion; similar to sliders; can lock in place by preventing rotation [MAYBE]
Universal joint → allows a rod to swing or bend or move from translated rotary motion; not sure how to implement in guide [MAYBE]
Cylindrical joint → can rotate and translate; two degrees of freedom; may offer too much freedom for single joint [MAYBE]
Planar joint → gliding joint; can rotate plus translate in two directions; three degrees of freedom; may offer too much movement for a single joint [MAYBE]

Row 5, guiding multiple cannulas:
Multiple guide tubes on single base → restricts movement of individual guide tubes to certain areas on the base; conserves space with using only one base; possibly more limiting to leg access [YES, circumstances]
Single guide tube on multiple bases → allows full movement of the guide since it does not interfere with other guides; multiple bases may take up too much space [YES, circumstances]
Multiple guide tubes on multiple bases → offers most flexibility with amount of area covered; most amount of equipment required [YES, circumstances]

Row 6, guiding varied diameter cannulas:
Modular guide tube inner diameter sizes → offers most flexibility to handle different sized cannulas; gives the surgeon more choice; swapping guide tubes may be difficult if mechanism is not strong [YES]
Adjustable inner diameter on guide tube → adjustability feature may be challenging to implement; would require an extra locking technique [NO]
Separate full base structures → most amount of equipment required; unnecessary and wasteful [NO]

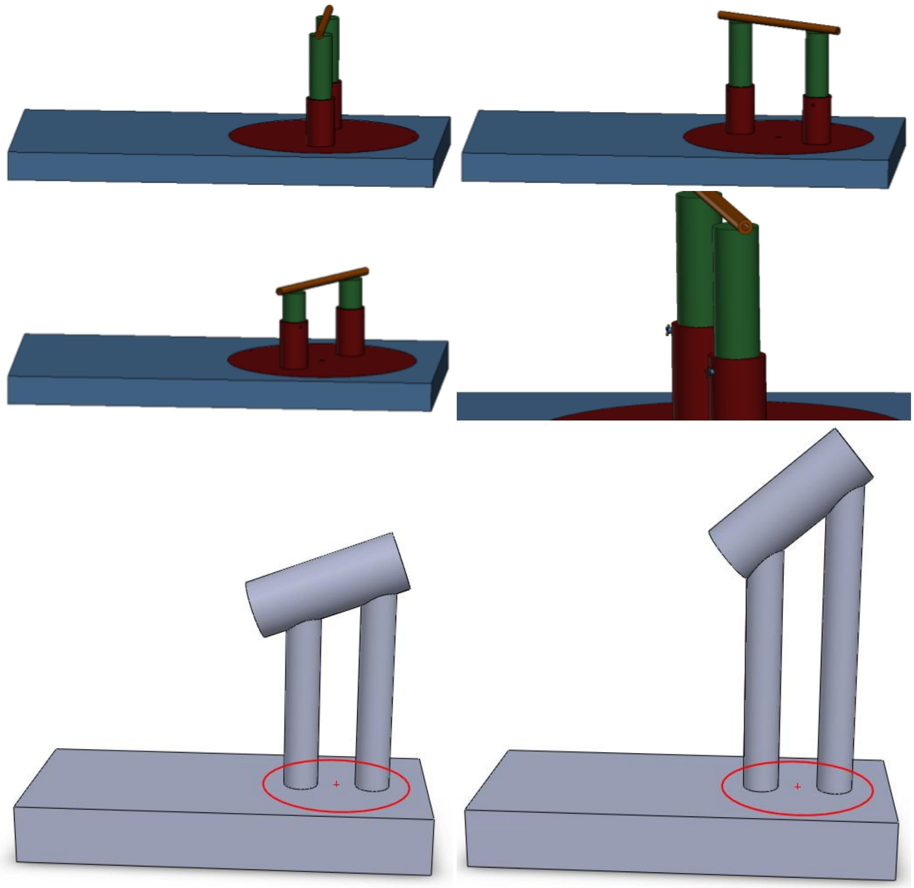
Row 7, not interfering with leg surface:
Modular guide tube total length → too many different combinations of leg sizes (heights) to be suitable [NO]
Slotted guide tube which can slide toward and away from leg → easy to adapt to leg sizes per patient [YES]
Having multiple starting positions for the guide which can reach same end point in leg → gives surgeon multiple options for positioning the guide tube; may complicate the relationship between starting point and ending point by adding more combinations; may be difficult to define a specific starting point with a corresponding ending point [MAYBE]

Row 8, measuring angle and position of guide:
Numbers written at intervals → easy to see what angle is chosen; important to give an exact number value at some location; not good for small areas [YES]
Tick marks to indicate measures → good for use in small places; may be difficult to read all measurements; need to combine with numbers [YES]
Electronic readout → easy to read what angle is chosen; extra electronics system is needed [NO]
Level tool, accelerometer (gravimeter) → requires proper calibration; simple measurement tool only needed; widely available [YES]

Row 9, adjusting position of guidance tube in (3) planes:
Linear movement along length of leg (x-axis only) → movement in one plane; simple; combine with other [YES, must be combined with others]
Circumferential movement over width of leg (y-axis only) → movement in one plane; combine with other [YES, must be combined with others]
Pitch adjustment into leg (z-axis only) → movement in one plane; necessary for angled entry in leg; combine with other methods [YES, must be combined with others]
Rotational movement → 360° movement but in one plane; combine with other techniques; may add too many angle/position combinations [MAYBE]
Hinged motion; swinging hinge → simple motion; helps to bend for the pitch adjustment; allows bending in one plane [MAYBE, circumstances]
Combined rotational and pitch movement → many combinations of movement in a single joint; may be difficult to measure as a single entity [YES, but includes already 2 standard options of motion]
Gimbal → permits bending in all planes; difficult to implement; may not be necessary [MAYBE]

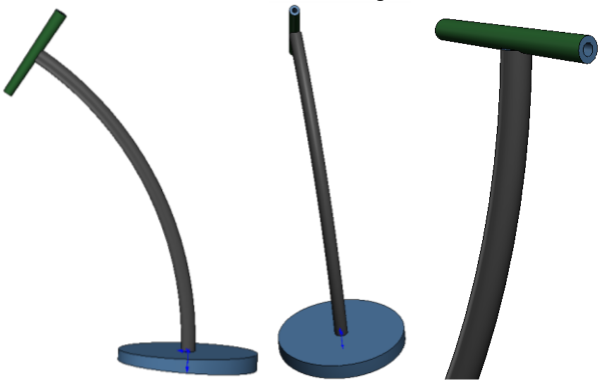
Function mechanism combinations from reduced morphological table

1. **<u>Concept 1: stationary rotational guide</u>**
    a. Positioned on the table
    b. Stationary guide with rotating base;
        i. (On rails to slide the full length of leg);
    c. Adjustable pitch to enter top of leg
    d. Additional base to access other side of leg
        i. (Reposition same 1 base)
        ii. (Set up 2 bases)
    e. Suction cup to the table
        i. (Adhesive to the table)
        ii. (Place under weight of patient)
    f. Movement of rotational base
        i. 1 loose plate that can spin on top of 1 fixed plate
        ii. 1 fixed plate that is sandwiched by 2 loose plates that can spin
    g. Movement of pitch adjustment
        i. 2 sets of tubes within a tube, both can adjust height level
        ii. 2 sets of tubes within a tube, only one can adjust height level
    h. Locking rotational movement of base in place
        i. Pins through interval holes inserted from top
        ii. Pin that comes from bottom of spinning plate after pushing a button
        iii. Friction or squeezing plates together
    i. Locking of pitch of guide in place
        i. Quick release clamp
        ii. Pinch bolt
    j. Specific mechanical joints not necessary
    k. Guidance of multiple cannulas requires separate full bases
        i. Larger base with multiple rotational plates
    l. Different diameter cannulas require modular guide tubes
    m. Reading angle measurements
        i. On rotational plate numbers and/or tick marks at interval holes
        ii. On pitch adjustment a gravimeter/level balancer

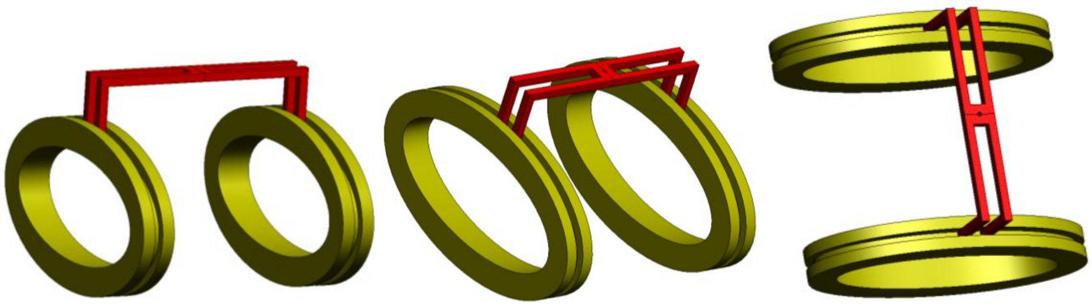


*****Note: "Bottom rotating plate" assembly cannot rotate**

2. **Concept 2: Flexible guide**
    a. Positioned on the table
    b. Mounted on a flexible arm (like desk lamp)
    c. Additional base to access other side of leg
        i. (Flexible arm can bend “backwards” to reach far side of leg)
    d. Anchored to table with suction cup
        i. (Base set up on rails, sliders)
    e. Locking the guide in position can be done with friction and inertia
    f. Measure the angle with level tool on guidance tube
    g. No specific mechanical joints needed – only flexible tube
    h. Guiding multiple cannulas with multiple flexible tubes on a single base
        i. Multiple bases with multiple flexible tubes
    i. Modular diameter guide tube can be swapped in and out



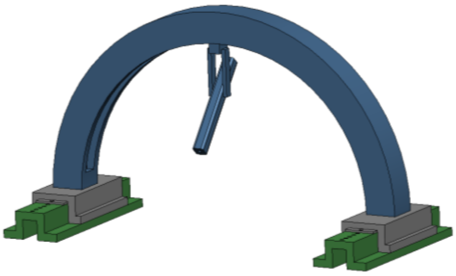
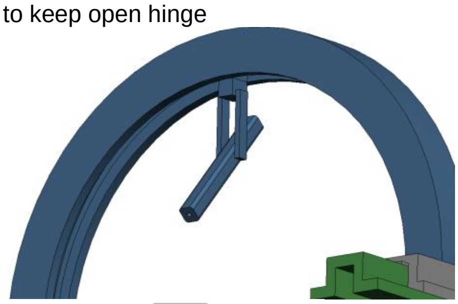
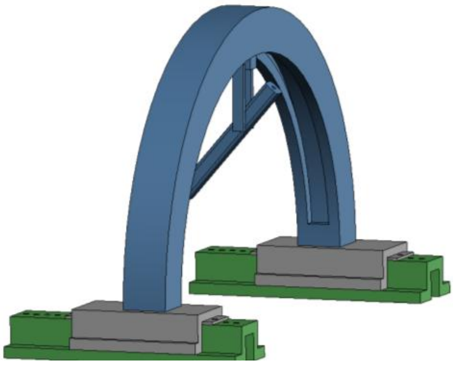
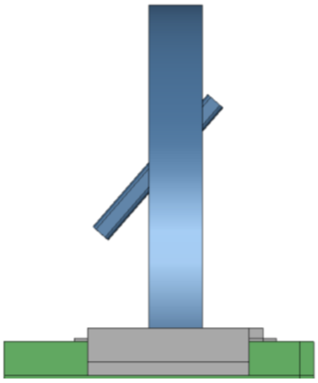
3. **Concept 3: Leg wrap U**
    a. Positioned around patient leg
    b. Velcro [NL: klittenband] straps around both top and bottom part of leg
    c. Stiff (double) U-shape can connect between the Velcro wraps (and have central circle joining the 2 U-shapes)
        i. Arm can rotate around leg circumference (with a handle)
        ii. A guide tube can hang from the central circle
    d. Hinge where guide tube meets arm, U-arm, central circle
        i. Ball and socket
    e. Guide tube could slide (up and down) to allow for different sized legs
    f. Locking U-shape in place with clamps, (like a ski boot)
    g. Measure angle using gravimeter on guide tube



4. **Concept 4: Leg wrap flexible**
    a. Positioned around patient leg
    b. Velcro straps only around top or bottom part of leg to increase accessible space
    c. Flexible arm can be mounted to Velcro wrap
    d. Hinge where guide tube meets flexible arm
    e. Flexible arm can be locked from its own stiffness

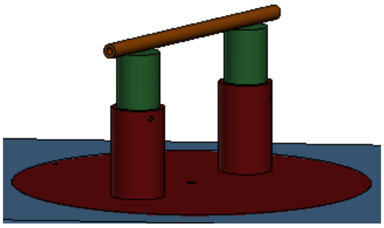
5. **Concept 5: Arc on table**
    a. Positioned on table
    b. Base mounted on rail system running length of leg
    c. Guide attached to arc that spans the width of leg
        i. Arc attached to rails
        ii. (Arc can be curved formation or straight like goal posts)
    d. Rails attached on table with adhesive
    e. Guide connected by hinge to roller which can roll along arc formation

f. Roller can be locked in place with pin through holes
    i. Friction needed to stop rotation of roller
    ii. Internal plunger (with grooves) can be activated by pushing/pulling/tightening a switch
g. Arc on slider can be locked with pins through holes
h. [Guide tube can be slotted on side so it can slide up and down to compensate for different sized height of legs]
    i. Locking mechanism on slider needs to apply friction
i. Guide tube can be modular for different diameter cannulas
j. Multiple guide tubes can be set up on same arc
    i. Multiple arcs can be set up at same time, also with multiple arcs
k. Angle measurement done with numbers and tick marks on large arc
    i. Guide tube can use smaller tick marks or a gravimeter
    ii. Railings can have measurements like a ruler
l. [Arc can be hinged on the rails so that it can bend]
    i. Hinge would need to lock in place; pin through and clamp the center shaft of hinge to prevent rotation
    ii. Pin with flanges to keep open hinge

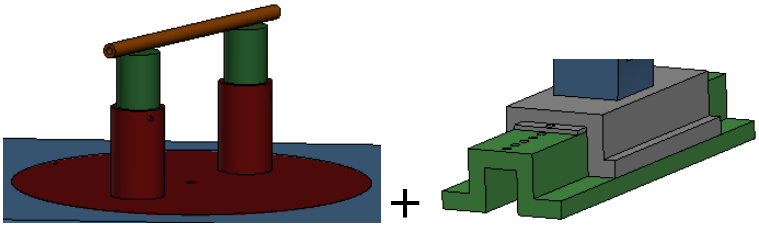





Design variations

Concept 1



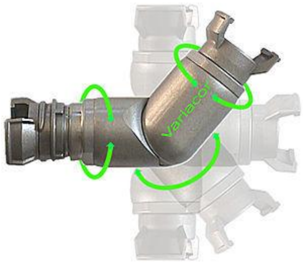
Rotating base with single attachment point under base. No elongated base under patient leg

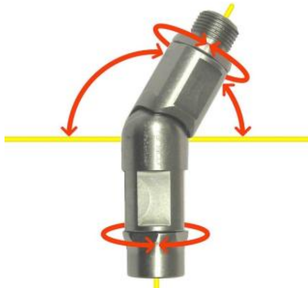


Rotating base mounted on rail system with attachment point under base. No elongated base under patient leg.

Concept 2

Variacor

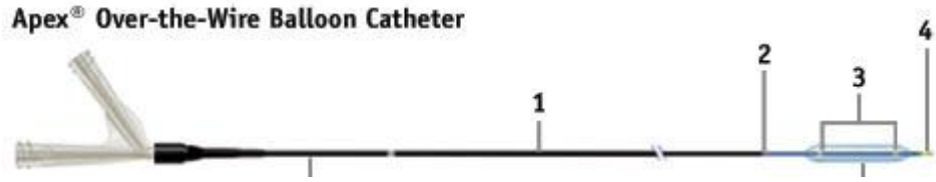




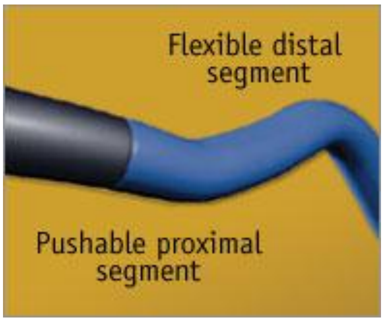
Freely adjustable coupling for fire hose

Hydraulic adjustable rotary union

Boston Scientific catheters



Slope Outer Shaft smoothly transitions from stiff to flexible, all in one piece, for more efficient push transmission

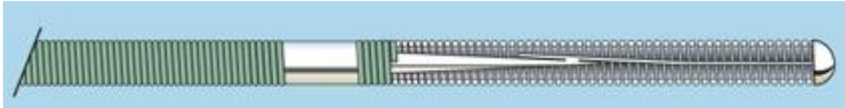


Bi segmented inner shaft provides flexible and stiff segments

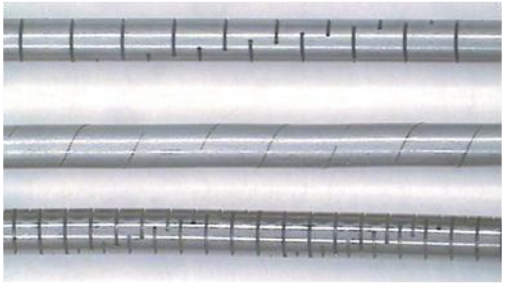
<u>AngioDynamics catheters</u>

Unique tip weld transitions smoothly and securely from stiff shaft to flexible tip

<u>Cook Medical</u>

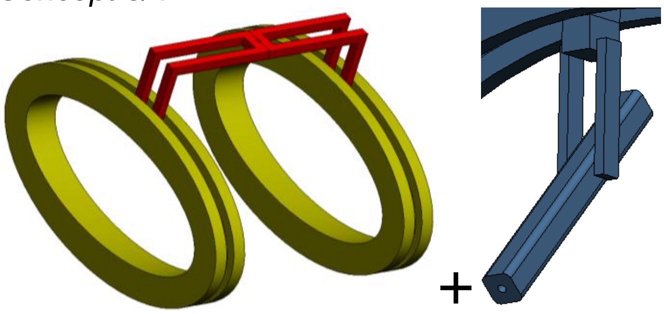


The wire guide has a stiff shaft and a gradual transition to a very flexible distal tip

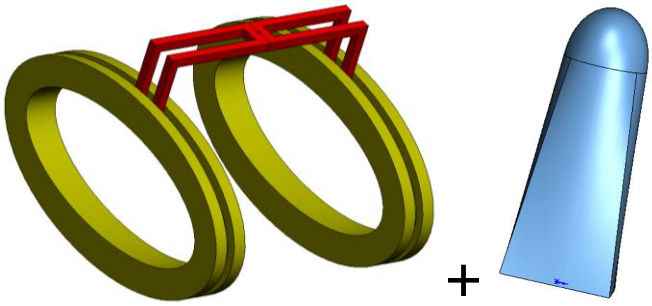


Flexible and stiff metal shafts which perform best: Braided shaft, slotted metal shaft, laser profiled shaft
Patterns that improve flexibility

Concept 3/4



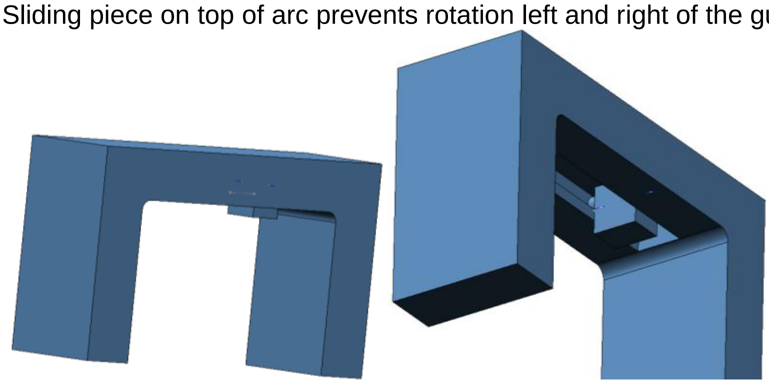
Guidance tube hangs from hole in center of U-arm



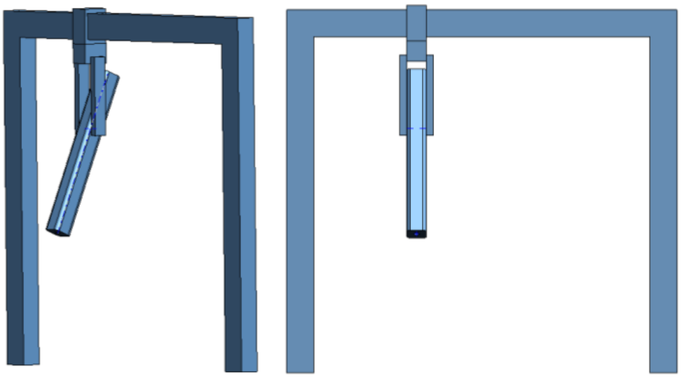
Guidance tube hangs from hole in center of U-arm and includes a ball and socket joint

Concept 5

Sliding piece on top of arc prevents rotation left and right of the guidance tube and roller block

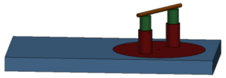
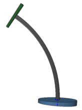
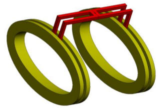
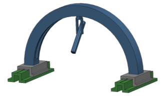


Or the straight arc …With rollers



…With sliding cover over the arc

Table 3A: Evaluation of the 4 main designs

		Concept 1 		Concept 2 		Concept 3 		Concept 4 	
Evaluation criteria	Weight (1-5, with 5 being most important)	Score (1-5, with 5 being best)	Total score	Score (1-5, with 5 being best)	Total score	Score (1-5, with 5 being best)	Total score	Score (1-5, with 5 being best)	Total score
1	5	3	15	4	20	3.5	17.5	5	25
2	5	3.5	17.5	3.5	17.5	3	15	4	20
3	5	4.5	22.5	1.5	7.5	3	15	4	20
4	4	3	12	4	16	3	12	4.5	18
5	4	3.5	14	4	16	3	12	3	12
6	4	3.5	14	2.5	10	3	12	5	20
7	3.5	4	14	4	14	3	10.5	4	14
8	3	3.5	10.5	4.5	13.5	4	12	2.5	7.5
9	3	2.5	7.5	2.5	7.5	2	6	4.5	13.5
10	2	2.5	5	3.5	7	3	6	2	4
11	2	2.5	5	3	6	4	8	2	4
Final Score			**137**		**135**		**126**		**158**

1. How well does the device (as a single base) provide access to all parts of leg?
2. How easily is the base of the guide stabilized?
3. How likely is the chosen position, once locked, able to stay at that position?
    a. Does not slip
    b. How stable is the device once it is locked?
4. How easy is it to adjust the device and move the device in different positions?
5. How well can it be determined where the cannula enters the leg based on the initial guidance tube position?
6. How easy is it to determine what initial position the guide is set at? [coordinates or angles]
7. Does the device cause the patient discomfort?
8. How quickly can the joints be locked and unlocked and how loose or stiff is the device to adjust?
9. How easy is it to guide multiple cannulas?
10. How many joints are there? Movable parts and total parts?
11. How well does device accommodate for sterilization sheets on the procedure table?

