Title: Hybrid-Drive Prosthesis

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Brief Description:

The proposed invention is a hybrid-drive prostheses, an example embodiment provided herein of this invention is of upper-limb prostheses. This prosthetic device strategically combines body-powered and electronically-driven motor actuation. This prosthetic device has benefits over current electronically-powered technology in that it is light weight, ergonomic, permits body-powered control, and is less expensive. This example embodiment of the prosthetic device has clinical applications by providing upper-limb affected individuals with an alternative product that contains improved functionality over current body-powered devices combined with decreased muscle fatigue and cost of current electronically-powered devices.

Claims:

1. A novel hybrid-drive upper-limb prosthesis that strategically combines body-powered and electronically-driven motor actuation.
2. The device of claim 1, wherein an independently controlled tensioning component has been optimally placed to maximize range of motion and force production.
3. The device of claim 1, wherein motors were optimally placed on the ventral side of the most proximal area of the prostheses to minimize weight and maximize actuator efficiency.
4. The device of claim 1, wherein motors are controlled by a wireless mechanism either by the user or environmental cues.
5. A method of designing and constructing an upper-limb prosthetic that augments muscle functionality of the affected limb.
6. A method of designing and constructing an ergonomic upper-limb prostheses that mimics body weight distribution of the unaffected limb.

Additional Description:

Traditional electronically-powered prostheses have two common downfalls; heaviness and a lack of manual, body-powered control. To solve these universal issues, a novel, hybrid prosthesis design has been developed. Utilizing a body-powered prosthetic base, manual control is still entirely possible (and encouraged) – this allows for the development of healthy and strong muscles in children who would normally abandon the use of their affected limb, which leads to long-term weakness and even postural problems like scoliosis. To reduce weight and enhance ease of use, fewer (and lighter-weight) motors are used. Rather than developing all of the force needed to grip objects, the motors in this hybrid design are intended to augment the user's strength to both make using the prosthetic easier and to encourage them to use what strength they have.

Additional embodiment descriptions, data, and views of an example embodiment are provided below.

Mechanical and Electrical Design Considerations for the Development of a 3D Printed, Hybrid-Drive Upper-Limb Prosthesis

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Abstract

The development of 3D printing for the manufacturing of prostheses and orthoses has resulted in cost reduction strategies, better accessibility and customization of prosthetic designs. The widespread use of 3D printing and the existence of myriad prosthetic designs available on the internet allows clinicians and researchers from different disciplines to manufacture their own devices. Given the dearth of studies discussing the practical application of 3D printed upper limb prostheses, the current paper describes the technical and clinical considerations for the implementation of these devices in rehabilitation and research settings. Specifically, considerations on fitting procedures, assembly, durability, regulatory implications, and patient functional outcomes are discussed.

Keywords

3D printing, computer-aided design, low-cost prostheses, FDA regulations, transitional prosthesis, prosthesis for children, prosthetic function.

Background

Children's prosthetic needs are complex due to their small size, constant growth, and psychosocial development. Socio-economical background and financial resources play a crucial role in prescription of prostheses for children, especially when private insurance and public funding are insufficient. Electric-powered units (i.e., myoelectric) and mechanical devices (i.e., body-powered) have improved to accommodate children's needs, but their maintenance and replacement costs make access difficult for many families. Voluntary-closing upper-limb prostheses are more suitable for children and could improve gross motor development. Currently, the best cost-effective option for pediatric populations is a passive prosthetic hook; although functional, these devices have a high rejection rate, in part due to weight, cost and low visual appeal. Most clinically-recommended prostheses do not adapt to the typical growth of children's limbs and require regular visits to health care providers for adjustments or replacement, which may ultimately lead to device abandonment.

Advancements in computer-aided design software and additive manufacturing techniques (i.e., three dimensional or 3D printing), offer the possibility of designing, printing, and fitting prosthetic hands and other assistive devices at a very low cost. Previous studies have described low cost prosthetic hands, arms and shoulders with practical and easy fitting procedures that can be performed remotely. Importantly, in children the durability of the 3D printed prostheses is challenged continuously due to their activity levels and outgrowth of the prostheses. Therefore, the cost effectiveness of 3D printing makes repairs and upgrades of prostheses substantially more affordable. In general, previous publications have presented different aspects of the development of 3D printed prostheses for children, and the consensus is that 3D printing is a promising manufacturing method for the development of these devices.

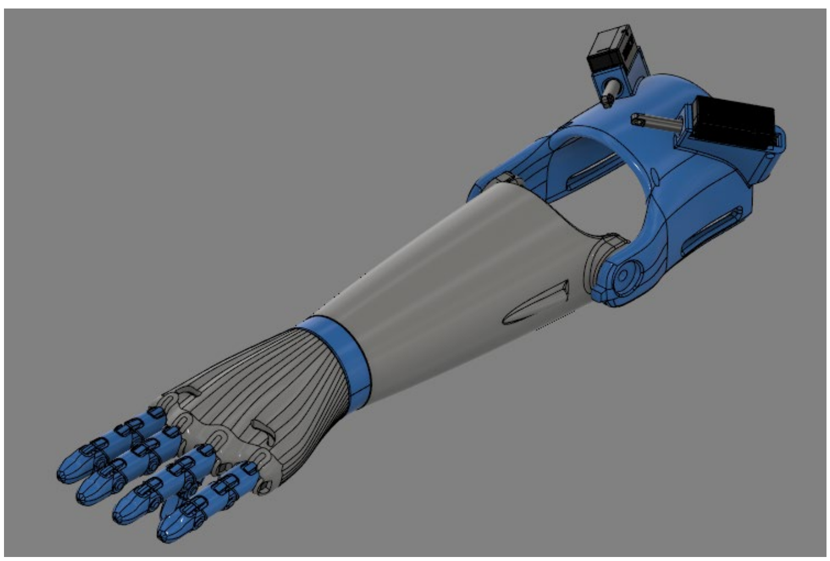
1. General design considerations

The hand was designed to possess 5 fingers with 