Evaluation Scores Justifications

Note: The numbers correspond to the evaluation criteria

Concept 1: Rotating base

1. Device can provide access to 2 sides of a leg, not 3. But access to those 2 sides is good.
2. Base is held in place mainly by putting the extended piece under the leg of the patient. Can also be combined with other adhesive measures.
3. There are several mechanisms to hold the position in place. On the rotating disk is a pin and on the tubes controlling the height, there are pinch bolts
4. Easy to rotate the spinning part of the base, but may take time to adjust the tubes within tubes to get it in the desired position.
5. From the rotating platform and pitch adjustment of the guide tube, a trajectory can be made
6. Easy to know the positions based on the rotation and adjusting the tube within tube. But it cannot incorporate positional information for the third side of the leg.
7. The base platform sits under the patient leg. May cause slight discomfort.
8. System has several locks with the most time demanding being pinch bolts that need to be turned tight
9. On a single base it is difficult to add multiple cannulas, but several bases can be added together
10. There are several moveable and rotating parts.
11. Device may interfere with sterile sheets if it uses adhesives, but part of base is placed under leg which can be good enough for stabilizing purposes.

Concept 2: Bendable shaft

1. Device can provide access to 3 sides of leg, but depends on length and reach of flexible arm
2. Base is held in place at a single location, with adhesive material under the platform.
3. Uses its own stiffness and static balancing to maintain held position. Can also incorporate a crutch or test tube grasper to maintain bent position
4. Very easy to adjust a flexible arm. It reacts very logically. But the base may need to be relocated if the arm is not long enough to reach all parts of the leg.
5. The guide tube can be stretched/flexed to a position close to the leg surface.
6. Difficult to determine orientation in space. Difficult to set up a system for recognizing positions.
7. Under normal circumstances, the guide does not make contact with patient leg
8. There are no joints to lock in position, unless the base is moved to a different spot or the flexible arm is held by a grasper.
9. Extra guide tubes can be placed on a single base with flexible arm, but additional bases can also be used to reach other areas of the leg
10. Device does not have many moveable parts. Mainly the flexible arm.
11. Device has a small base that can be located at various parts of the table. It can be secured at a suitable location, but may have limited options for its usage of adhesives.

Concept 3: U- leg wrap

1. Device can provide access to most parts of leg, but straps around leg block those areas for treatment
2. Base is stabilized on patient leg. Depends on tightness around leg and movement of patient.
3. Guide tube can be locked as a rotating joint, and the red U-bars can be stopped in position with blocks.
4. Easy to rotate the U-bars and adjust the guide tube, but straps around leg may block access to the desired location.
5. Tube can rotate around leg and also adjust its pitch. May be difficult to know exact position without additional help
6. The guide can show at what rotation around the leg it is, but cannot show at which length along the leg it is.
7. The device is strapped around the patient's leg. It may cause some discomfort.
8. Locking does not take much time as the U-bar needs to be stopped in position and then the guide tube needs to be locked
9. The guidance system is strapped on the leg in one location so adding more bases is not possible, but having multiple guide tubes on the single base is also challenging

10. Device has moveable parts with the U-bar and the guide tube. The base is not normally moved often.
11. Device is attached to leg so it avoids interference with sterile sheets

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Concept 4: Arc shape

1. Device can provide access to all parts of leg via a single base
2. Base (rails) is stabilized on adhesives, but additionally is locked in place by pins at the sliding portion
3. There are several locks in the design. Locks on the rails, lock to hold the guide in place along the arc, and for the guidance tube itself a lock on rotation
4. Device can be easily moved along leg length on the rails. It can be adjusted along the width of the leg by the arc movement. The pitch can be adjusted on the guide tube.
5. The distance between the guide tube and leg varies with the tube position. Angle and position markers help to determine where the cannula ends up.
6. The labeling system on the device is simple to understand. It has angle and position markings in all directions (x,y,z)
7. Device should not make contact with patient leg. If guide tube is too long it may contact the leg, but the guide can be adjusted in another direction to compensate
8. The design has at least 4 locks, but most are of simple design which does not take too long to do.
9. Multiple guide tubes can be added along arc easily to access more parts of leg. More bases can easily be added to the rails too.
10. Device consists of many moveable parts and joints.
11. Device uses system of rails that need to be attached on the table surface. This can pose difficulties for securing the base.

Appendix B: MATLAB analysis

MATLAB code

```
clc
clf
close all
clear all

% In solidworks model the axis is different
than in matlab. In matlab the
% x coordinate is along the length of the leg,
which corresponds to z in
% solidworks...In matlab the z coordinate is
the height, which corresponds
% to y in solidworks. In matlab the y
coordinate is the width across the
% leg, which corresponds to x in solidworks.

syms beta gamma
syms x

% Leg coordinates
r_b = 15; %bone radius
n_b = 20; %points around bone circumference
[y_b,z_b,x_b] = cylinder(r_b,n_b); %create
shape of bone as cylinder
x_b(2, :) = 300; %make the length of bone 300

r_l = 50; % leg radius
n_l = 40; % points around leg circumference
[y_l,z_l,x_l] = cylinder(r_l,n_l); % create
shape of leg as cylinder
x_l(2,:)=300; %make the leg length 300


%Fibrous tissue location
FT=[0; 0; 0; 1]; % extra 1 in the fourth
dimension used for translation and rotation
purposes later on
%coordinates of guidance tube
x_t=[FT(1);FT(1)+15];
y_t=[FT(2);FT(2)+ r_l];
z_t=[FT(3);FT(3)+23];
FT_end = [x_t(2); y_t(2); z_t(2); 1]; %
coordinate at ending point; only used for
geometric reference
GT = 30; % length of guidance tube from exit
point to connection point

figure(1)
subplot(221)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3(x_t,y_t,z_t,'r'); hold on % plots the
guidance tube and holds it on graph
title('Used for calculating angles')
xlabel('x')
ylabel('y')
zlabel('z')
grid on % turns on grid
axis square % squares the axes
axis equal % makes axes same size

subplot(222)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3(x_t,y_t,z_t,'r'); hold on; % this makes
guidance tube. needed to separate the plot3
commands so the linewidth can be different
title('Side view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([0 0]) % zx side view
axis square % squares the axes
axis equal % makes zx axis same length

subplot(223)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3(x_t,y_t,z_t,'r'); hold on % plots the
guidance tube
title('Top view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 90]) % yx top view
axis square % squares the axes
axis equal % makes yx axis same length

subplot(224)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3(x_t,y_t,z_t,'r'); hold on % plots the
guidance tube
title('Cross-sectional view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 0]) % yz front view
axis square % squares the axes
axis equal % makes yz axis same length
%%
% calculating length of needle in leg from
fibrous tissue location (origin/reference
point) to connector point

% Use the view in the xz plane to start
 % the angle used is beta and corresponds to
the pitch angle of the guidance tube
 % also corresponds to a rotation around the y-
axis
tube_sxz = (x_t(2)-x_t(1)) / sin(beta); %
pythagorean relationship using angle from
vertical
tube_cxz = (z_t(2)-z_t(1)) / cos(beta); %
pythagorean relationship using angle from
vertical
% tube_sxz = tube_cxz;
% (z_t(2)-z_t(1)) = (x_t(2)-x_t(1))*
sin(beta)/cos(beta) % rearranging variables
with algebra

% Now let's calculate the angles using the
made-up endpoints. The fibrous
% tissue starting location is only known but
not the actual endpoint.
% However, the angle will be the same as long
as the trajectory is kept
% consistent

beta = atan( (x_t(2)-x_t(1)) / (z_t(2)-z_t(1))
); % calculating the angle beta and rearranging
the geometric equation
beta_deg = beta*180/pi

% Use the view in yz plane next
```

```
 % the angle used is gamma and corresponds to the position of the guidance tube around the arc
 % also corresponds to a rotation around the x-axis
tube_syz = (y_t(2)-y_t(1)) / sin(gamma); % pythagorean relationship using angle from vertical
tube_cyz = (z_t(2)-z_t(1)) / cos(gamma); % pythagorean relationship using angle from vertical
% tube_syz = tube_cyz;
% (z_t(2)-z_t(1)) = (y_t(2)-y_t(1))* sin(gamma)/cos(gamma) % rearranging variables with algebra

gamma = atan( (y_t(2)-y_t(1)) / (z_t(2)-z_t(1)) ); % calculating the angle gamma and rearranging the geometric equation
gamma_deg = gamma*180/pi

% further substitutions can be made to write the variables
    % (z_t(2)-z_t(1)) = (x_t(2)-x_t(1)) / tan(beta) % note: tan(beta) = sin(beta)/cos(beta)
    % (z_t(2)-z_t(1)) = (y_t(2)-y_t(1)) / tan(gamma) % note: tan(gamma) = sin(gamma)/cos(gamma)
    %...follows that: (x_t(2)-x_t(1)) / tan(beta) = (y_t(2)-y_t(1)) / tan(gamma)
    % and to write in terms of x: (y_t(2)-y_t(1))=(tan(gamma)*(x_t(2)-x_t(1)))/tan(beta)

% using the relationships in the 2D projections, the 3D case can be written with the distance formula
 % sqrt(x^2 + y^2 +z^2)
% this formula can be written all in terms of x with the relationships derived above with the projections

% Create the 3D distance formula
X = x_t(2)-x_t(1); % x2 is not known so it needs to be solved for in the distance equation
Y = (tan(gamma)*(X))/tan(beta); % y distance written in terms of x
Z = (X)/tan(beta); % z distance written in terms of x
Length = rat(sqrt((X)^2 + (Y)^2 + (Z)^2)) % written with only X, actual length of segment in figure 1

% Now let's solve for the endpoint (x2) now that we calculated the beta and
% gamma angles previously. Substitutions have been made so that only one
% variable is used (x) and it is in the form as above
Length2 = sqrt((x-x_t(1))^2 + ((tan(gamma)*(x-x_t(1)))/tan(beta))^2 +((x-x_t(1))/tan(beta))^2) % distance formula written with unknown x variable angles from calculation above

% solve for x (end point) while substituting "known" length for guidance path
% x = Length = Length2
[x] = solve('57 + 1/(23 + 1/(-5)) = ((3254*x^2)/225)^(1/2)') % uses result from Length2 since solve function can't handle extra variables or fill them in, and solves for x2 (ending point)
x_dec = double(x) % converts the above solution in decimal form

% Ending coordinates
x2 = (x(1))
y2 = ((tan(gamma)*(x2-x_t(1)))/tan(beta)) + y_t(1)
z2 = ((x2-x_t(1))/tan(beta)) + z_t(1)

% Translation matrix
dx = -FT(1); dy = -FT(2); dz = -FT(3); % Translate fibrous tissue (starting point) to origin
T = [1 0 0 dx; 0 1 0 dy; 0 0 1 dz; 0 0 0 1]; % translation matrix written for column vectors, will move starting point to origin (0,0,0)
Tt = [1 0 0 -dx; 0 1 0 -dy; 0 0 1 -dz; 0 0 0 1]; % undoes the translation that moved the object to the origin.
%% Fibrous tissue at origin. Using previous cell information to calculate 3D angles from the 2D planes

% Calculating the [x';y';z'] coordinates
% [x2;y2;z2]=Rx*Ry*[x;y;z]; with this equation need to solve for beta and
% gamma in the rotation matrices. All coordinates are known.
% [x;y;z]=[0;0;length]

syms beta gamma

% Create (symbolic) rotation matrix to represent guidance tube rolling around the arc and also changing its pitch angle
% IMPORTANT NOTE: Rx matrix has negative sign on the second sin(beta). This is opposite to the right-hand convention, but due to the geometry of the
% device this is how the movements are in practice.
Rx = [1 0 0 0; 0 cos(gamma) sin(gamma) 0; 0 -sin(gamma) cos(gamma) 0; 0 0 0 1]; % Rotation matrix around x-axis (angle gamma) roll around arc; added extra row to include translation information
Ry = [cos(beta) 0 sin(beta) 0; 0 1 0 0; -sin(beta) 0 cos(beta) 0; 0 0 0 1]; % Rotation matrix around y-axis (angle beta) pitch angle; added extra row to include translation information;
R = Rx*Ry % combined rotations to act as single matrix
%Rz = [cos(beta) -sin(beta) 0 0; sin(beta) cos(beta) 0 0; 0 0 1 0; 0 0 0 1];


% R =
%
% [              cos(beta),           0,              sin(beta), 0]
% [ -sin(beta)*sin(gamma),  cos(gamma),  cos(beta)*sin(gamma), 0]
% [ -cos(gamma)*sin(beta), -sin(gamma),  cos(beta)*cos(gamma), 0]
% [                     0,           0,                      0, 1]

% x2 = cos(beta)*x + 0*y + sin(beta)*z
% y2 = -sin(beta)*sin(gamma)*x + cos(gamma)*y + cos(beta)*sin(gamma)*z
% z2 = -cos(gamma)*sin(beta)*x + -sin(gamma)*y + cos(beta)*cos(gamma)*z

% beta is y and gamma is z
% This gives the rotation angles for the device when Rx*Ry is used

[betaR,gammaR] = solve('(32515*3254^(1/2))/123652 = cos(y)*0 + 0*0 + sin(y)*(57 + 1/(23 + 1/(-5)))',...

'(162575*3254^(1/2))/185478 = -sin(y)*sin(z)*0 + cos(z)*0 + cos(y)*sin(z)*(57 + 1/(23 + 1/(-5)))')

betaR_deg=double(betaR*(180/pi))
```

```
gammaR_deg=double(gammaR*(180/pi))

% Now using these calculated degrees, they
should be substituted back into
% the matrix to plot the rotation of the
guidance path
% Since there are 4 sets of angles, the correct
pairings need to be found

Rx = [1 0 0 0; 0 cos(gammaR(1)) sin(gammaR(1))
0; 0 -sin(gammaR(1)) cos(gammaR(1)) 0; 0 0 0 1]
% Rotation matrix around x-axis (angle gamma)
roll around arc; added extra row to include
translation information
Ry = [cos(betaR(1)) 0 sin(betaR(1)) 0; 0 1 0 0;
-sin(betaR(1)) 0 cos(betaR(1)) 0; 0 0 0 1] %
Rotation matrix around y-axis (angle beta)
pitch angle; added extra row to include
translation information;

R = [                cos(betaR(1)),
0,               sin(betaR(1)), 0;
      -sin(betaR(1))*sin(gammaR(1)),
cos(gammaR(1)), cos(betaR(1))*sin(gammaR(1)),
0;
      -cos(gammaR(1))*sin(betaR(1)), -
sin(gammaR(1)), cos(betaR(1))*cos(gammaR(1)),
0;
                                  0,
0,                            0, 1;]

% Rotating the guidance tube with the given
length
Rot_t = Rx*Ry*[0; 0; (57 + 1/(23 + 1/(-5))); 1]
% the tube being rotated from vertical
position, the full distance of the tube in z-
coordinate
Rot_t2= R*[0; 0; (57 + 1/(23 + 1/(-5))); 1] %
uses combined matrix

% Starting position of guidance tube in
vertical position [0; 0; length]
Start=[x_t(1); y_t(1); (57 + 1/(23 + 1/(-5)))];
% coordinates of the starting vertical position
of guidance tube

figure(2)
subplot(221)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_t2(1)], [y_t(1) Rot_t2(2)],
[z_t(1) Rot_t2(3)], 'b'); hold on % plots the
rotated guidance tube and holds it on graph
title('Used for calculating angles')
xlabel('x')
ylabel('y')
zlabel('z')
grid on % turns on grid
axis square % squares the axes
axis equal % makes axes same size

subplot(222)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_t2(1)], [y_t(1) Rot_t2(2)],
[z_t(1) Rot_t2(3)], 'b'); hold on % plots the
rotated guidance tube and holds it on graph
title('Side view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([0 0]) % zx side view
axis square % squares the axes
axis equal % makes zx axis same length

subplot(223)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_t2(1)], [y_t(1) Rot_t2(2)],
[z_t(1) Rot_t2(3)], 'b'); hold on % plots the
rotated guidance tube and holds it on graph
title('Top view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 90]) % yx top view
axis square % squares the axes
axis equal % makes yx axis same length

subplot(224)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_t2(1)], [y_t(1) Rot_t2(2)],
[z_t(1) Rot_t2(3)], 'b'); hold on % plots the
rotated guidance tube and holds it on graph
title('Cross-sectional view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 0]) % yz front view
axis square % squares the axes
axis equal % makes yz axis same length
%% Add in connector joint, block leading to
arc, and arc

% Calculate perpendicular line which
corresponds to the connection joint on the
guidance tube
CJ = [[0; -7.5; Start(3); 1], [0; 7.5;
Start(3); 1]]; % These are the coordinates of
the line representing the perpendicular
connection joint. The first row matrix is the
"left half" of the line and the second row
matrix is the "right half", and z-coordinate
total length in vertical position
```

```
CJ_R = Rx*Ry*CJ; % the joint rotates with the
guidance tube


% Calculate the block piece above the connector
joint (CJ)
Bhb = 10; % length of block piece below CJ
Bha = 50; % length of block piece above CJ
BP_l = [[0; CJ(2,1); Start(3)-Bhb; 1], [0;
CJ(2,1); Start(3)+Bha; 1]];
BP_r = [[0; CJ(2,2); Start(3)-Bhb; 1], [0;
CJ(2,2); Start(3)+Bha; 1]];
BP_l_R = Rx*BP_l; % left side of the block
piece being rotated about x-axis for roll
BP_r_R = Rx*BP_r; % right side of the block
piece being rotated about x-axis for roll


% Creating the arc, the main structure that
connects to the block piece
    % equation of a circle: x^2 + y^2 = r

angle_arc= 0:pi/20:pi; % the arc should extend
the top half of the leg
radius_arc = 150;
y_arc = radius_arc*cos(angle_arc); % the y-
coordinates are functions of the radius and an
angle
z_arc = radius_arc*sin(angle_arc);
x_arc = CJ(1)*ones(size(angle_arc)); % the x-
coordinate of the arc while it is set at the
reference condition
x_arcR = CJ_R(1)*ones(size(angle_arc)); % the
x-coordinate is set along the length of the leg
and is the same as the connector joint x
coordinate, this is after rotation

% Calculate the slider. This is the piece that
attaches onto the actual arc and slides along
it.
% This piece also hangs below the arc and is
attached to the BP block piece
Shb = 8; % start below the block piece
Sha = 4; % amount above the arc
SL_l = [[0; BP_l(2,1); BP_l(3,2)-Shb; 1], [0;
BP_l(2,1); radius_arc+Sha; 1]]; % starts  below
the "block piece" and attaches to the arc. It
fits in between the 2 pieces BP_l and BP_r
SL_r = [[0; BP_r(2,1); BP_r(3,2)-Shb; 1], [0;
BP_r(2,1); radius_arc+Sha; 1]]; % right side of
slider
SL_t = [[0; SL_l(2,1); SL_l(3,2); 1], [0;
SL_r(2,2); SL_r(3,2); 1]]; % top part of slider
SL_b = [[0; SL_l(2,1); SL_l(3,1); 1], [0;
SL_r(2,2); SL_r(3,1); 1]]; % bottom part of
slider
SL_v = [SL_l, SL_r]; % the vertical portion of
the slider
SL_h = [SL_t, SL_b]; % the horizontal portion
of the slider
SL_v_R = Rx*SL_v; % rotated vertical portion,
only roll no pitch
SL_h_R = Rx*SL_h; % rotated horizontal portion,
only roll no pitch


figure(3)
subplot(221)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in reference position before the guidance
tube is rotated
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Used for calculating angles')
xlabel('x')
ylabel('y')
zlabel('z')
grid on % turns on grid
axis square % squares the axes
axis equal % makes axes same size

subplot(222)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
```

```
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in reference position before the guidance
tube is rotated
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Side view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([0 0]) % zx side view
axis square % squares the axes
axis equal % makes zx axis same length

subplot(223)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in reference position before the guidance
tube is rotated
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Top view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 90]) % yx top view
axis square % squares the axes
axis equal % makes yx axis same length

subplot(224)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1) Start(1)],[y_t(1)
Start(2)],[z_t(1) Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in reference position before the guidance
tube is rotated
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Cross-sectional view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 0]) % yz front view
axis square % squares the axes
axis equal % makes yz axis same length
%% Create new set of guidance lines
% Fibrous tissue not at origin, translate after
rotation

syms x
```

```
%Fibrous tissue location
FT=[15; 10; 7; 1]; % extra 1 in the fourth dimension used for translation and rotation purposes later on
dx = -FT(1); dy = -FT(2); dz = -FT(3); % Translate fibrous tissue (starting point) to origin

%coordinates of guidance tube, not translating it to origin
x_t=[FT(1);FT(1)*3]; % the "test" path is starting at the fibrous tissue location and then triples in length linearly
y_t=[FT(2);FT(2)*3];
z_t=[FT(3);FT(3)*3];

T = [1 0 0 dx; 0 1 0 dy; 0 0 1 dz; 0 0 0 1]; % translation matrix written for column vectors, will move starting point to origin (0,0,0)
Tt = [1 0 0 -dx; 0 1 0 -dy; 0 0 1 -dz; 0 0 0 1]; % undoes the translation that moved the object to the origin.


% Use the view in the xz plane to start
    % the angle used is beta and corresponds to the pitch angle of the guidance tube
    % also corresponds to a rotation around the y-axis

% Now let's calculate the angles using 2 points along the path. In this case one the origin is still used along with the fibrous tissue location or another on the trajectory.
% IMPORTANT to note: The end point can be extended and the angle will be unchanged as long as the trajectory is kept consistent

% substituting x_t(1)=0 and x_t(2)=x_t(1), etc... will have no effect on the angle in 2D
% ANGLES are the same regardless of x2-x1 or x1-0!!!

beta = atan( (x_t(2)-x_t(1)) / (z_t(2)-z_t(1)) ); % calculating the angle beta and rearranging the geometric equation
beta_deg = beta*180/pi

% Use the view in yz plane next
 % the angle used is gamma and corresponds to the position of the guidance tube around the arc
 % also corresponds to a rotation around the x-axis

gamma = atan( (y_t(2)-y_t(1)) / (z_t(2)-z_t(1)) ); % calculating the angle gamma and rearranging the geometric equation
gamma_deg = gamma*180/pi


% using the relationships in the 2D projections, the 3D case can be written with the distance formula
 % sqrt(x^2 + y^2 +z^2)
% this formula can be written all in terms of x with the relationships derived above with the projections

% Create the 3D distance formula
    % Use one combination of X for the segment length. Each length is different!!

%X = x_t(2)-x_t(1); % length of segment between the stated end point of the guidance path and fibrous tissue
X = x_t(2)-0; % length of segment between stated end point of the guidance path and the origin
%X = x_t(1)-0; % length of segment between the fibrous tissue location and origin
Y = (tan(gamma)*(X))/tan(beta); % y written in terms of x
Z = (X)/tan(beta); % z written in terms of x
Length = rat(sqrt((X)^2 + (Y)^2 + (Z)^2)) % written with only X, actual length of segment with given coordinates

% Now let's solve for the endpoint (x2) now that we calculated the beta and gamma angles previously.
% Substitutions have been made so that only one variable is used (x) and it is in the form as above
% Choose either having a length between the "end point" and fibrous tissue, or the "end point" and origin.
% The x will correspond to the length chosen in the formula for "X" and "Length" above
%Length2 = sqrt((x-x_t(1))^2 + ((tan(gamma)*(x-x_t(1)))/tan(beta))^2 +((x-x_t(1))/tan(beta))^2) % distance formula written with unknown x variable angles from calculation above
Length2 = sqrt((x-0)^2 + ((tan(gamma)*(x-0))/tan(beta))^2 +((x-0)/tan(beta))^2) % substituted x_t(1)=0 again, distance formula written with unknown x variable and angles from calculation above

% solve for x (end point) while substituting "known" length for guidance path from above
% x = solve('Length = Length2')
% the total length is the same regardless if translated or not. But must be
% consistent when solving for end points, depending on which "X" used: x_t(2)-0, etc.

[x] = solve('58 + 1/(58) = ((374*x^2)/225)^(1/2)') % uses result from Length2 since solve function can't call variables and requires numbers directly. solves for x2 (ending point)
x_dec = double(x)

% getting the end points of the guidance tube
x2 = (x(1)) % x from above solve function
y2 = (((tan(gamma)*(x2-x_t(1)))/tan(beta))) + y_t(1) % need to add in y_t(1) because this solves for a coordinate y2! And not just the total length this time (y_t(2)-y_t(1)). Need to matchs the coordinate of the "created" end point in the beginning, or must lie on the trajectory of the line
z2 = ((x2-x_t(1))/tan(beta)) + z_t(1)% need to add back in z_t(1) be consistent with using either 0 or x_t(1)


% Create rotation matrix to represent guidance tube rolling around the arc and also changing its pitch angle
% ***IMPORTANT*** NOTE: Rx matrix has negative sign on the second sin(beta). This is not inline with the right-hand convention, but due to the geometry of the device this is how the movements are represented in practice.

syms beta gamma
Rx = [1 0 0 0; 0 cos(gamma) sin(gamma) 0; 0 -sin(gamma) cos(gamma) 0; 0 0 0 1]; % Rotation matrix around x-axis (angle gamma) roll around arc; added extra row to include translation information
Ry = [cos(beta) 0 sin(beta) 0; 0 1 0 0; -sin(beta) 0 cos(beta) 0; 0 0 0 1]; % Rotation matrix around y-axis (angle beta) pitch angle; added extra row to include translation information;
```

```
R = Rx*Ry % combined rotations to act as single
matrix

% R =
%
% [              cos(beta),          0,
sin(beta), 0]
% [ -sin(beta)*sin(gamma),  cos(gamma),
cos(beta)*sin(gamma), 0]
% [ -cos(gamma)*sin(beta), -sin(gamma),
cos(beta)*cos(gamma), 0]
% [                      0,          0,
0, 1]

% x2 = cos(beta)*x + 0*y + sin(beta)*z
% y2 = -sin(beta)*sin(gamma)*x + cos(gamma)*y +
cos(beta)*sin(gamma)*z
% z2 = -cos(gamma)*sin(beta)*x + -sin(gamma)*y
+ cos(beta)*cos(gamma)*z

% beta is y and gamma is z
% This gives the rotation angles on the device
when Rx*Ry is used

% It is still possible to use the origin for
the x and y starting
% coordinates because the rotation angle is the
same according to geometric
% laws with parallel lines. The parallel lines
are the vertical axes that
% pass through the origin and the fibrous
tissue and the bisecting line is the guidance
path.

% however it needs to have x1,y1 = 0 and z1 =
guidance length
[betaR,gammaR] = solve('(50475*374^(1/2))/21692
= cos(y)*0 + 0*0 + sin(y)*(58 + 1/(58))',...
                       '(16825*374^(1/2))/10846
= -sin(y)*sin(z)*0 + cos(z)*0 +
cos(y)*sin(z)*(58 + 1/(58))')

betaR_deg=double(betaR*(180/pi))
gammaR_deg=double(gammaR*(180/pi))


% Now using these calculated degrees, they
should be substituted back into
% the matrix to plot the rotation of the
guidance path
% Since there are 4 sets of angles, the correct
pairings need to be found
% to match

Rx = [1 0 0 0; 0 cos(gammaR(1)) sin(gammaR(1))
0; 0 -sin(gammaR(1)) cos(gammaR(1)) 0; 0 0 0 1]
% Rotation matrix around x-axis (angle gamma)
roll around arc; added extra row to include
translation information
Ry = [cos(betaR(1)) 0 sin(betaR(1)) 0; 0 1 0 0;
-sin(betaR(1)) 0 cos(betaR(1)) 0; 0 0 0 1] %
Rotation matrix around y-axis (angle beta)
pitch angle; added extra row to include
translation information;


% Rotating the guidance tube with the given
length
Rot_t = Rx*Ry*[0; 0; (58 + 1/(58)); 1] -
2*[dx;dy;dz;0]; % the tube being rotated from
vertical position, the full distance of the
tube in z-coordinate
% to keep the same rotation angle and
trajectory, but ONLY extend the guidance path
longer, add the translations AFTER rotation!!
%Rot_trans = Rx*Ry*[-dx; -dy; ((58 + 1/(58))-
dz); 1];

Start=[x_t(1)+dx; y_t(1)+dy; (58 + 1/(58))]; %
coordinates of the starting vertical position
of guidance tube, centered at origin

figure(4)
subplot(221)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube at [0,0,0]
plot3(x_t,y_t,z_t,'b'); hold on % plots the
guidance path with the "created" coordinates
and the rotation needs to match this!
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube starting from the fibrous
tissue location
%plot3([x_t(1) Rot_trans(1)], [y_t(1)
Rot_trans(2)], [z_t(1) Rot_trans(3)],'c'); hold
on
title('Used for calculating angles')
xlabel('x')
ylabel('y')
zlabel('z')
grid on % turns on grid
axis square % squares the axes
axis equal % makes axes same size

subplot(222)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3(x_t,y_t,z_t,'b'); hold on
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_trans(1)], [y_t(1)
Rot_trans(2)], [z_t(1) Rot_trans(3)],'c'); hold
on
title('Side view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([0 0]) % zx side view
axis square % squares the axes
axis equal % makes zx axis same length

subplot(223)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3(x_t,y_t,z_t,'b'); hold on
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_trans(1)], [y_t(1)
Rot_trans(2)], [z_t(1) Rot_trans(3)],'c'); hold
on
title('Top view')
xlabel('x')
ylabel('y')
zlabel('z')
```

```
grid on
view([-90 90]) % yx top view
axis square % squares the axes
axis equal % makes yx axis same length

subplot(224)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3(x_t,y_t,z_t,'b'); hold on
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
%plot3([x_t(1) Rot_trans(1)], [y_t(1)
Rot_trans(2)], [z_t(1) Rot_trans(3)],'c'); hold
on
title('Cross-sectional view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 0]) % yz front view
axis square % squares the axes
axis equal % makes yz axis same length
%% Add in connector joint and block leading to
arc

% Start=[x_t(1)+dx; y_t(1)+dy; (58 + 1/(58))];
% coordinates of the starting vertical position
of guidance tube, centered at origin
% Calculate perpendicular line which
corresponds to the connection joint on the
guidance tube when not starting at origin
% center to center distance between the base of
the joints where the guidance tube changes its
pitch
CJ = [[0; -7.5; Start(3); 1], [0; 7.5;
Start(3); 1]]; % These are the coordinates of
the line representing the perpendicular
connection joint. The first column matrix is
the "left half" of the line and the second
column matrix is the "right half", and z-
coordinate total length in vertical position
CJ_R = Rx*Ry*CJ -2*[dx dx;dy dy;dz dz;0 0];


% Calculate the block piece above the connector
joint (CJ)
Bhb = 10; % length of block piece below CJ
Bha = 50; % length of block piece above CJ
BP_l = [[0; CJ(2,1); Start(3)-Bhb; 1], [0;
CJ(2,1); Start(3)+Bha; 1]];  % the coordinates
of the block piece (left side)
BP_r = [[0; CJ(2,2); Start(3)-Bhb; 1], [0;
CJ(2,2); Start(3)+Bha; 1]];  % and right side
BP_l_R = Rx*BP_l;  % left side of the block
piece being rotated about x-axis then y-axis
BP_r_R = Rx*BP_r;  % right side of the block
piece being rotated about x-axis then y-axis

% Creating the arc, the main structure that
connects to the block piece
    % equation of a circle: x^2 + y^2 = r
angle_arc= 0:pi/20:pi; % the arc should extend
the top half of the leg
radius_arc = 150;
y_arc = radius_arc*cos(angle_arc); % the y-
coordinates are functions of the radius and an
angle
z_arc = radius_arc*sin(angle_arc);
x_arc = CJ(1)*ones(size(angle_arc)); % the x-
coordinate of the arc while it is set at the
reference condition
x_arcR = CJ_R(1)*ones(size(angle_arc)); % the
x-coordinate is set along the length of the leg
and is the same as the connector joint x
coordinate, this is after rotation

% Calculate the slider. This is the piece that
attaches onto the actual arc and slides along
it.
% This piece also hangs below the arc and is
attached to the BP block piece
Shb = 8; % start below the block piece
Sha = 4; % amount above the arc
SL_l = [[0; BP_l(2,1); BP_l(3,2)-Shb; 1], [0;
BP_l(2,1); radius_arc+Sha; 1]]; % starts  below
the "block piece" and attaches to the arc. It
fits in between the 2 pieces BP_l and BP_r
SL_r = [[0; BP_r(2,1); BP_r(3,2)-Shb; 1], [0;
BP_r(2,1); radius_arc+Sha; 1]]; % right side of
slider
SL_t = [[0; SL_l(2,1); SL_l(3,2); 1], [0;
SL_r(2,2); SL_r(3,2); 1]]; % top part of slider
SL_b = [[0; SL_l(2,1); SL_l(3,1); 1], [0;
SL_r(2,2); SL_r(3,1); 1]]; % bottom part of
slider
SL_v = [SL_l, SL_r]; % the vertical portion of
the slider
SL_h = [SL_t, SL_b]; % the horizontal portion
of the slider
SL_v_R = Rx*SL_v;  % rotated vertical portion
SL_h_R = Rx*SL_h;  % rotated horizontal portion

figure(5)
subplot(221)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in the reference position
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after guidance tube rotation
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
```

```
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Used for calculating angles')
xlabel('x')
ylabel('y')
zlabel('z')
grid on % turns on grid
axis square % squares the axes
axis equal % makes axes same size

subplot(222)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in the reference position
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Side view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([0 0]) % zx side view
axis square % squares the axes
axis equal % makes zx axis same length

subplot(223)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.2) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.2) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis left block piece above the
connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the rotated
x-axis then y-axis right block piece above the
connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc
in 3d in the reference position
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc
in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold
on % plots the original vertical slider from
block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold
on % plots the original horizontal slider that
spans the block piece
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
vertical slider from block piece to arc
plot3([CJ_R(1,:)
CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold
on % plots the rotated x-axis then y-axis
horizontal slider that spans the block piece
title('Top view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 90]) % yx top view
axis square % squares the axes
axis equal % makes yx axis same length

subplot(224)
surf(x_b,y_b,z_b, 'FaceColor', [0,1,0]); hold
on % plots bone (as inner cylinder)
alpha(0.5) % transparency
surf(x_l,y_l,z_l, 'FaceColor', [1,0.62,0.4]);
hold on %plots leg/skin (as outer cylinder)
alpha(0.5) % transparency
plot3([x_t(1)+dx Start(1)],[y_t(1)+dy
Start(2)],[z_t(1)+dz Start(3)],'r'); hold on %
plots the vertical guidance tube
plot3([x_t(1) Rot_t(1)], [y_t(1) Rot_t(2)],
[z_t(1) Rot_t(3)], 'm'); hold on % plots the
rotated guidance tube and holds it on graph
plot3(CJ(1,:),CJ(2,:), CJ(3,:), 'k') % plots
the connector joint before rotation
plot3(CJ_R(1,:),CJ_R(2,:), CJ_R(3,:), 'k');
hold on % plots the calculated connector joint
after rotation
plot3(BP_l(1,:),BP_l(2,:),BP_l(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original left block piece above the connector
joint
plot3(BP_r(1,:),BP_r(2,:),BP_r(3,:), 'c',
'LineWidth' , 1.5); hold on % plots the
original right block piece above the connector
joint
```

```
plot3(CJ_R(1,:),BP_l_R(2,:),BP_l_R(3,:), 'c', 'LineWidth' , 1.5); hold on % plots the rotated x-axis then y-axis left block piece above the connector joint
plot3(CJ_R(1,:),BP_r_R(2,:),BP_r_R(3,:), 'c', 'LineWidth' , 1.5); hold on % plots the rotated x-axis then y-axis right block piece above the connector joint
plot3(x_arc,y_arc,z_arc,'g'); % plots the arc in 3d in the reference position
plot3(x_arcR,y_arc,z_arc,'g'); % plots the arc in 3d after the guidance tube is rotated
plot3(SL_v(1,:),SL_v(2,:),SL_v(3,:), 'r'); hold on % plots the original vertical slider from block piece to arc
plot3(SL_h(1,:),SL_h(2,:),SL_h(3,:), 'r'); hold on % plots the original horizontal slider that spans the block piece
plot3([CJ_R(1,:) CJ_R(1,:)],SL_v_R(2,:),SL_v_R(3,:), 'r'); hold on % plots the rotated x-axis then y-axis vertical slider from block piece to arc
plot3([CJ_R(1,:) CJ_R(1,:)],SL_h_R(2,:),SL_h_R(3,:), 'r'); hold on % plots the rotated x-axis then y-axis horizontal slider that spans the block piece
title('Cross-sectional view')
xlabel('x')
ylabel('y')
zlabel('z')
grid on
view([-90 0]) % yz front view
axis square % squares the axes
axis equal % makes yz axis same length
```

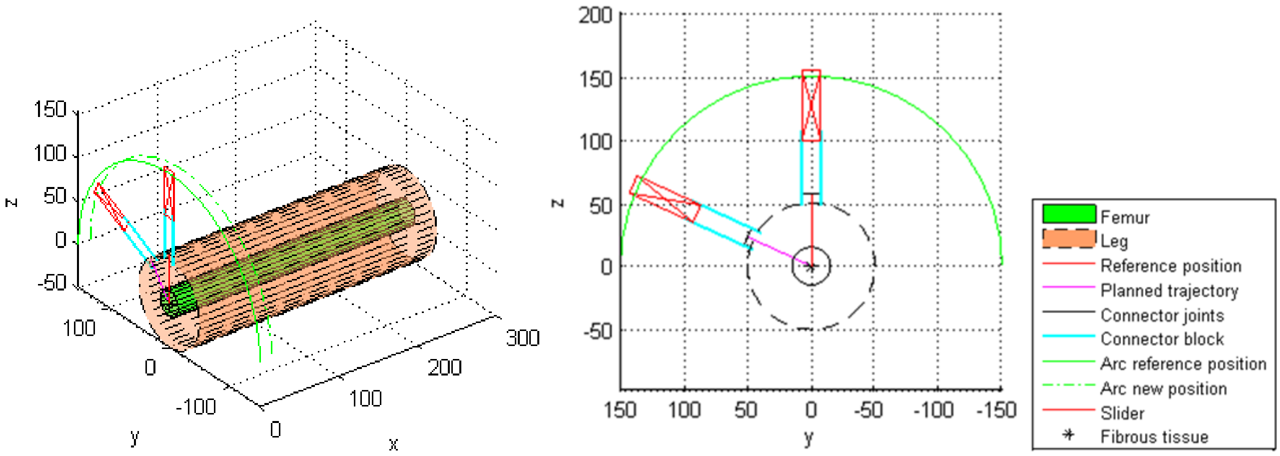


Fig. 1B: MATLAB interpretation of the SolidWorks model in isometric (left) and cross-sectional (right) views. The green arc is pictured around the leg with the red rectangular slider attached to it. Below the slider is the blue connector block which attaches to a connection joint and eventually the guidance tube. The guidance path is shown in two states: reference position at γ=β= 0° and rotated position at γ=+65°, β=+15° heading toward the fibrous tissue located at [0,0,0].

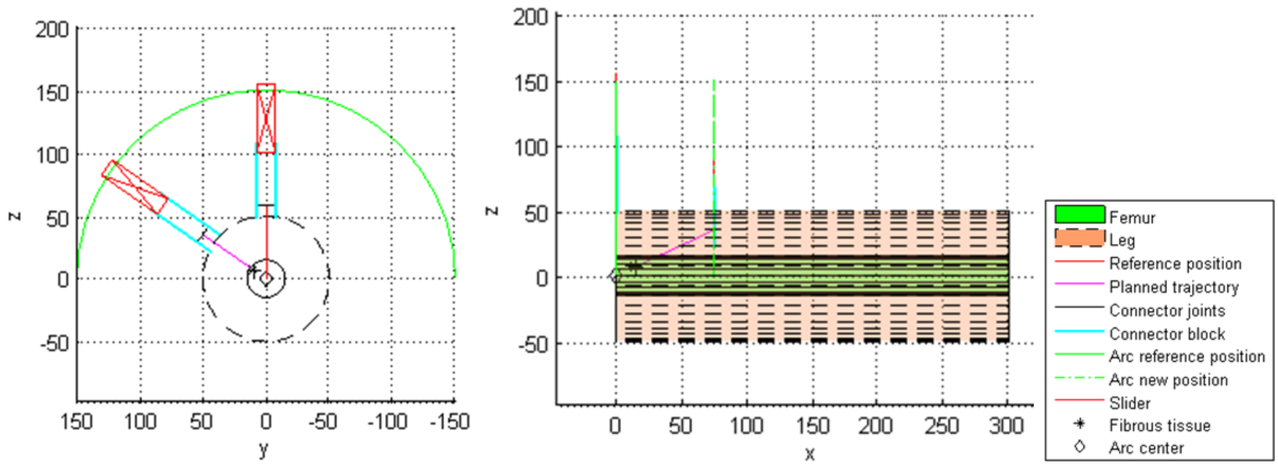


Fig. 2B: 2D projections of cross-section (left) and side (right). The fibrous tissue is located off-center of the leg at [15,10,7] and arc with the arc remaining concentric with the leg. Again the reference position is at γ=β= 0° and the rotated position at γ=+55°, β=+51°.

Rotation matrices and equations

The vertical z-axis is shared in both viewpoints, so a set of Pythagorean equations relate the angles and distances of the line.

In the cross-sectional view:

$$\tan\gamma = \frac{y2 - y1}{z2 - z1} \text{ [Eq. 1]}$$

In the side view:

$$\tan\beta = \frac{x2 - x1}{z2 - z1} \text{ [Eq. 2]}$$

Rotation matrices, R_x and R_y, were used to determine the arc angle settings γ and β, respectively.

$$R_x = \begin{bmatrix} 1 & 0 & 0 \\ 0 & \cos\gamma & \sin\gamma \\ 0 & -\sin\gamma & \cos\gamma \end{bmatrix} \text{ [Eq. 3]}$$

$$R_y = \begin{bmatrix} \cos\beta & 0 & \sin\beta \\ 0 & 1 & 0 \\ -\sin\beta & 0 & \cos\beta \end{bmatrix} \text{ [Eq. 4]}$$

It is important to note that these matrices reflect practical usage and the geometry of the designed medical device. As written, the R_x matrix does not fully abide by the traditional right-handed system because of the negative on sin γ in the third row instead of a negative on the sin γ in the second row, while the R_y matrix does follow the standard convention. This only determines direction and how a positive or negative rotation angle is defined.

The actual angles for setting the device in 3D (β and γ) can be calculated with Eq. 5 by inputting the starting (x_1, y_1, z_1) and ending (x_2, y_2, z_2) coordinates gathered from the 2D information.

$$\begin{bmatrix} x_2 \\ y_2 \\ z_2 \end{bmatrix} = R_x * R_y * \begin{bmatrix} x_1 \\ y_1 \\ z_1 \end{bmatrix} \text{ [Eq. 5]}$$

As long as the new coordinates and any others lie along the same trajectory the angles of rotation will also be the same. After solving Eq. 5, the result is a set of up to four combinations of β and γ angles, which can be chosen correctly by plotting the result. Since multiplication order is important for matrices it should be noted that R_y*R_x would give an incorrect result.

Appendix C: Protocol and procedure

Protocol

Total width of table	700 mm
Space for each leg	350 mm
Width of one leg (large)	250 mm
Inside diameter of arc	400 mm
Total assembly footprint	425 mm
Leftover space for other leg	275 mm

- Put outside railing as close to edge of table as possible, so that no parts fall outside table boundaries
- Make one leg straight through arc center
- Place other leg so that inside railing does not interfere
    - Legs should NOT be parallel to each other (Fig. 1C)
    - Instead, one leg straight and parallel to railing and other leg at an angle
    - Non parallel leg should be at as large an angle as possible so that it is still within table boundary (~275 mm space to use)
    - Both legs toes pointed up. This keeps proper leg orientation and femur with top side perpendicular with the table

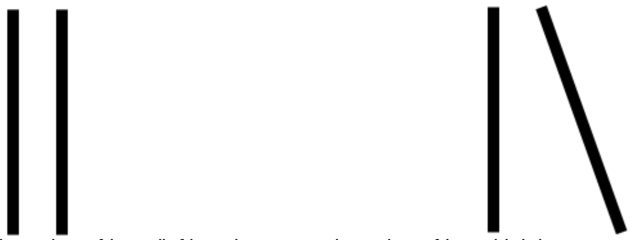


Fig. 1C: Incorrect orientation of legs (left) and correct orientation of legs (right)

- Arc can be setup with angle numbers facing the head of the patient or away from the head of the patient (Not applicable if numbers are engraved on both sides)
- Front piece of the arc slider (side containing indexing plunger) should face the head of the patient (should be on opposite side of top end of guide tube, to guarantee extra space for tool entry through the guidance tube)
- Guidance tube should rotate so that the top end of the tube faces away from patient head (Fig. 2C, left) (which is also opposite the front piece of arc slider). This should give more space for the tools to be inserted through without interfering with the inside of the leg
- The tools enter from the direction distal to proximal (from bottom of the leg) rather than proximal to distal (Fig. 2C, right) (from the top of the leg)
- Also, this orientation will allow access into the upper portion of the femur when tools approach from distal leg side rather than proximal side

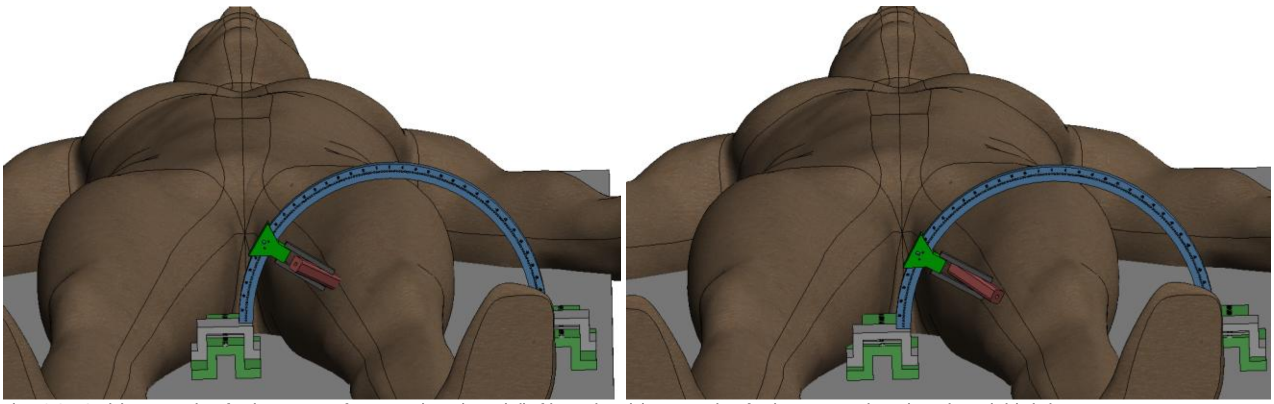


Fig. 2C: Guidance tube facing away from patient head (left) and guidance tube facing toward patient head (right)

Procedure

The procedure itself can be divided into two areas: pre-operative and intra-operative (Table 1C). During the pre-operative stage the surgeon must first image the patient with the guidance device frame properly aligned with the patient and CT scanner and determine where the fibrous tissue is located. After the tissue is found, the center of the arc should be set in the same plane as the tissue with respect to the sagittal (side) view, and this becomes the reference position (Fig. 3C).

Table 1C: Steps in the procedure

Pre-operative:	
1)	Check alignment of guidance device with respect to CT scanner
2)	Locate area of fibrous tissue and create reference point
3)	Use CT images in 2 planes to plan path from arc center to tissue to point along arc
4)	Input path into computer program which will measure lengths, angles and find coordinates on the trajectory and will output device settings
Intra-operative:	
1)	Setup patient supine and arc at reference point, properly aligned
2)	Move guidance tube to calculated angles: roll around arc and pitch
3)	Place end of guidance tube as close to skin as possible.
4)	Adjustments to the pitch angle can be made while coupled to the arc movement along the length of the leg
5)	Insert tools through guidance tube to arrive at fibrous tissue, to remove it and to introduce bone cement

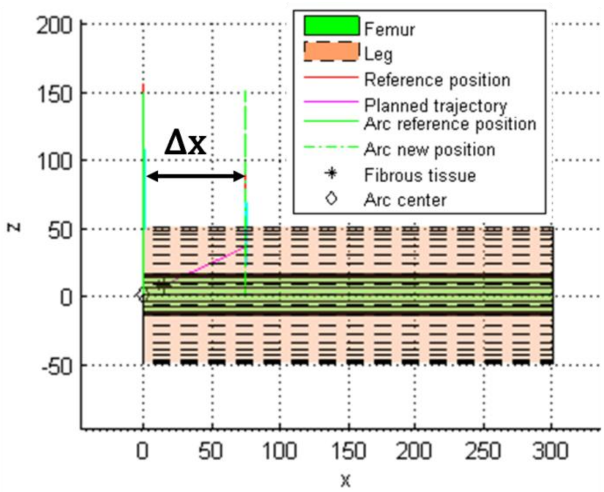


Fig. 3C: Setting the arc reference position, x, after γ and β angles have been transformed. The center of the leg and the fibrous tissue location must lie on the same trajectory. Where the trajectory intersects the leg center is the reference point for the arc. In this case the reference position is at x=0.

Then the surgeon uses two planes of view (cross-section and side) to create the path he will take with the guidance tube. On these planes, lines should be drawn from the leg center, through the fibrous tissue, and upwards toward the arc (Fig. 4C and 5C).

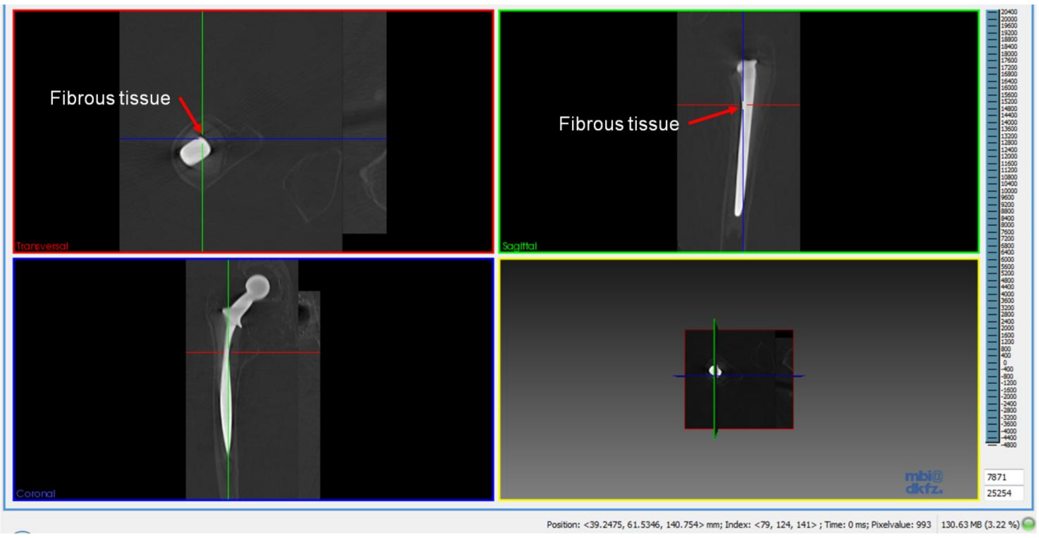


Fig. 4C: Actual pre-operative CT images of leg, femur, fibrous tissue, and hip prosthesis. These images (cross-section, top left and side, top right) are used to plan the guidance path to the fibrous tissue location. A line is drawn from the fibrous tissue outward so blood vessels and nerves are avoided. The line's angle can be determined and transformed to the arc settings using the computer software. Preoperative images must be overlaid the images done on the day of the procedure in order to confirm correct patient orientation.

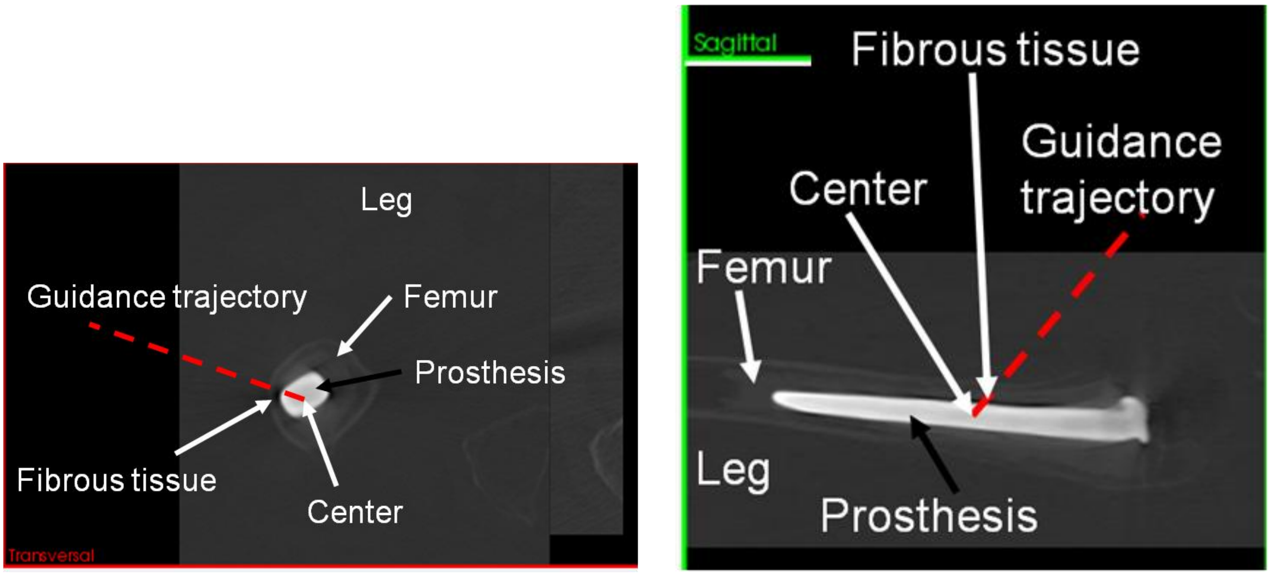


Fig. 5C: Using the cross-section (left) and side (right) views, guidance paths can be drawn from the leg center to the fibrous tissue, which determines the angle of approach. The intersection of the guidance trajectory and the center is the reference point for the arc.

Using the computer software with the CT imaging, the lengths and coordinate positions of the lines and the angles can be measured. When those data are known, it can be inputted into the transformation matrices to get the actual angles that need to be set on the arc device.

Because the guidance tube reference position has starting angles at $\gamma = \beta = 0°$ and the trajectory passes through the leg center, two of the starting coordinates are zero while the other is the path length (Fig. 6C). The ending coordinates of the drawn guidance path can be measured with the computer software. As long as the ending coordinates lie along the guidance tube trajectory the rotation angles will be the same. However, the ending coordinates are very important for setting the arc at the correct Δx distance because the end coordinates correspond to the location of the connection joint, the point at which the guidance tube rotates, and also where the center axis of the arc is.

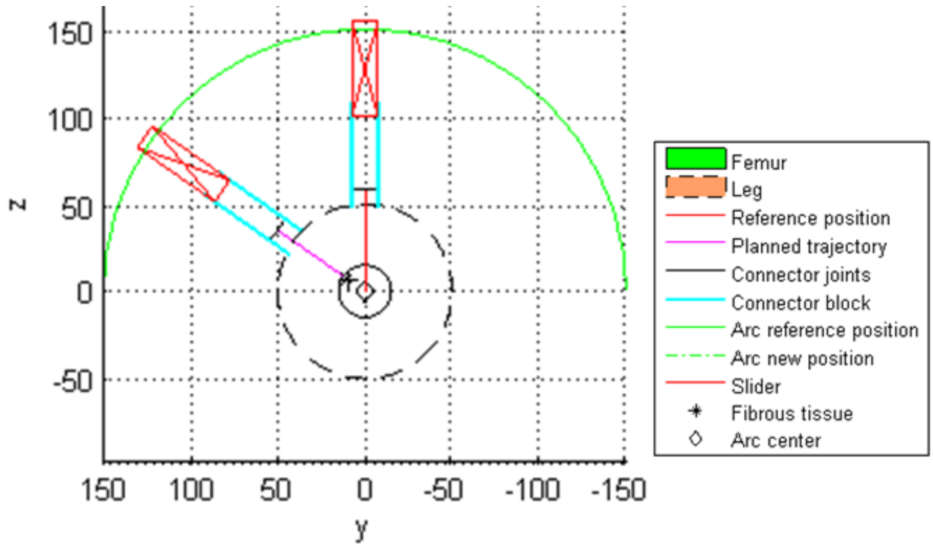


Fig. 6C: Calculating the guidance path. The planned trajectory is drawn on the CT image and the reference position remains vertical through the leg and arc center. The starting coordinates in this case are x=0, y=0, z=58. The planned trajectory is the rotated form of the reference position, meaning the lengths are equal. The rotation angles can be calculated and the arc position can be set, based on the rotated end coordinates.

After the preoperative stage is complete the surgery can begin with setting up the patient and the arc in the correct positions, making sure the device is properly aligned. The patient lies supine and the arc is set up along its track of rails. Using the fibrous tissue information from the preoperative imaging to set the reference point of the arc, the guidance tube angles for the roll and pitch can then be adjusted, as well as the arc position along the leg length. Once the positions are locked, a cannula is inserted through the guidance tube and into the leg up to the bone surface. Then a specialized needle or drill pierces the bone to gain access to the fibrous tissue. Once a pathway is made, the fibrous tissue removal tool can be used and then the cavity can be filled with bone cement.

As may be the situation with several patients, there is more than one location in the leg where fibrous tissue is present. In fact, fibrous tissue can be in both legs, if conditions are met. In those situations it is beneficial to remove all the fibrous tissue before cementing. Therefore, multiple arcs may be used at the same time. If both legs contain fibrous tissue, the procedure should be done one leg at a time and the railings should be setup around the second leg after the first leg is cemented.

Once a cannula is put in position, the guidance tube can be detached from the arc and the arc can be removed to make more space to guide another cannula to a different location. Since the end of the cannula is usually T-shaped, the guidance tube cannot be removed. Without the arc holding the guidance tube and cannula in position, however, the stability may be reduced, although the leg muscles act as an extra stabilizer. Having multiple arcs on the table at the same time though can create a cluttered working environment and be cumbersome for the surgeon.

Appendix D: Mechanical analysis and calculations

Fault tree

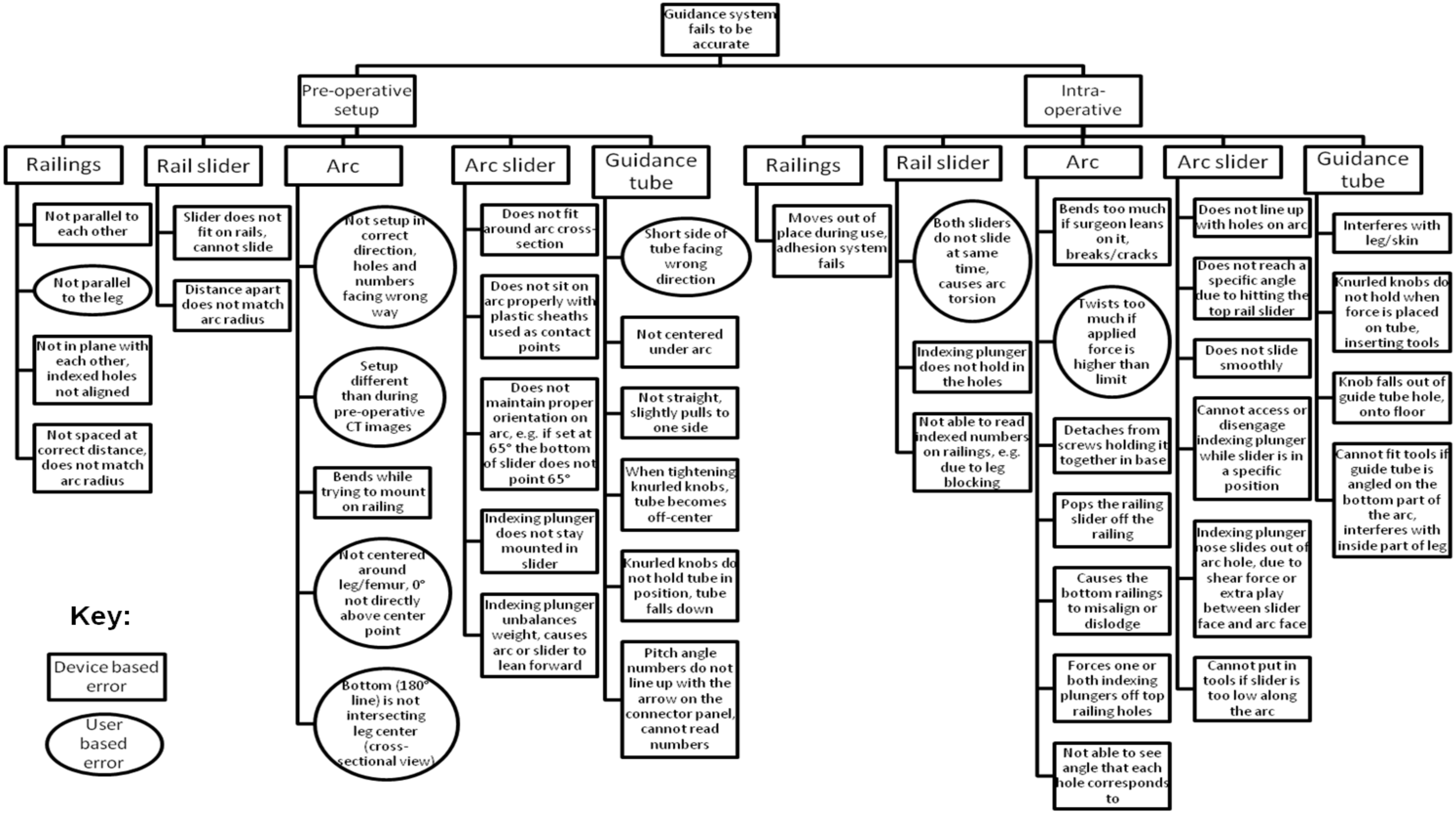


Fig. 1D: Fault tree for guidance device that classifies errors into two categories: those that are based on user control (oval shaped boxes) or those that are inherent to the device (rectangular shaped boxes). Any fault either during the procedure or in preparation leading up to the start can cause the device to guide inaccurately.

Failure modes and effects analysis (FMEA)

Table 1D: Key for use in FMEA. Adapted from [1D,2D]

Probability of occurrence

Rating	Meaning
1	No known occurrences on similar products or processes
2/3	Low (relatively few failures)
4/5/6	Moderate (occasional failures)
7/8	High (repeated failures)
9/10	Very high (failure is almost inevitable)

Severity

Rating	Meaning
1	No effect
2	Very minor (only noticed by discriminating customers)
3	Minor (affects very little of the system, noticed by average customer)
4/5/6	Moderate (most customers are annoyed)
7/8	High (causes a loss of primary function; customers are dissatisfied)
9/10	Very high and hazardous (product becomes inoperative; customers angered; the failure may result unsafe operation and possible injury)

[1D] Pahl G., Beitz W., Feldhusen J., and Grote K.-H., 2007, Engineering Design: A Systematic Approach, Springer-Verlag, London.
[2D] Otto K. N., and Wood K. L., 2001, Product design: techniques in reverse engineering and new product development, Prentice Hall.

Table 2D: Failure modes and effects analysis (FMEA). Ways in which each part of the guidance device can fail and the effects that failure has on other parts is determined. Also listed are adaptations to the device that help reduce the effect of that specific failure.

1. ID	2. Function	3. Failure mode	4. Effect on other parts	5. Effect on system	6. Severity	7. Occurrence	8. Method to reduce occurrence
Rails	Anchors guidance system to table and provides path for arc to move over	Are not parallel to each other	Arc will not be able to slide	Cannot be set in correct position, will not guide tools to correct location	8	2	Rails are held together and aligned with cross bars
			CT images are not oriented correctly	Will not guide tools to correct location			
		Are not parallel to leg	CT images are not oriented correctly		7	5	Can use CT to check if alignment is straight
			Arc is not centered correctly				Follow protocol for aligning legs to rails
			Arc and other parts will interfere with leg	Cannot be set in correct position, will not guide tools to correct location			
		Are not aligned with holes lined up	Arc cannot lock into correct position	Will not guide tools to correct location	6	2	Rails are held together and aligned with cross bars
			Arc may not be able to lock in any position	System is not stable			
			May cause twisting to arc	Excessive forces resulting in breakage			
		Are not spaced apart correctly	Arc will not fit in place	System cannot adjust and move	5	3	Cross bars hold together the rails at specified distance. Pre-assembled arc will hold position in place
		Moves out of place during use	May disconnect arc or sliders	System is not stable	7	3	Suction system is air-locked to the table
Rail slider	Allows arc to move along the length of the leg	Does not fit on rails	Arc cannot slide along leg	Cannot be set in correct position, will not guide tools to correct location	7	2	Parts are dimensioned and toleranced tightly
			May not be able to lock into holes	System is not stable			
		Holes do not align with rails or with arc base	Indexing plungers do not find correct holes or any holes to lock into		6	2	Parts are dimensioned and toleranced tightly
				Cannot be set in correct position, will not guide tools to correct location			
			Arc end is not stable	System is not stable			
		Both do not slide at same time	Increases torsional forces on arc structure	System is not stable, can cause cracks or breaking	3	3	Both handles of the indexing plungers need to be in same position
		Indexing plunger does not hold locked position	Arc slides out unintentionally	Will not guide tools to correct location	5	1	Reliable off the shelf part is used
		Position cannot be determined, numbers cannot be read	Arc may be put in incorrect position		3	3	Increase size of numbers

Arc	Provides the path that the arc slider and guidance tube moves along	Not setup in correct direction, holes and numbers facing wrong way	May cause guidance tube to be oriented incorrectly	Will not guide tools to correct location	3	2	Careful setup necessary by user, have numbers located on both sides of arc with through holes
		Bends while trying to mount on railing	May cause guidance tube and arc slider to not slide properly	Will not be able to adjust the positions	5	2	Tight tolerancing of parts, Arc and slider can be pre-assembled
			May cause guidance tube to set at an incorrect angle	Will not guide tools to correct location			
		Not centered around femur, 0° directly above center point	Guidance tube aims incorrectly		7	4	Use CT images to align femur and arc
			CT information is incorrect				Follow protocol for aligning legs to rails/arc
		Bottom of arc (180° line) is not inline with leg center (in cross-sectional view)	Guidance tube aims incorrectly		5	4	Use CT images to align femur and arc
			CT information is incorrect				Elevate leg if necessary
		Bends too much while surgeon leans	May force out indexing plunger	System is not stable	8	2	Manufactured from strong materials
			Guidance tube aims incorrectly	Will not guide tools to correct location			
			May cause arc to move out of position	Will not guide tools to correct location			
		Twists too much under applied force	May force out indexing plunger	System is not stable	8	2	Manufactured from strong materials
			May cause arc to move out of position	Will not guide tools to correct location			
			Guidance tube aims incorrectly				
		Detaches from screws holding it together in base	Arc moves out of position		8	2	Manufactured from strong materials
			Base is not stable	System is not stable			
		Dislodges the railing sliders from the railings	Arc moves out of position	Will not guide tools to correct location	7	2	Indexing plunger holds position in place
			Guidance tube aims incorrectly				
		Causes bottom railings to misalign or dislodge	Guidance tube aims incorrectly		7	2	Suction system is air-locked to the table
			Arc cannot slide along leg	Cannot be set in correct position, will not guide tools to correct location			
			Base is not stable	System is not stable			
		Forces one or both indexing plungers off top railing holes	Arc moves out of position	Will not guide tools to correct location	4	2	Reliable off the shelf part is used
		Not able to see the angle that each hole corresponds to	Cannot set arc to correct position		3	2	Increase size of numbers, have numbers on both sides of arc

Arc slider	Moves along the arc to put the guidance tube in various angled positions	Does not fit around arc cross section	Will not slide properly and move guidance tube into position	Will not guide tools to correct location	8	2	Tight tolerancing of parts
		Does not sit properly on arc surface with plastic sheath contact points	Will not slide properly and move guidance tube into position Guidance tube aims incorrectly		7	3	Manufactured with tight tolerances Sheaths have large enough and equal diameters to maintain contact
		Does not maintain proper angled orientation on arc			7	3	Sheaths maintain even contact due to its tolerancing and large enough diameters
		Indexing plunger does not stay mounted in slider	Slider moves out of position, guidance tube moves incorrectly		4	2	Reliable off the shelf part is used Sheaths maintain contact with arc and holds slider
		Indexing plunger causes arc to be unbalanced	Arc may lean forward	System is not stable, will not guide correctly	3	2	System is strong enough to not be affected by weight of indexing plunger
		Does not line up with holes on arc	Indexing plungers do not find correct holes or any holes to lock into		5	2	Manufacturing quality and tight tolerances, holes are big enough for plunger to enter easily
		Does not reach stated angles	Guidance tube aims incorrectly	Will not guide tools to correct location	8	2	Aim guidance tube from a point higher up along arc Use CT images to plan alternative routes and angles
		Does not slide smoothly	User becomes frustrated and applies extra force to slider	Breaks or cracks may form	3	2	Materials have low friction coefficient
		Cannot disengage/access indexing plunger	Positions and angles cannot be changed	Will not guide tools to correct location	3	3	Handle of indexing plunger is large enough to grab and turn
		Indexing plunger slides out due to shear forces or extra play in between arc face and slider face	Guidance tube aims incorrectly Parts move out of position unintentionally		7	2	Reliable off the shelf part is used

Guidance tube	Provides access for tools to pass through at specific trajectories	Short side of tube facing wrong direction	May interfere with patient leg	Cannot fit tools through	4	4	Add arrows or direction information for assembly of parts
		Not centered under arc	CT information is incorrect	Will not guide tools to correct location	7	3	Threaded holes are equally spaced, dimensioned, toleranced, and manufactured Arc slider is balanced on the arc with the sheaths
		Not straight, pulls to one side	Tools follow wrong trajectory		6	3	Knobs have equal pull force when they are tightened equally; threaded holes on tube are same depth, manufactured tightly
		Knobs do not hold tube in position	Positions and angles cannot be set	System is not stable	6	3	Friction between threaded holes surface and knob is high Make guidance tube thicker, increasing the depth of the threaded holes and more surface area to hold on to
		Pitch angle numbers do not line up correctly with marker	Trajectory is set incorrectly	Will not guide tools to correct location	3	3	Holes on connection joints are manufactured tightly, guidance tube is assembled first in a "check" position to make sure known angles are lined up, e.g. 0°
		Interferes with leg/skin	Positions and angles cannot be set correctly		4	4	Pitch angle of tube can be adjusted to avoid skin contact, but the arc distance must be moved to compensate for the change of angle (follow protocol for adjusting pitch and arc distance) Some skin has extra leeway when compressed
		Tools cannot fit through on low angles around arc	Interferes with patient legs	Cannot fit tools through	6	4	Arc distance can be adjusted (away from the proximal leg) while at the same time adjusting the guidance tube pitch angle Tools should be limited to less than 100 mm length Follow protocol for leg setup and spacing

Drill path exponentially growing longer

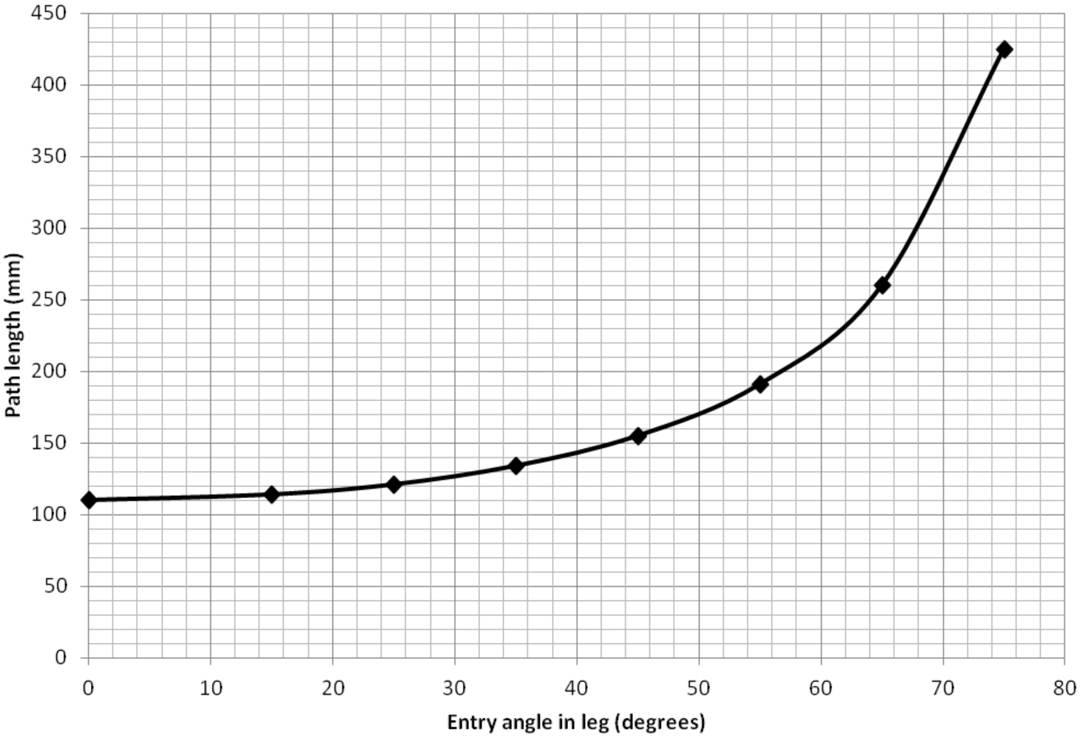


Fig. 2D: The path length in the leg increases as a function of the cannula entry angle. Above the angle range stated in the requirements the path length is too long. Path length assumes a 110 mm starting vertical path from connector joint to fibrous tissue

Device bending and allowable error

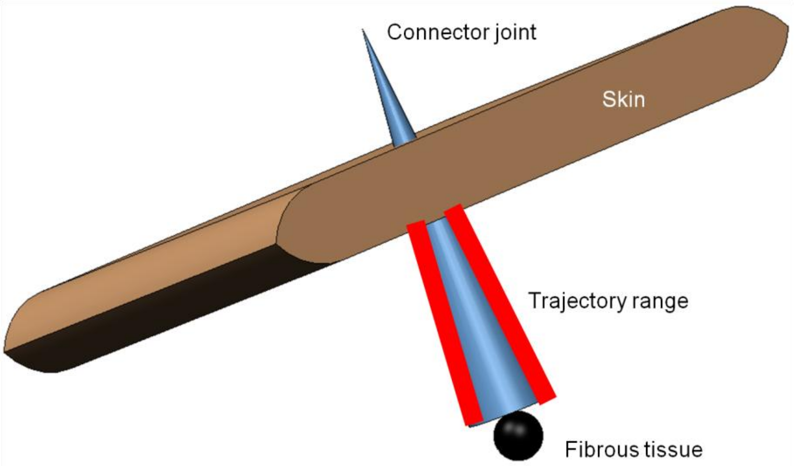


Fig. 3D: The guidance trajectory as it approaches the fibrous tissue represented as a conical area. At the top of the cone is the connector joint from where the tube can deviate due to bending. If the surgical tools fall within the center portion of the trajectory range then they can access the fibrous tissue, but if they are in the highlighted zones of the cone then they will miss the fibrous tissue.

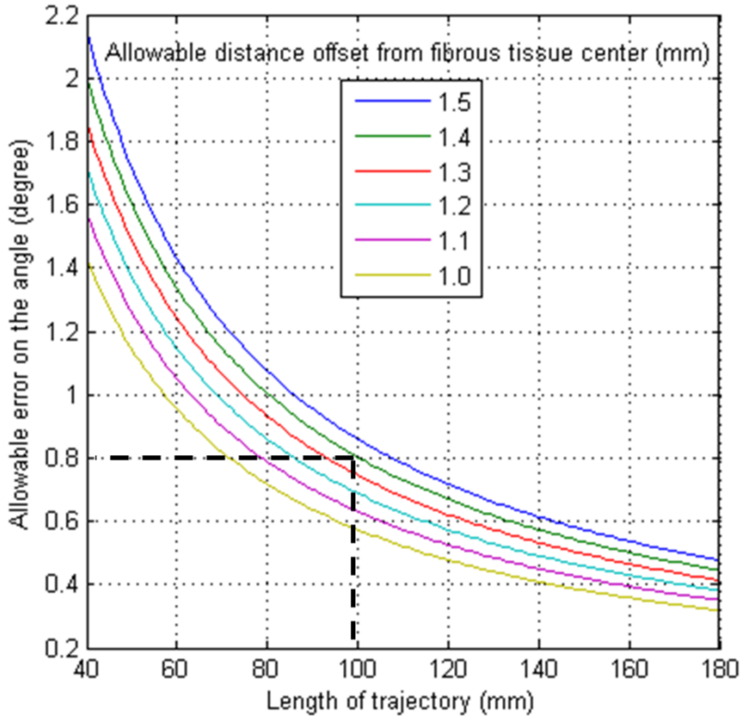


Fig. 4D: As the starting height above the leg increases, the amount of error permitted in the guidance tube angle is reduced. As the error range on the fibrous tissue is tightened below 1.5 mm, the allowable angle error drops further. For example, if the guidance tube is allowed to be off the center of its target by only 1.4 mm, then at a trajectory length of 100 mm, the error on the angle can be maximally 0.8°.

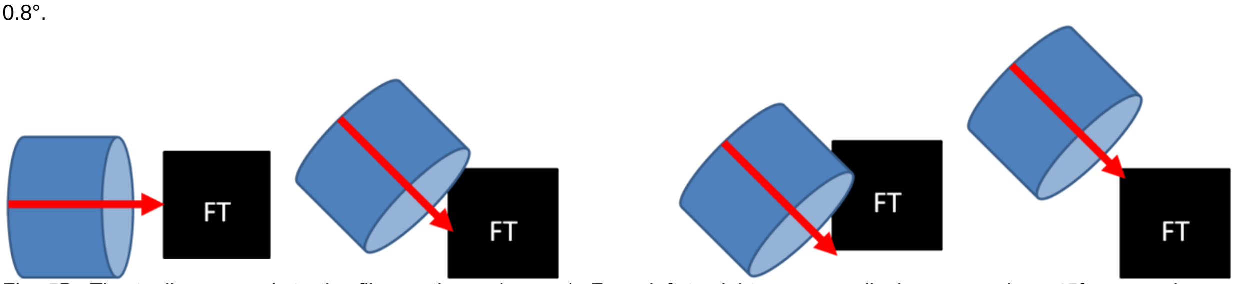


Fig. 5D: The tool's approach to the fibrous tissue (square). From left to right: a perpendicular approach; a 45° approach on target; overshooting the target by 1.5 mm at 45° trajectory; undershooting the target by 1.5 mm at 45° trajectory. Best approaches are first and last scenario.

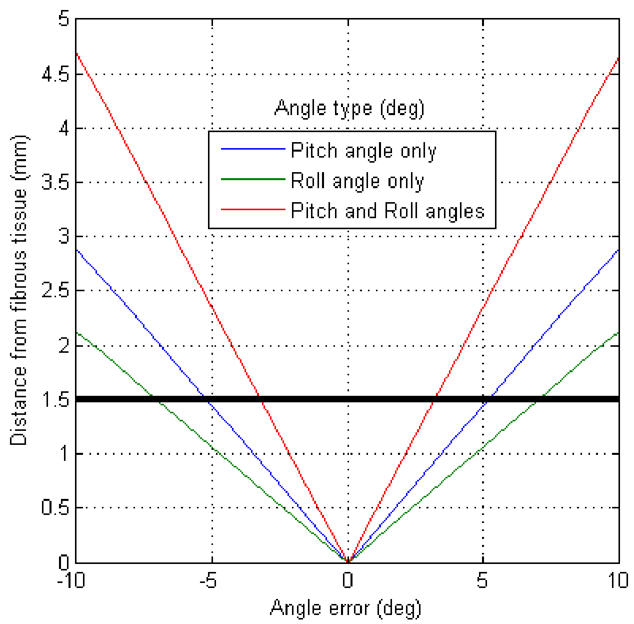


Fig. 6D: The effect of a pitch or roll angle error on the guidance tube exit point's distance from the fibrous tissue. When the pitch and roll angles are set incorrectly at the same time the distance from the fibrous tissue is greatest. When only the roll angle is set incorrectly the error is least.

Table 3D: Accuracy calculations when the roll and pitch angles change in opposite directions. The effect is compensatory and the error is less than a single angle error or errors in both angles in the same direction

Roll Angle (+/-)	Pitch Angle (+/-)	X	Y	Z	Distance from fibrous tissue (mm)	X error	Y error	Z error
-10	10	15.99	9.10	5.96	1.69	0.07	-0.09	-0.15
-9	9	15.91	9.16	6.08	1.54	0.06	-0.08	-0.13
-8	8	15.83	9.23	6.19	1.39	0.06	-0.08	-0.12
-7	7	15.74	9.30	6.30	1.24	0.05	-0.07	-0.10
-6	6	15.65	9.38	6.41	1.07	0.04	-0.06	-0.08
-5	5	15.55	9.47	6.52	0.91	0.04	-0.05	-0.07
-4	4	15.45	9.56	6.62	0.74	0.03	-0.04	-0.05
-3	3	15.35	9.66	6.72	0.56	0.02	-0.03	-0.04
-2	2	15.24	9.77	6.82	0.38	0.02	-0.02	-0.03
-1	1	15.12	9.88	6.91	0.19	0.01	-0.01	-0.01
0	**0**	**15.00**	**10.00**	**7.00**	**0.00**	**0.00**	**0.00**	**0.00**
1	-1	14.88	10.13	7.09	0.20	-0.01	0.01	0.01
2	-2	14.75	10.26	7.17	0.40	-0.02	0.03	0.02
3	-3	14.61	10.39	7.24	0.60	-0.03	0.04	0.03
4	-4	14.48	10.54	7.31	0.81	-0.03	0.05	0.04
5	-5	14.33	10.68	7.38	1.03	-0.04	0.07	0.05
6	-6	14.19	10.84	7.44	1.25	-0.05	0.08	0.06
7	-7	14.04	11.00	7.49	1.47	-0.06	0.10	0.07
8	-8	13.88	11.16	7.54	1.70	-0.07	0.12	0.08
9	-9	13.72	11.33	7.58	1.93	-0.09	0.13	0.08
10	-10	13.56	11.50	7.62	2.17	-0.10	0.15	0.09

Cannula bending (calculations)

The longer the path is for a cannula, the more it is affected by bending forces. The guidance tube is assumed to hold the cannula in place at one end so that it acts as a cantilever beam under a single load at one end (Fig. 7D). Although the cannula is stabilized additionally by the muscles in the leg, a cantilever assumption will provide a more conservative deflection estimate.

Fig. 7D: Deflection, δ, of the cannula under bending

The maximum deflection (δ) of the cannula can be represented by the equation:

$$\delta = \frac{F * L^3}{3 * E * I} \text{ [Eq. 1D]}$$

with F being the applied force, L the length of the cannula outside the guidance tube (50 mm), E the modulus of elasticity/Young's modulus (~200000 N/mm^2 for stainless steel), and I the area moment of inertia of the hollow circular cross-section, with outer radius (1.7 mm) and inner radius (1.35 mm),

$$I = \frac{\pi}{4} * (r_o^4 - r_i^4) \text{ [Eq.2D]}$$

Under forces of 30 N, the cannula does not bend more than 1.5 mm assuming the muscles play no role in stabilization (Fig. 8D, left). If the muscles do play a role in stabilizing the cannula, the exposed cannula length for bending is reduced to 30 mm and a force of 130 N would cause 1.5 mm of bending (Fig. 8D, right). By comparison, setting the pitch angle incorrectly by 10° is similar to putting more than 55 N of force on the end of the cannula in the no muscle stabilization case (3 mm displacement from fibrous tissue). Therefore, an error of 5° in any direction is acceptable under the 1.5 mm distance limit.

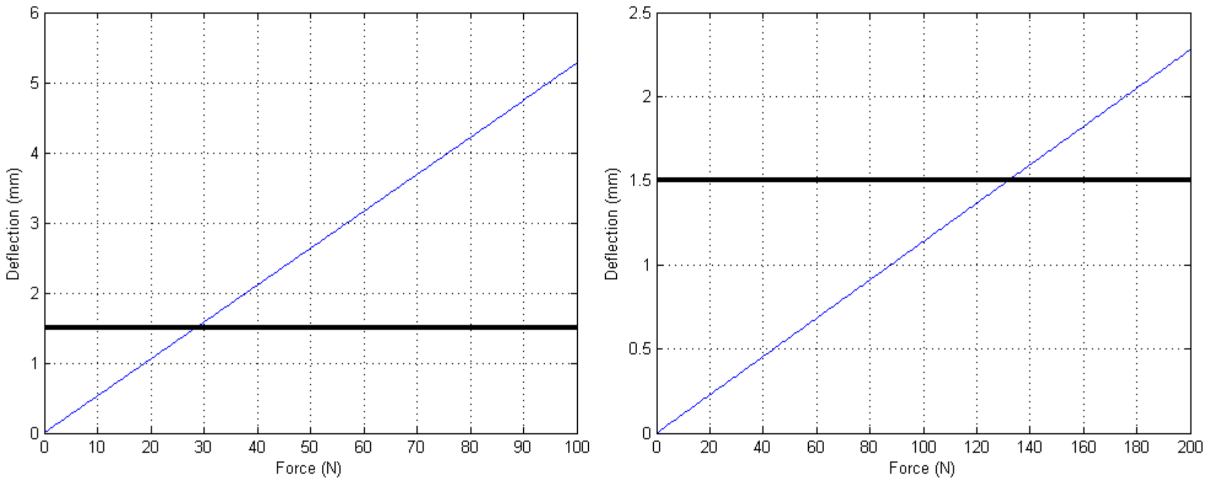


Fig. 8D: The amount of deflection at the end of the cannula of length 50 mm (left) and 30 mm (right) when a force is applied. The shorter length cannula assumes muscles act as an extra stabilizer and reduces the exposed length that experiences loading. The muscle stabilized cannula can resist up to 130 N.

Anchoring strength (calculations)

The 2 M4 countersunk screws securing the arc to each railing slider provide sufficient strength to withstand the 400 N loading case. An A4 grade class 70 stainless steel bolt has a tensile strength of 700 MPa and a proof stress of 450 MPa [3D,4D]. So, the strength of each bolt is characterized by the equation

$$F = R_{p0.2} * \pi * r^2 \quad \text{[Eq.3D]}$$
$$450 * \pi * 2^2 = 5654 \text{ N}$$

resulting in 5654 N. If that moment force becomes focused on only one of those bolts, (i.e. non-distributed load) the force that it needs to withstand is related to its distance from the edge.

$$M = F * x \quad \text{[Eq.4D]}$$
$$80 = F * 19.5 * 10^{-3}$$
$$F = 4103 \text{ N}$$

So, if a 400 N load is applied to the arc, the bolts must be able to withstand 4103 N. Since each bolt is rated for 5654 N, the structure is supported fine.

Using Eq. 3D again, the locking indexing plunger on the slide rails is able to withstand the applied load and hold its lock in the holes. The nose is made of type 303 stainless steel with a proof strength of 240 MPa [5D,6D]. To withstand at least 4103 N, the nose diameter of 5 mm is good.

$$240 * \pi * 2.5^2 = 4712 \text{ N}$$

The maximum deflection (δ) of the cannula can be represented by the equation:

$$\delta = \frac{F * L^3}{3 * E * I} \quad \text{[Eq. 5D]}$$

with F being the applied force, L the length of the cannula outside the guidance tube (50 mm), E the modulus of elasticity/Young's modulus (~200000 N/mm^2 for stainless steel), and I the area moment of inertia of the hollow circular cross-section, with outer radius (1.7 mm) and inner radius (1.35 mm),

$$I = \frac{\pi}{4} * (r_o^4 - r_i^4) \quad \text{[Eq.6D]}$$

$$\delta = \frac{30 * 50^3}{3 * 200000 * 3.95}$$

$$\delta = 1.58 \text{ mm}$$

Under forces of 30 N, the cannula does not bend more than 1.5 mm assuming the muscles play no role in stabilization. If the muscles do play a role in stabilizing the cannula, the exposed cannula length for bending is reduced to 30 mm and a force of 130 N would cause 1.5 mm of bending.

$$\delta = \frac{130 * 30^3}{3 * 200000 * 3.95}$$

$$\delta = 1.48 \text{ mm}$$

[3D] Beardmore R., 2008, “Strength Grade of Bolts and Screw,” Roymech.
[4D] International Organization for Standardization, 2009, “Mechanical Properties of Metric Fasteners.”
[5D] engineering-alloys, 2009, “Stainless Steel 303 UNS S30300 Data Sheet.”
[6D] Natal K. Z., 2011, “Stainless Steel Grades and Mechanical Properties.”

Arc deflection (calculations and simulation)

The arc should be able to withstand 40 kg of force Assuming a simplified scenario of an arc, half of the arc can be estimated as straight beam columns (Fig. 9D) [7D-9D]. Using Eq. 7D and 8D [10D], the 80 Nm moment force results in 0.34 mm of deflection (δ).

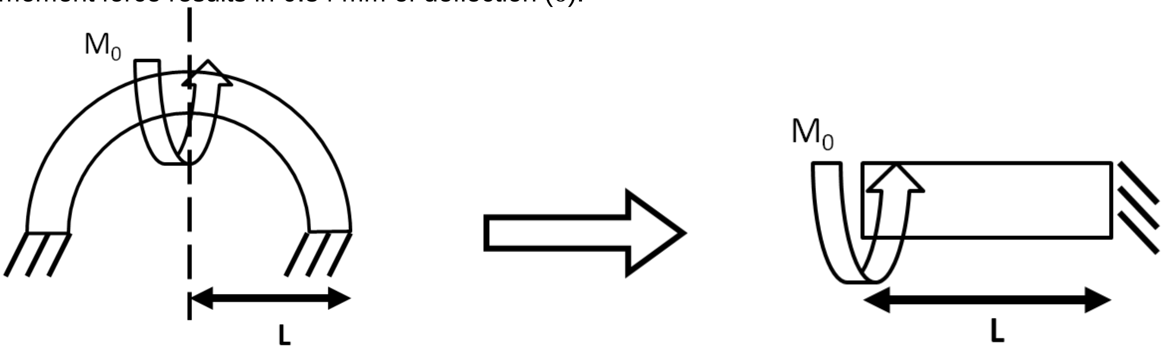


Fig. 9D: The arc half (left) with a moment force applied to the arc center can be estimated as a straight beam (right) with a moment force applied to the end. An arc will be stronger than the beam estimation.

Table 3D: List of characteristics used in the beam equation and Solidworks simulation

Characteristic	**Value**
F, applied force	400 N
L, arc radius	200 mm
M, moment force	80 Nm
E, modulus of elasticity	70 GPa
I, area moment of inertia of cross section	67500 mm^4
S, length of one side of base	30 mm
Poisson’s ratio	0.38

$$\delta = \frac{M_0 * L^2}{2 * E * I} \quad \text{[Eq. 7D]}$$

For a square cross-section:

$$I = \frac{s^4}{12} \quad \text{[Eq. 8D]}$$

With a 400 N force acting over an arm of 200 mm, the resultant moment is 80 Nm.

A Solidworks simulation was performed to determine the amount of deflection the arc exhibits when put under an applied force. The characteristics used are the same as those used in the beam calculation and are listed in Table 3D. In one case the 400 N applied force was distributed along the entire arc (Fig. 10D) and the other case the 400 N applied force was focused at the top of the arc (Fig. 11D). More deflection was seen in the second case compared to the first, 0.240 mm vs. 0.118 mm. The model used in the simulation was the arc geometry from the actual Solidworks model. Since it was previously calculated (in the anchoring strength section) that the indexing plunger and screws will be able to anchor the arc and withstand the applied force, the arc was assumed to be fixed at its bases.

Because the focused force case in Fig. 40 exhibits greater deformation, greater stress is present in the model. With the arc, the majority of the force is absorbed through the bases resulting in 11.2 MPa (Fig. 12D), where it is anchored by screws, each having a proof stress of 450 MPa. These results confirm that the beam simplification calculations are viable and that the arc does not deflect significantly and that the screws and indexing plunger stand up to the applied force.

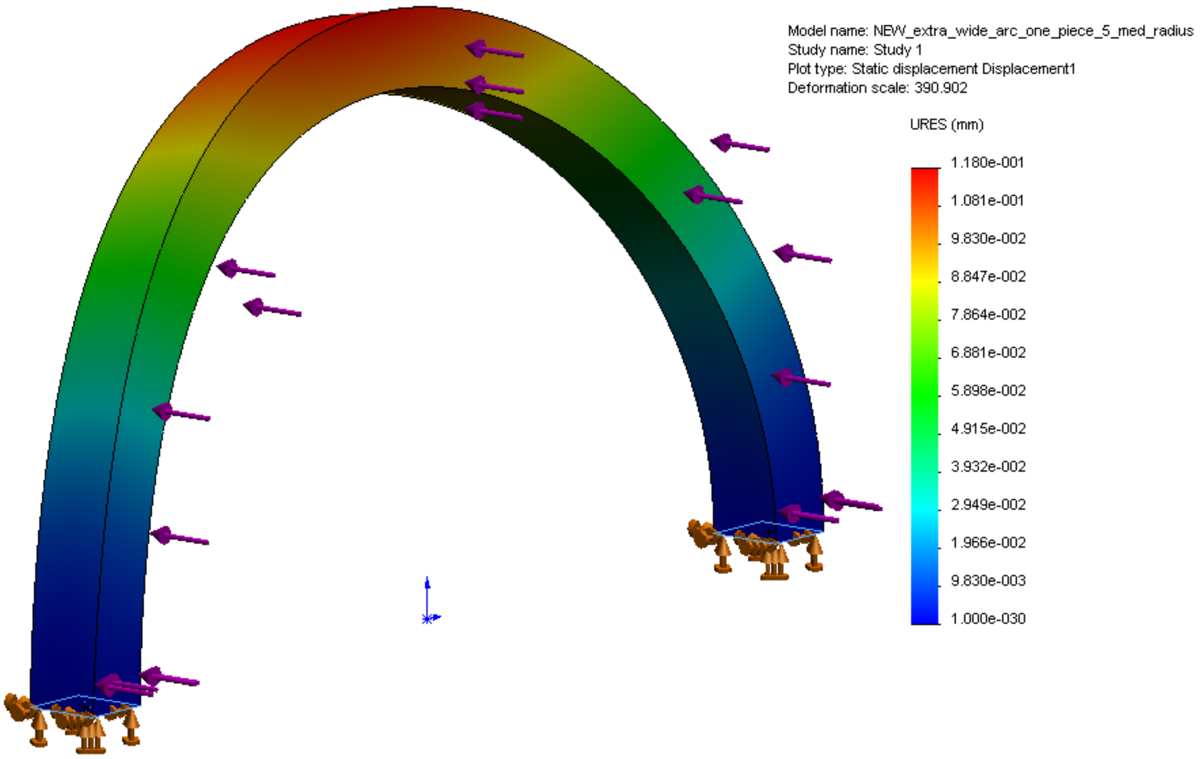


Fig. 10D: Arc with 30mm x 30mm fixed geometry base undergoing a distributed applied force of 400N. The greatest amount of deflection occurs at the top with 0.118mm. The material used for the simulation is carbon fiber with an elastic modulus of 70 GPa and Poisson's ratio of 0.38.

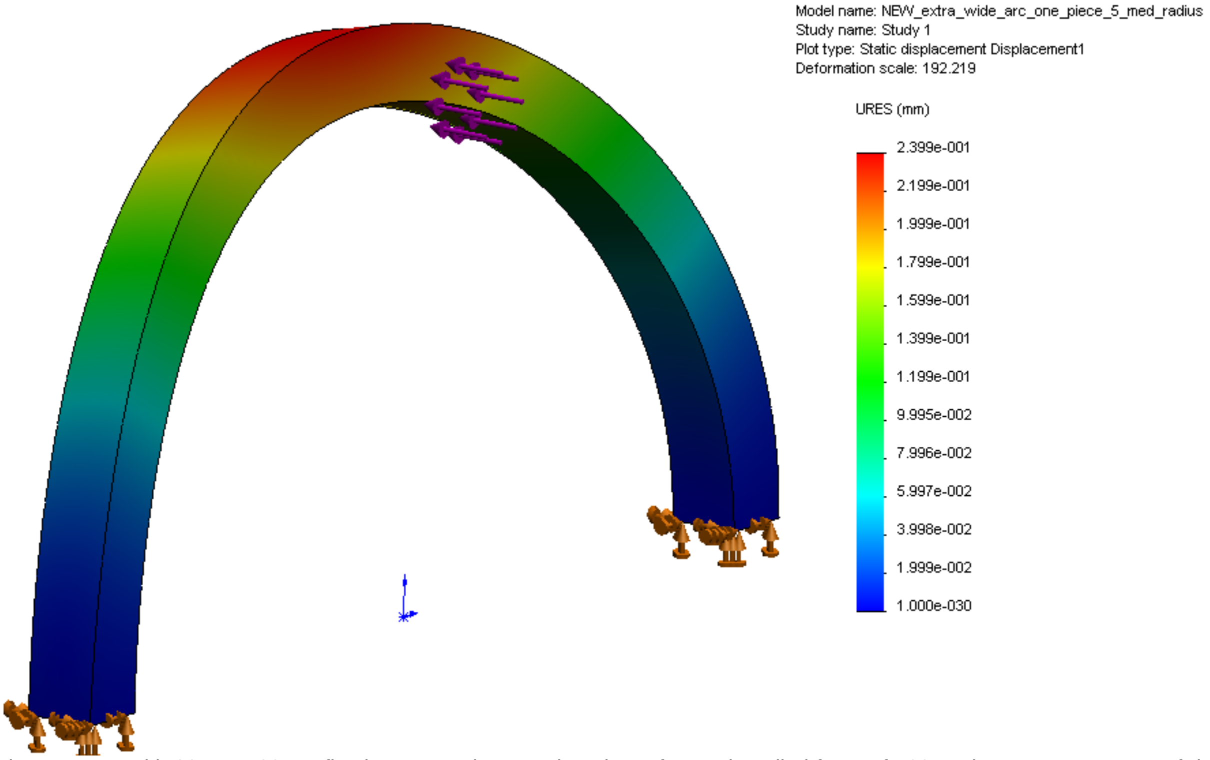


Fig. 11D: Arc with 30mm x 30mm fixed geometry base undergoing a focused applied force of 400N. The greatest amount of deflection occurs at the top with 0.240mm. The material used for the simulation is carbon fiber with an elastic modulus of 70 GPa and Poisson's ratio of 0.38. A focused load is worse than a distributed load and amounts to a worst case scenario.

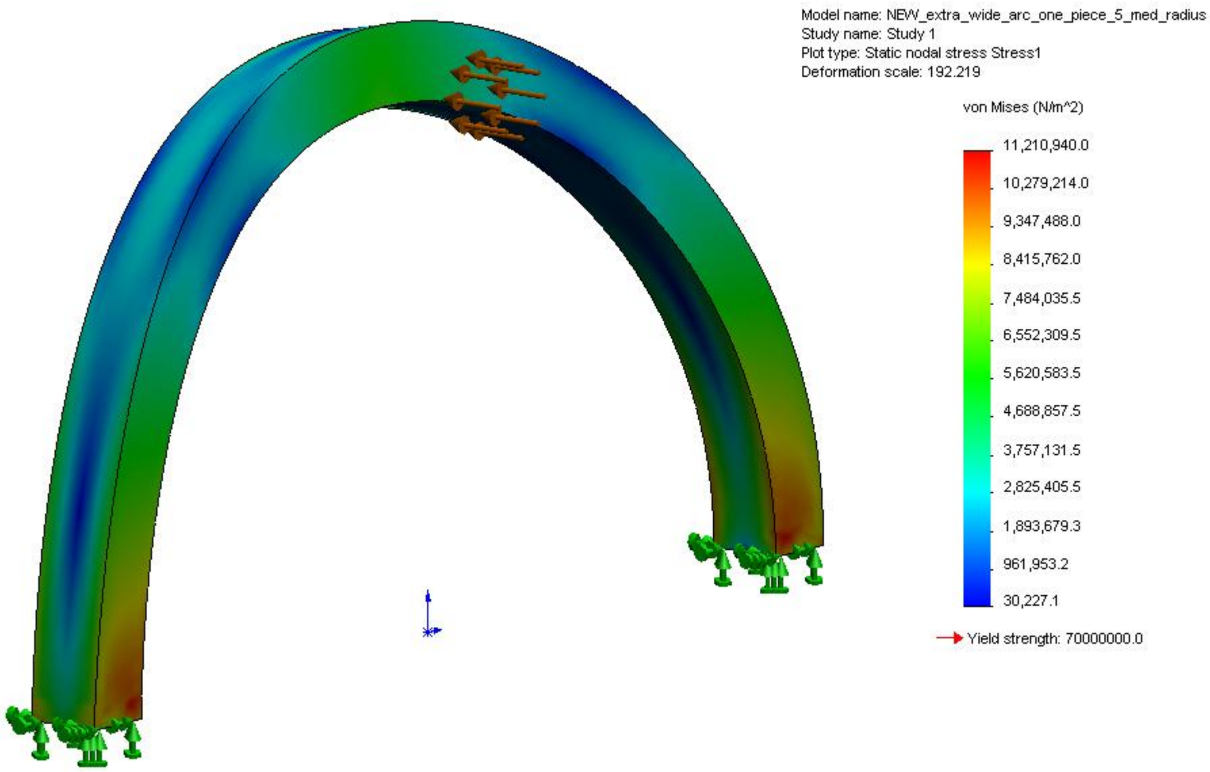


Fig. 12D: Arc with 30mm x 30mm fixed geometry base undergoing a focused applied force of 400N. The highest stresses occur at the base because an arc will distribute its stresses toward the bottom. The arc is anchored by screws that are able absorb the produced stresses of 11 MPa.

[7D] Verstappen I., Snijder H. ., Bijlaard F. S. ., and Steenbergen H. M. G. ., 1998, "Design rules for steel arches—In-plane stability," Journal of Constructional Steel Research, **46**(1–3), pp. 125–126.
[8D] la Poutre D., 2001, "Stability of Steel Arches," Start Document, Eindhoven University of Technology.
[9D] Dym C. L., and Williams H. E., 2011, "Stress and Displacement Estimates for Arches," J. Struct. Eng., **137**(1), pp. 49–58.
[10D] Gere J. M., and Timoshenko S. P., 1999, Mechanics of Materials, Stanley Thornes Publishers Ltd, United Kingdom.

Vacuum cups

Under the railings are vacuum cups that stabilize the system. Each cup is rated for a 36 kg horizontal load and 18 kg vertical load [11D], so two cups under each railing is sufficient to hold the guidance system in place, keeping the 400N loading case in mind.

[11D] Anver, Corp., "VP Series Flat Vacuum Cups with Ball Swivel Suspensions and Side Vacuum Ports: VP60, VP70, VP80 and VP90," Vacuum cups and suction cups

Guidance tube knobs (calculations)

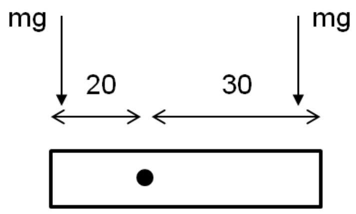


Fig. 13D: Guidance tube mass is 50 grams and is oriented horizontally at 0°. The knobs are off centered of the tube. Gravity acts on the tube creating a moment force.

Find the downward force acting on each side of the tube and determine net moment.

$$mg = 0.05 * 9.81 = 0.4905\ N$$
$$M = 0.4905 * 0.03 = 0.014715\ Nm$$
$$M = 0.4905 * 0.02 = 0.00981\ Nm$$

Net moment is 0.0049 Nm. Knobs must provide that amount of stability to keep tube balanced in horizontal position.

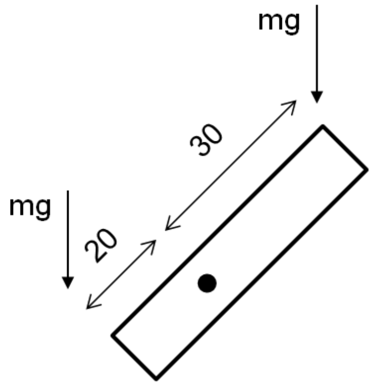


Fig. 14D: Guidance tube at 45° angle. The lever arm length is shortened in the angled position so moment is smaller.

Downward force calculation

$$mg = 0.05 * 9.81 * \cos(45) = 0.3468\ N$$

Lever arm calculation

$$\cos(45) = \frac{L_l}{0.030}; L_l = 0.02121m$$
$$\cos(45) = \frac{L_s}{0.020}; L_s = 0.01414\ m$$

Moment calculation

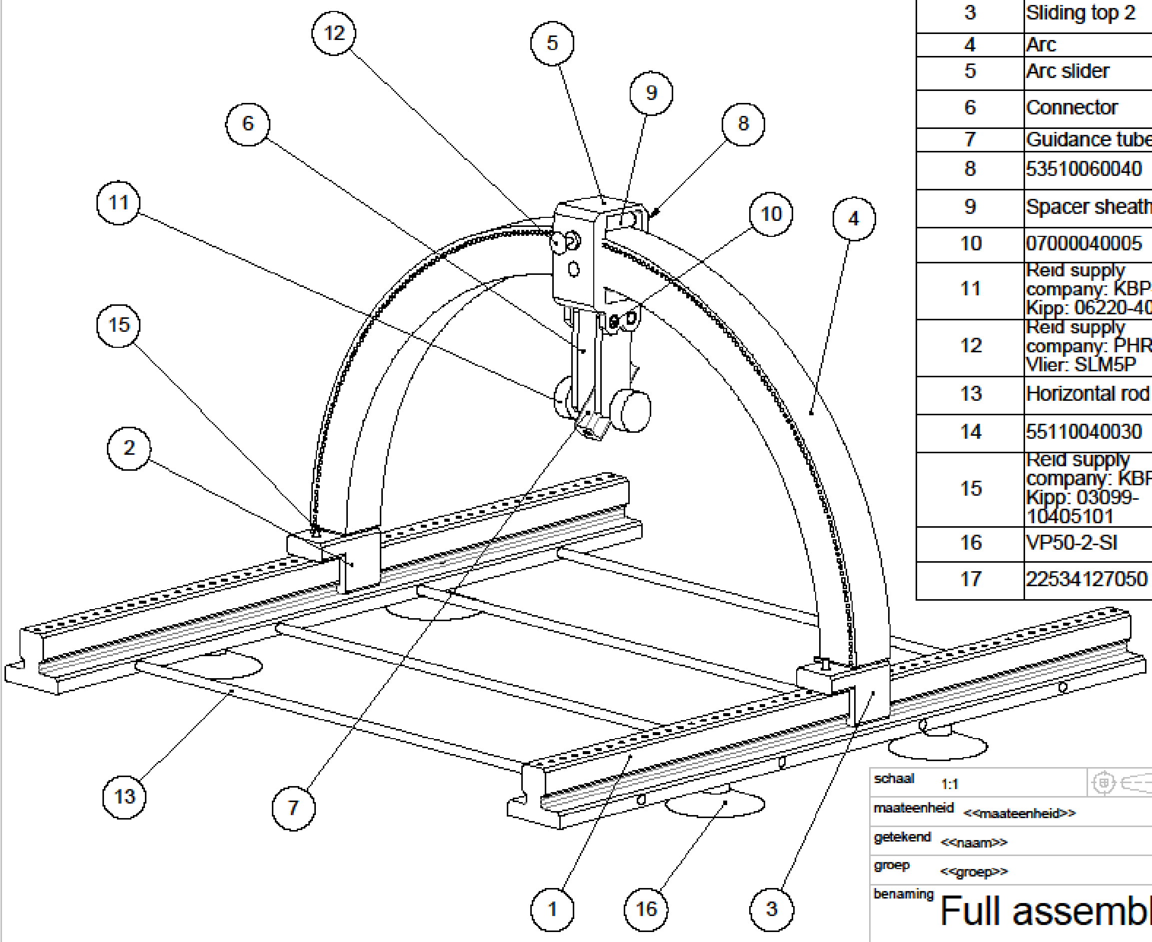
$$M_{xl} = 0.3468 * 0.02121 = 0.0073575\ Nm$$
$$M_{xs} = 0.3468 * 0.01414 = 0.004905\ Nm$$

Net moment for x-component is 0.0024545 Nm. Need to add in y-component.

$$M_r = \sqrt{0.0024545^2 + 0.0024545^2} = 0.003468\ Nm$$

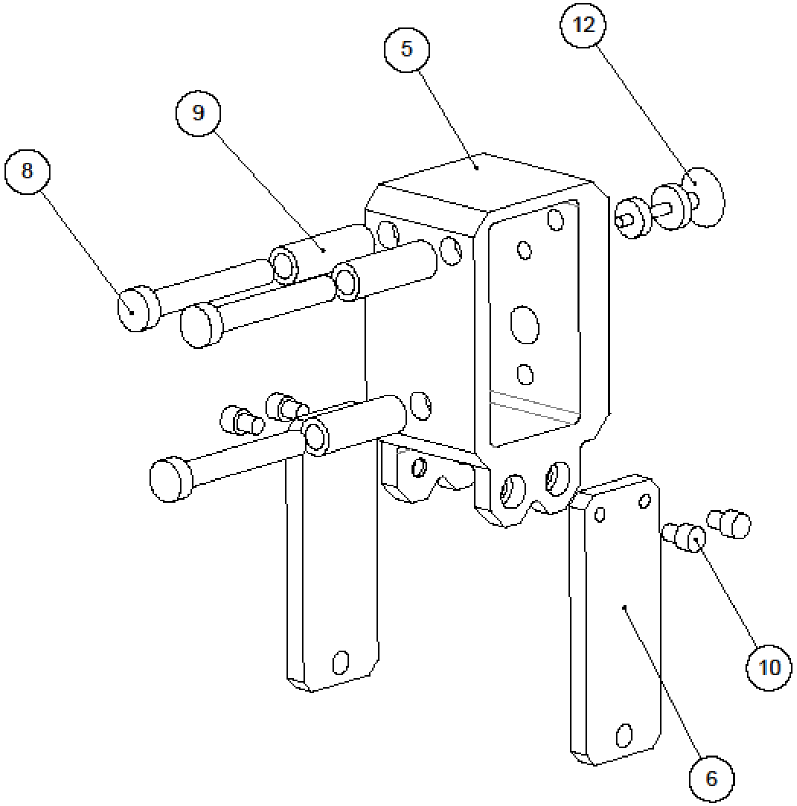
Resultant net moment is 0.003468 Nm. Knobs need to provide that force to keep the tube balanced in a 45° rotated position.

Appendix E: Engineering drawings



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Bottom rails	Bottom rails	2
2	Sliding top	Slides on top of bottom rail	1
3	Sliding top 2	Same as item no. 2 but different hole position	1
4	Arc	Arc 400 mm diameter	1
5	Arc slider	Slides along arc	1
6	Connector	Connects the arc slider with the guidance tube	2
7	Guidance tube	Guidance tube	1
8	53510060040	Fabory D931 STNL A4-80 hex bolt M6x40	3
9	Spacer sheaths	Forms sheath over hex bolts and contacts arc for sliding	3
10	07000040005	Fabory D912 12.9 SHCS M4x5	4
11	Reid supply company: KBP-1091 Kipp: 06220-405X10	Kipp studded thermoplastic seven lobe knob	2
12	Reid supply company: PHR-50N Vlier: SLM5P	Steel locking knurled knob spring plunger	1
13	Horizontal rod	Keeps the bottom rails aligned	4
14	55110040030	Fabory D963 STNL A4 countersunk screw slotted M4x30	4
15	Reid supply company: KBP-818 Kipp: 03099-10405101	Kipp indexing plunger with L-shaped handle	2
16	VP50-2-SI	Anver vacuum cup	4
17	22534127050	Vacuum cup connector - Fabory 1/2 - 13 UTC 2in SS bolt	4

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/9/2012	
getekend	<<naam>>		
groep	<<groep>>		
benaming	Full assembly		
TU Delft Biomedical Engineering		formaat A3	tekeningnummer 1



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
5	Arc slider	Slides along arc	1
6	Connector	Connects the arc slider with the guidance tube	2
8	53510060040	Fabory D931 STNL A4-80 hex bolt M6x40	3
9	Spacer sheaths	Forms sheath over hex bolts and contacts arc for sliding	3
10	07000040005	Fabory D912 12.9 SHCS M4x5	4
12	Reid supply company: PHR-50N Vlier: SLM5P	Steel locking knurled knob spring plunger	1

QTY. listed for this assembly only

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groep	<<groep>>		

benaming **Arc slider assembly**

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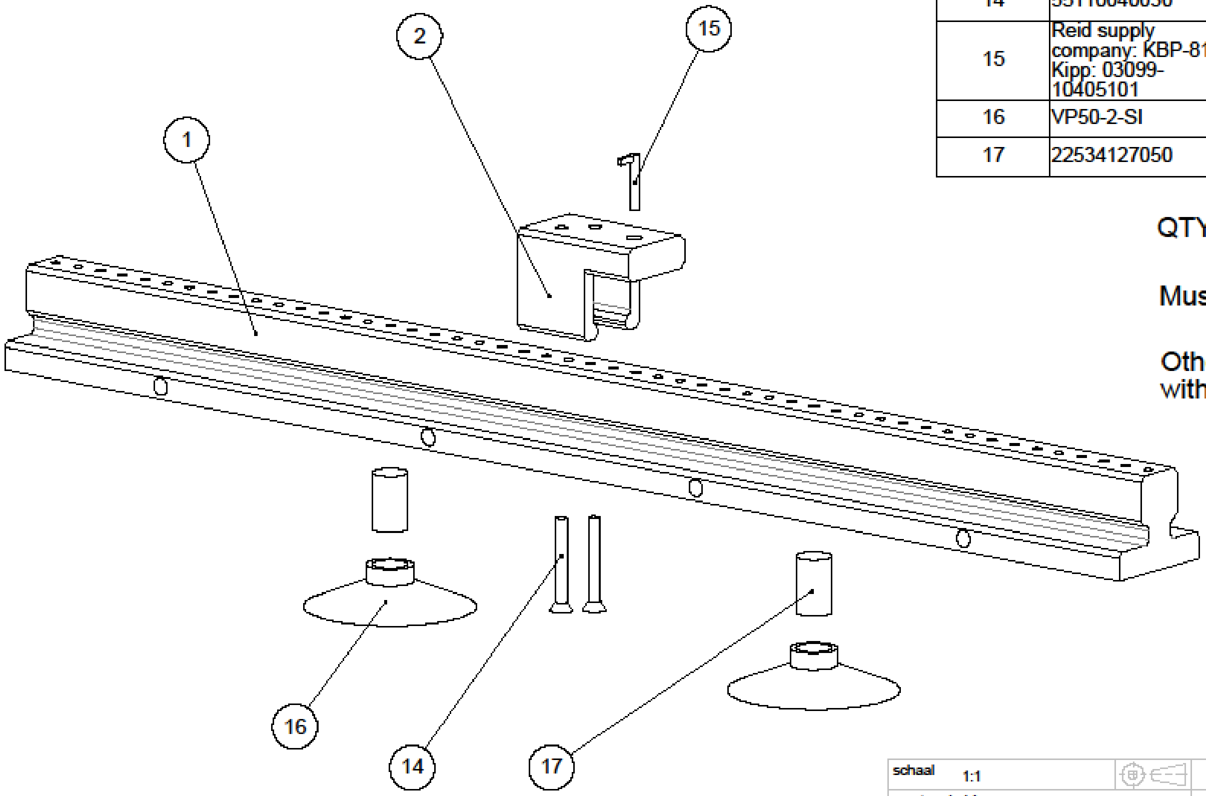
ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Bottom rails	Bottom rails	1
2	Sliding top	Slides on top of bottom rail	1
14	55110040030	Fabory D963 STNL A4 countersunk screw slotted M4x30	2
15	Reid supply company: KBP-818 Kipp: 03099-10405101	Kipp indexing plunger with L-shaped handle	1
16	VP50-2-SI	Anver vacuum cup	2
17	22534127050	Vacuum cup connector - Fabory 1/2 - 13 UTC 2in SS bolt	2



QTY. listed for this assembly only

Must make 2x rail assembly

Other rail assembly uses "Bottom rails" with "Sliding top mirror holes"

Cut ITEM NO. 17 to 32 mm length

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maateenheid <<maateenheid>>		8/9/2012	
getekend <<naam>>			
groep <<groep>>			
benaming Rail assembly			

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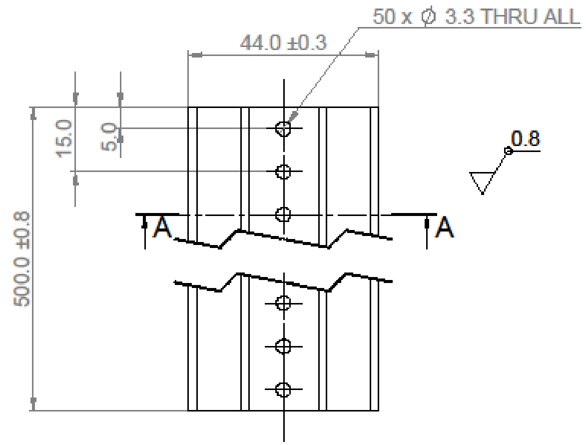

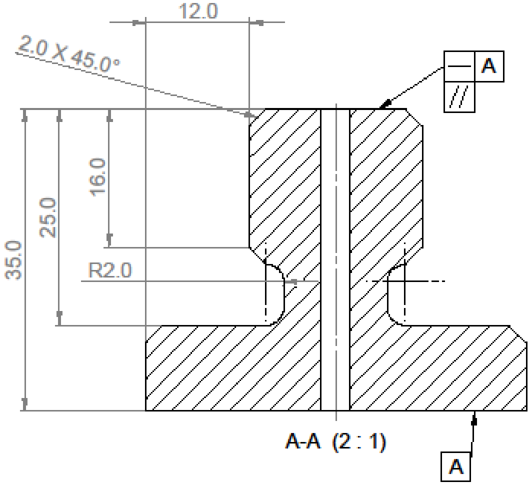

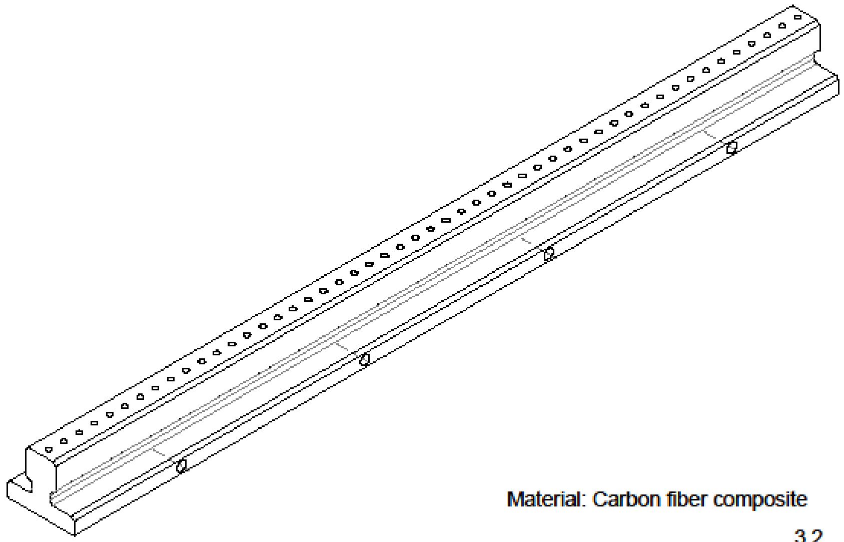

Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 3.2

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Bottom rails	Bottom rails	2

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getekend	<<naam>>		
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benaming **Bottom rails**

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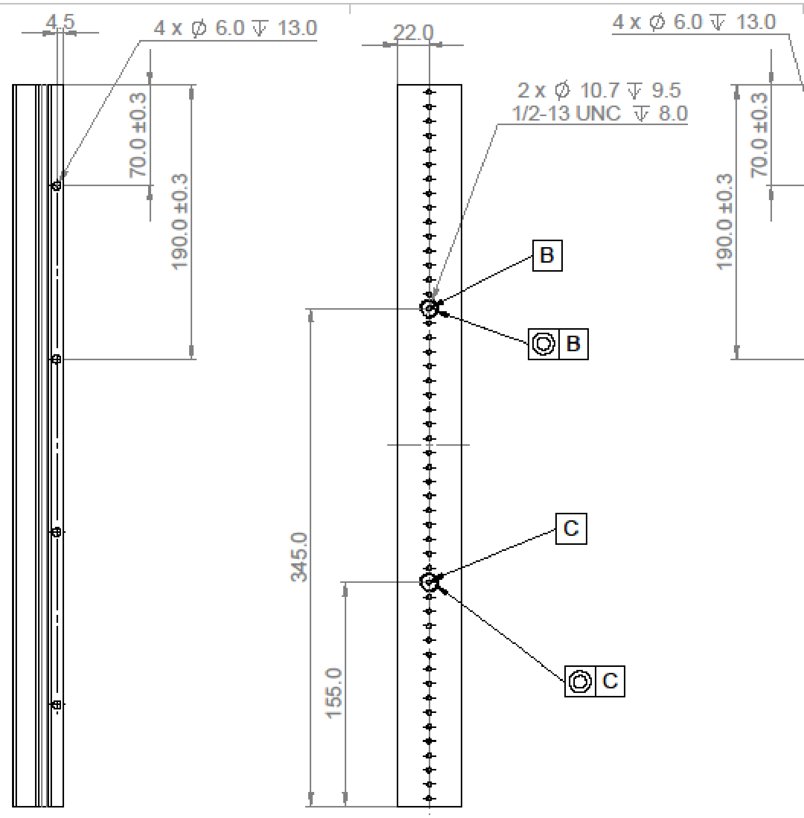
tekeningnummer 4. Sheet 1 of 2



Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 3.2

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Bottom rails	Bottom rails	2

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maateenheid	<<maateenheid>>	8/9/2012	
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groep	<<groep>>		
benaming	Bottom rails		

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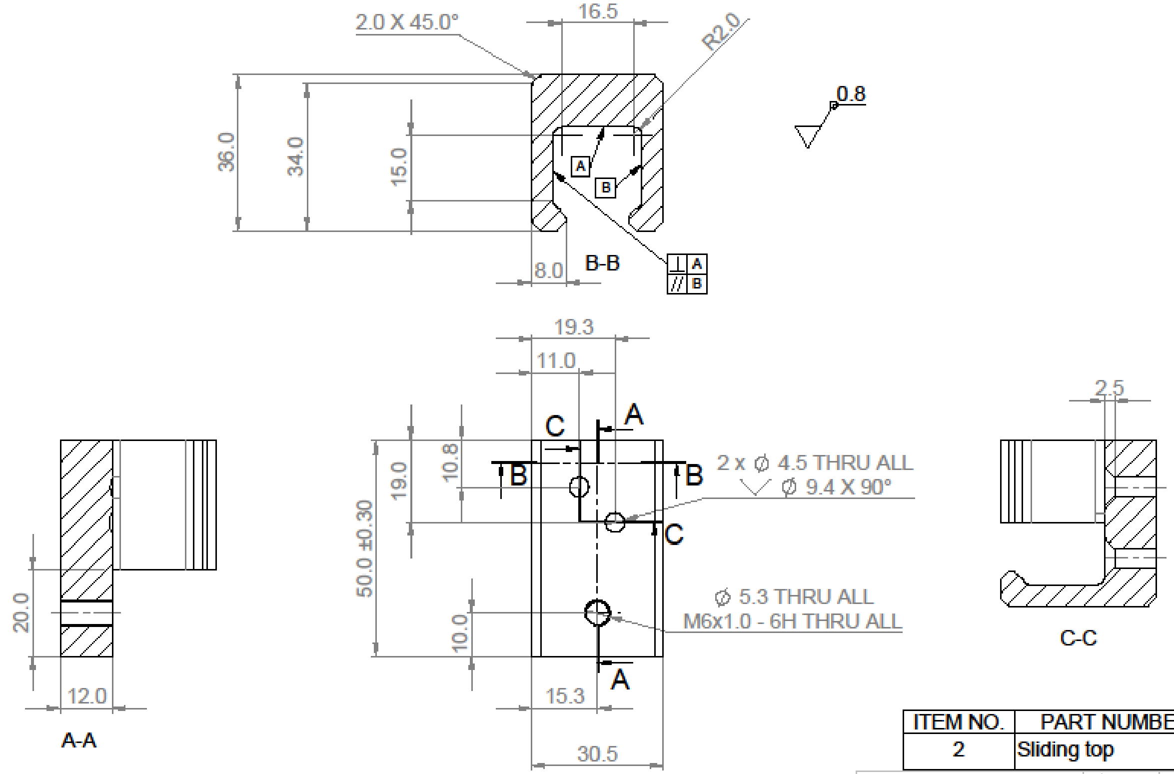
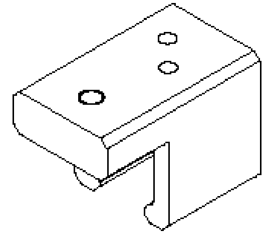
A3	4. Sheet 2 of 2





Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 3.2

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
2	Sliding top	Slides on top of bottom rail	1

schaal	1:1	datum	opmerkingen
maateenheid	<<maateenheid>>	8/10/2012	Item no. 2 must fit to slide on top of item no. 1 Item no. 2 is same as item no. 3, except position 2 x ⌀ 4.5 THRU ALL ⌀ 9.4 X 90°
getekend	<<naam>>		
groep	<<groep>>		
benaming	Sliding top		

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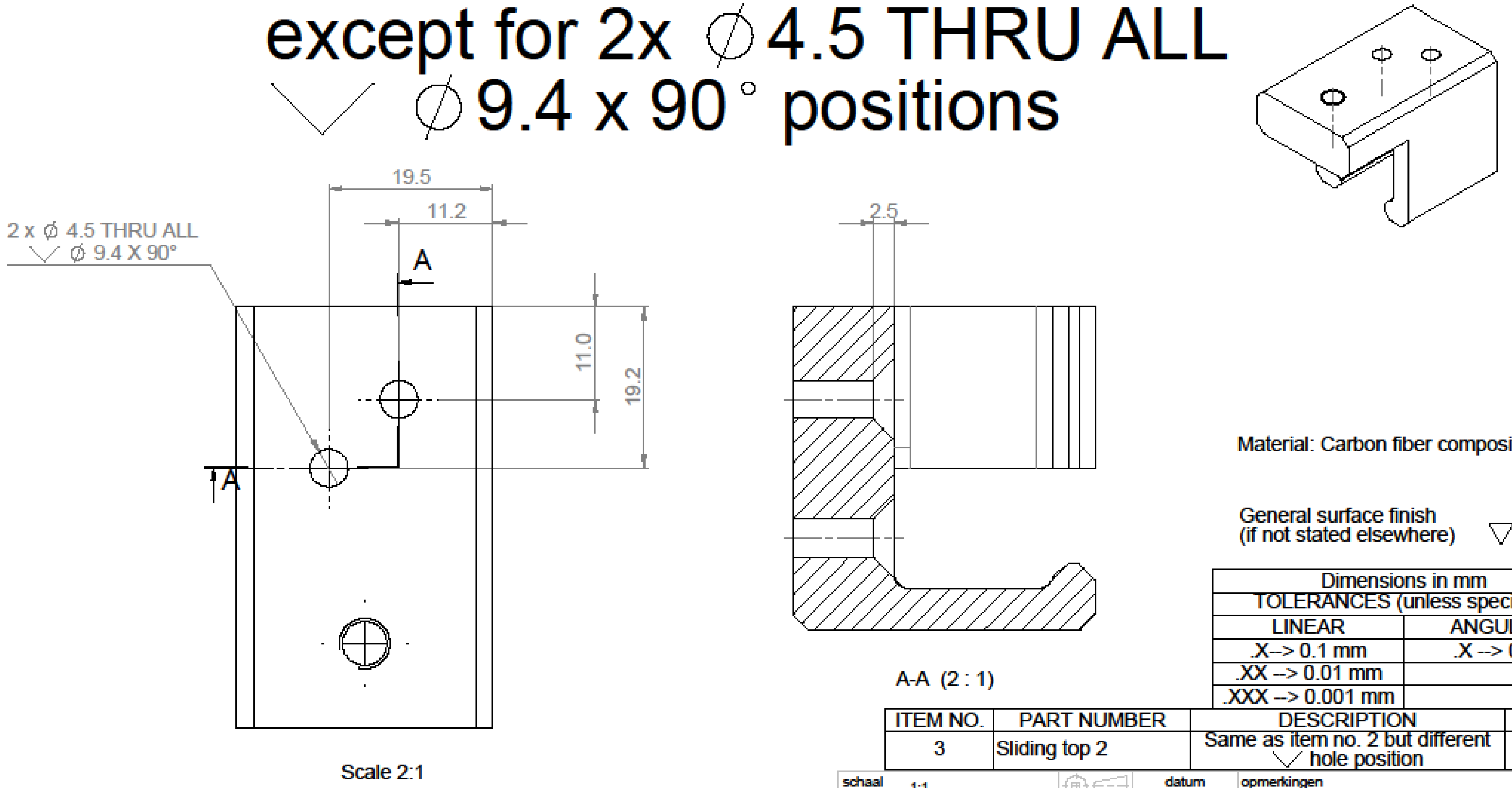
formaat: A3
tekeningnummer: 5

SolidWorks Educational Edition.
For Instructional Use Only.

Note: Same as item no. 2
except for 2x ∅4.5 THRU ALL
⌵ ∅9.4 x 90° positions



Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 3.2

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
3	Sliding top 2	Same as item no. 2 but different ⌵ hole position	1

schaal	1:1	datum	opmerkingen
maateenheid	<<maateenheid>>	8/10/2012	
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benaming	Sliding top 2		

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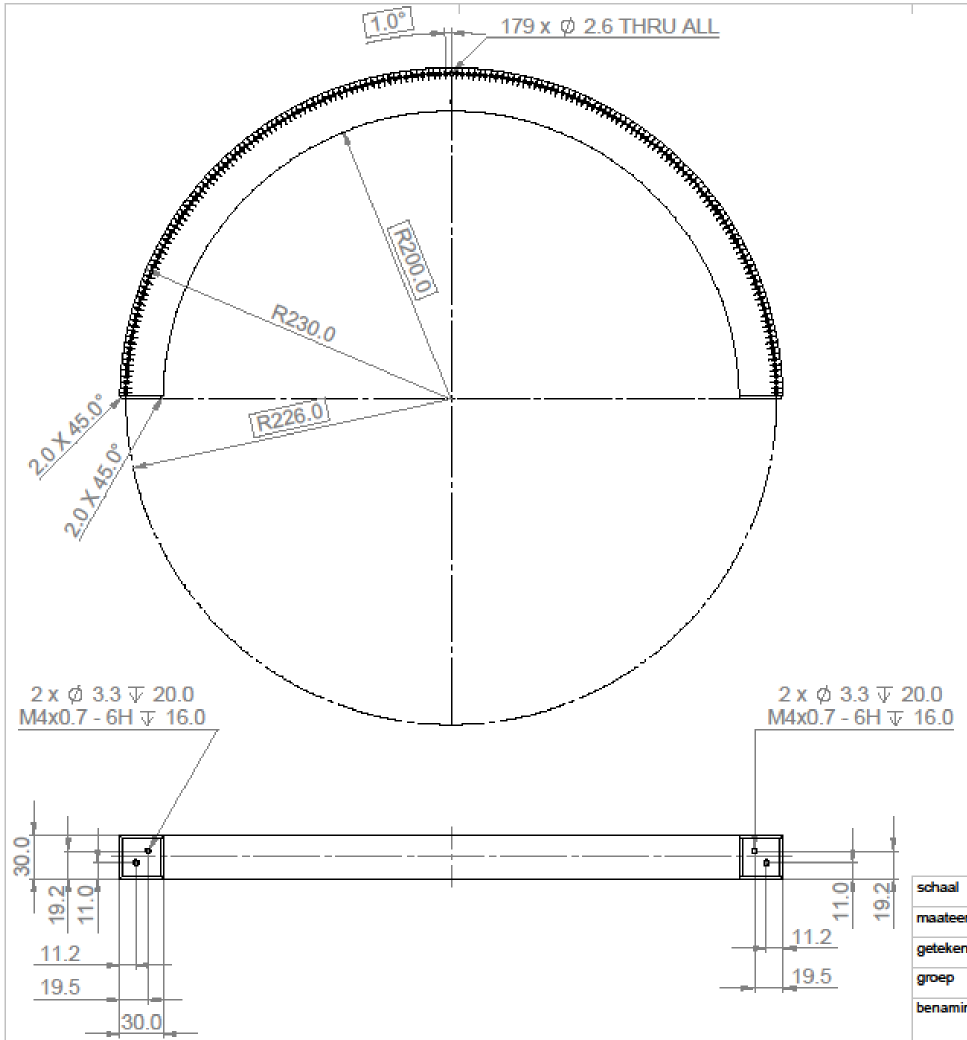
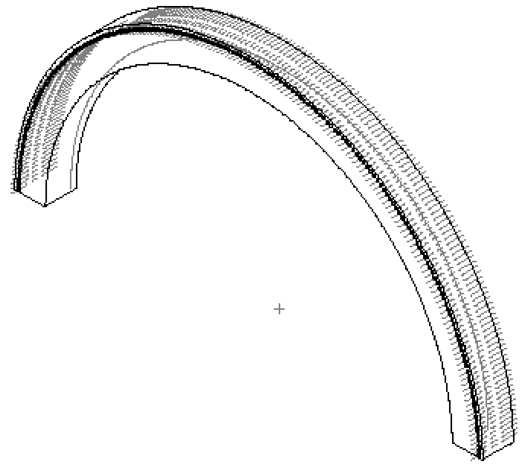
formaat	tekeningnummer
A3	6





Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 0.4

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
4	Arc	Arc 400 mm diameter	1

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/10/2012	
getekend	<<naam>>		
groep	<<groep>>		
benaming	Arc		

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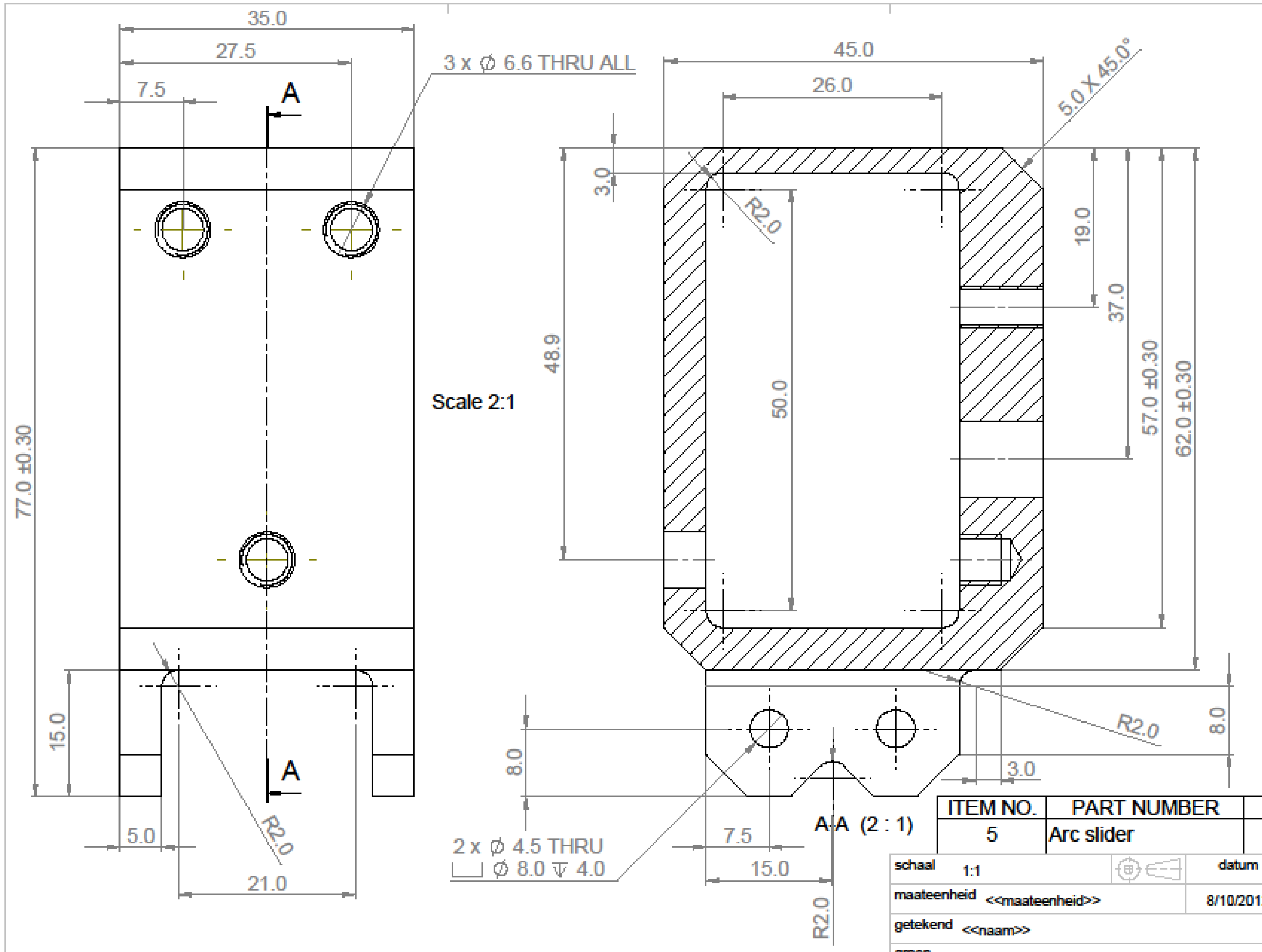
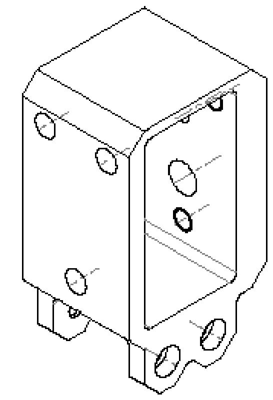
SolidWorks Educational Edition.
For Instructional Use Only.





Material: Carbon fiber composite

General surface finish (if not stated elsewhere) 1.6

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
5	Arc slider	Slides along arc	1

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/10/2012	
getekend	<<naam>>		
groep	<<groep>>		
benaming	Arc slider		

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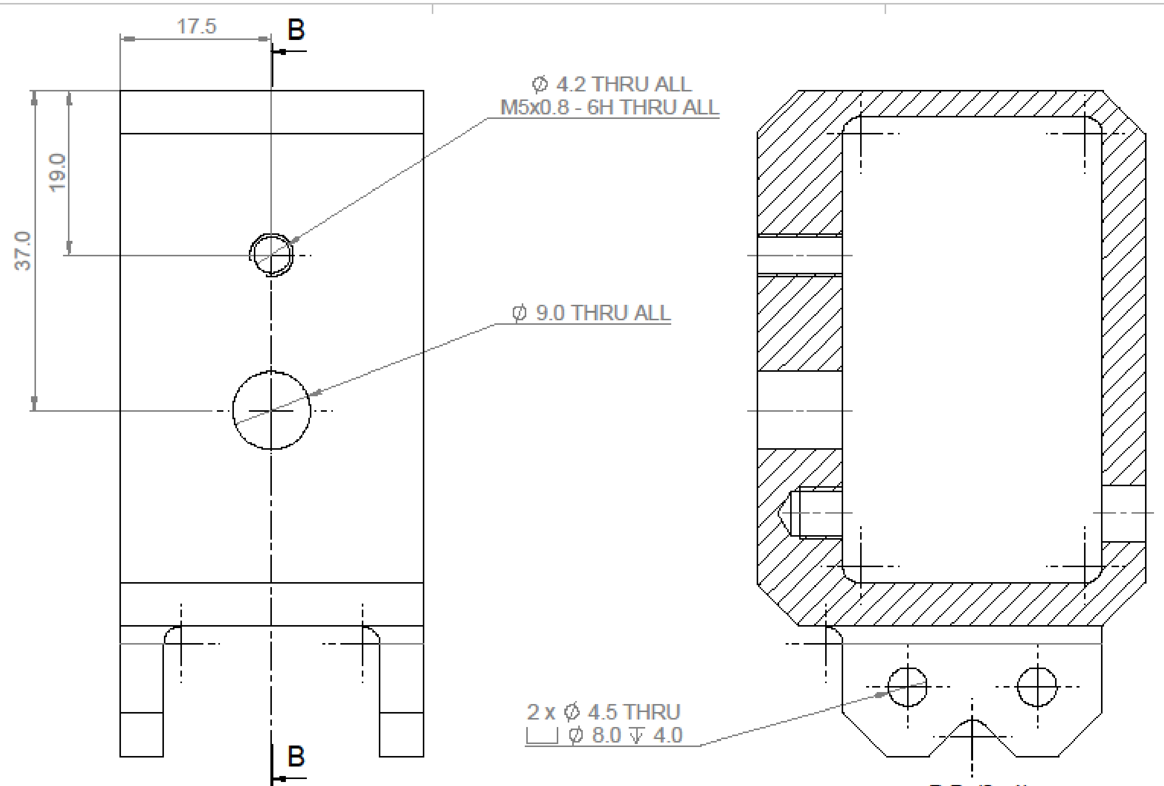
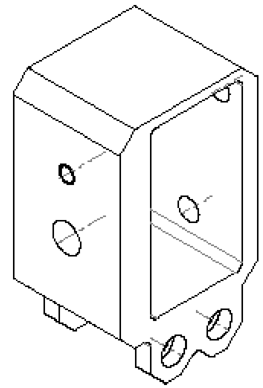


B-B (2 : 1)



Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 1.6

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
5	Arc slider	Slides along arc	1

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/10/2012	
getekend	<<naam>>		
groep	<<groep>>		
benaming	Arc slider		

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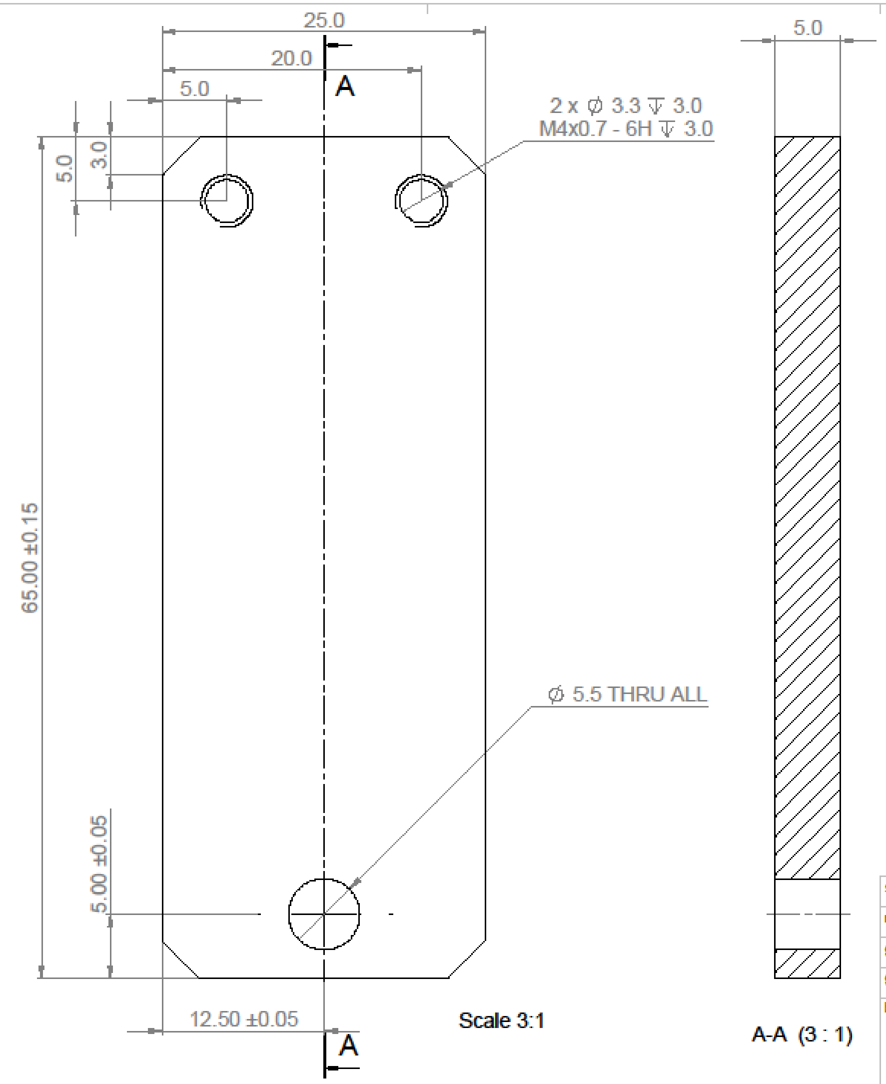

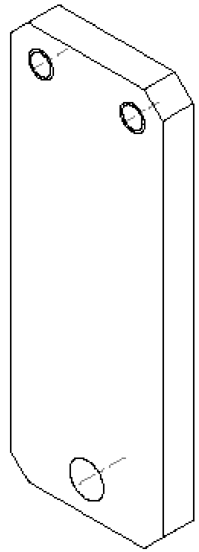

Material: Carbon fiber composite

General surface finish
(if not stated elsewhere) 1.6

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
6	Connector	Connects the arc slider with the guidance tube	2

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/10/2012	
getekend	<<naam>>		
groep	<<groep>>		

benaming **Connector**

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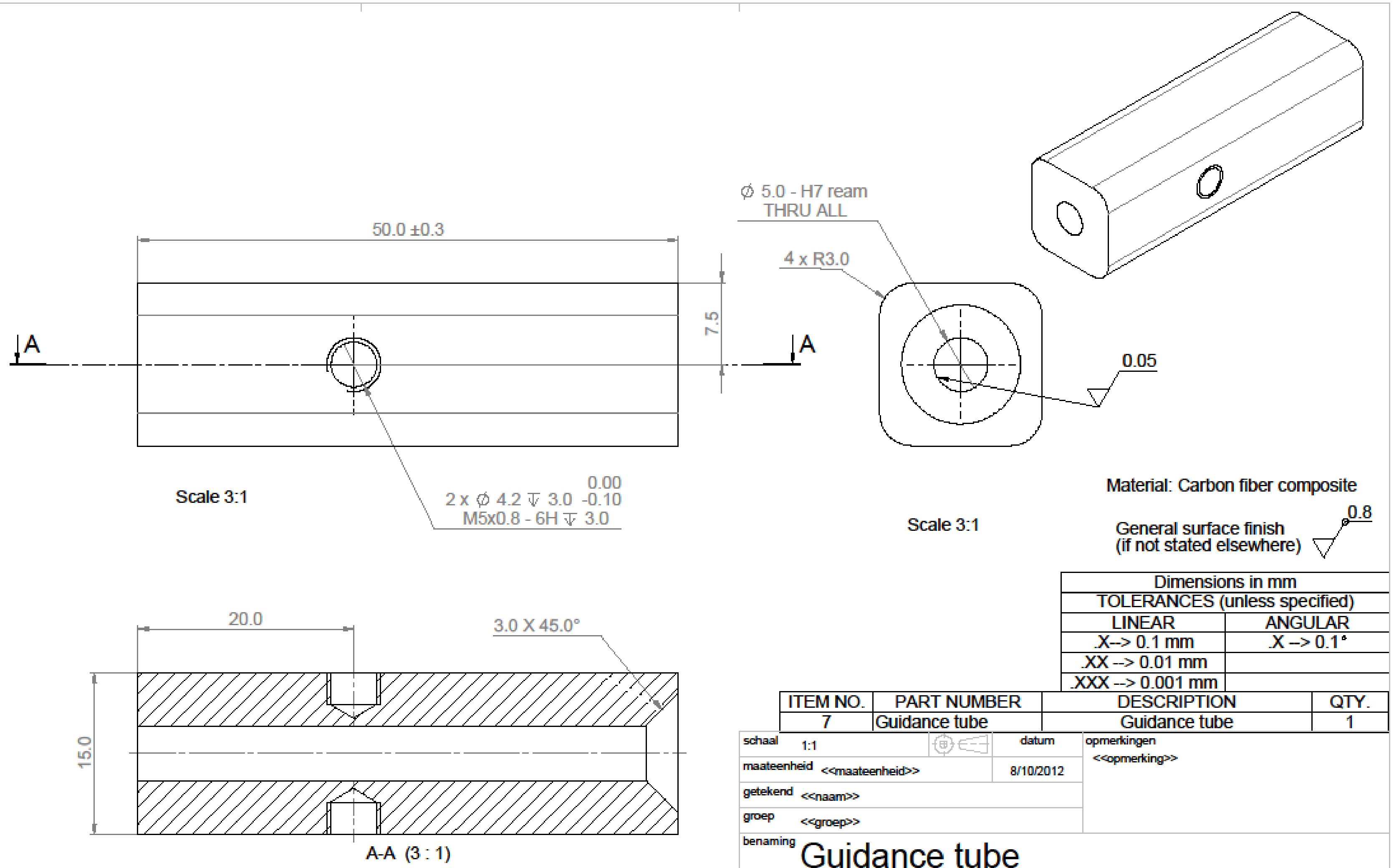

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
7	Guidance tube	Guidance tube	1

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/10/2012	
getekend	<<naam>>		
groep	<<groep>>		
benaming	Guidance tube		

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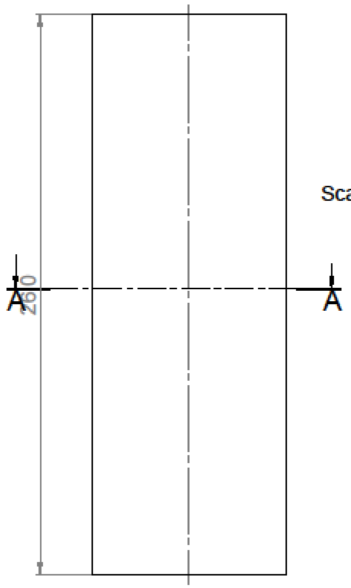
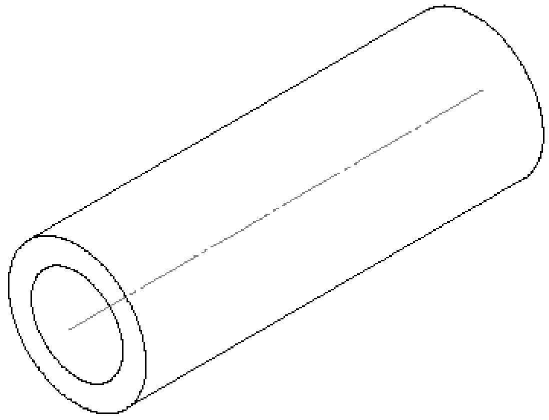
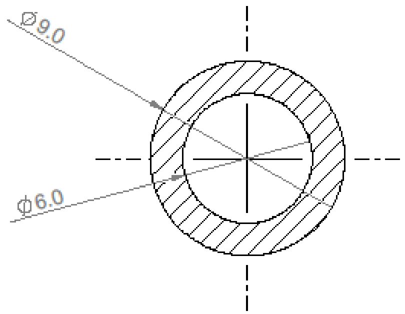


Scale 5:1





A-A (5 : 1)

Material: UHMWPE

General surface finish
(if not stated elsewhere) 0.05

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
9	Spacer sheaths	Forms sheath over hex bolts and contacts arc for sliding	3

schaal	1:1	datum	opmerkingen
maateenheid	<<maateenheid>>	8/10/2012	<<opmerking>>
getekend	<<naam>>		
groep	<<groep>>		

benaming **Spacer sheaths**

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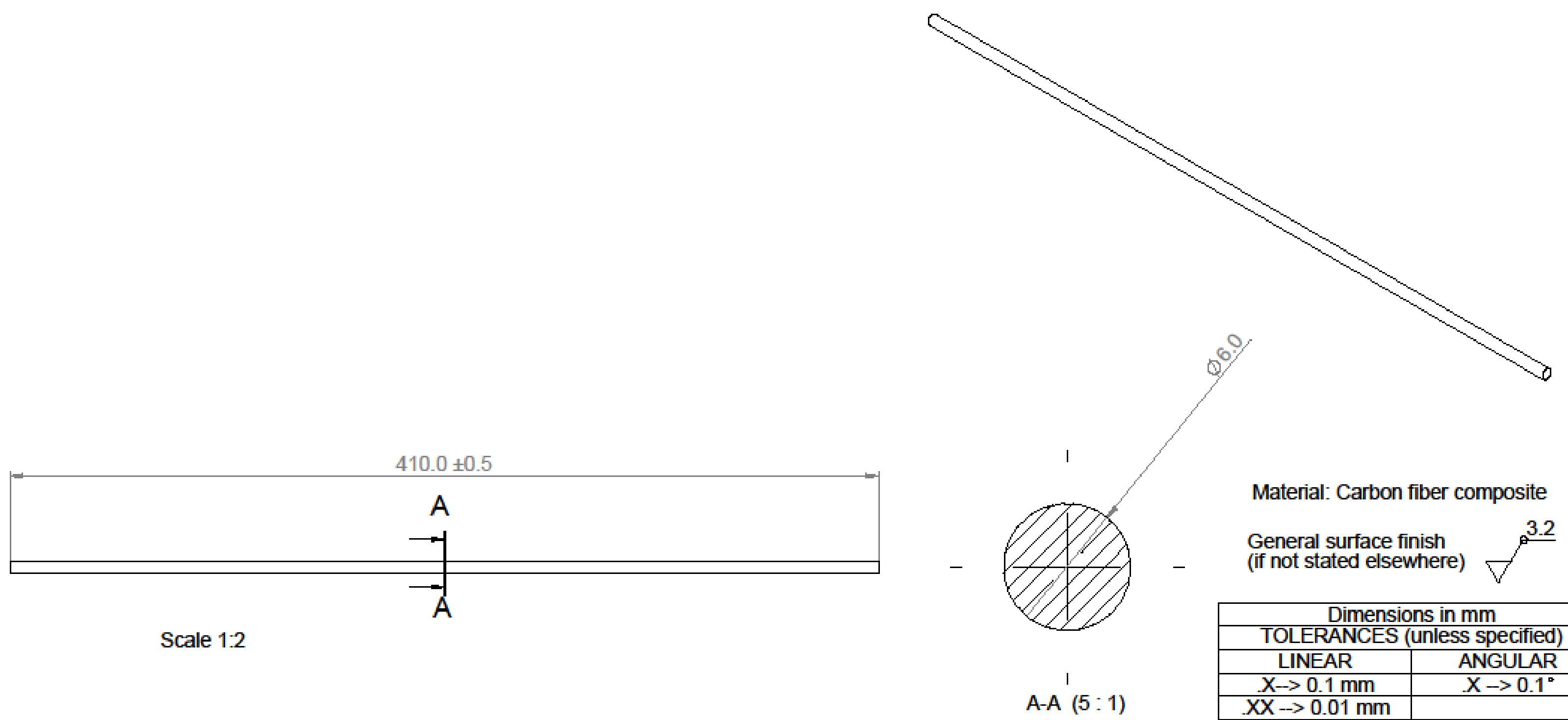

Material: Carbon fiber composite

General surface finish (if not stated elsewhere) 3.2

Dimensions in mm	
TOLERANCES (unless specified)	
LINEAR	ANGULAR
.X--> 0.1 mm	.X --> 0.1°
.XX --> 0.01 mm	
.XXX --> 0.001 mm	

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
13	Horizontal rod	Keeps the bottom rails aligned	4

schaal	1:1	datum	opmerkingen <<opmerking>>
maateenheid	<<maateenheid>>	8/10/2012	
getekend	<<naam>>		
groep	<<groep>>		

benaming **Horizontal rod**

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tekeningnummer 12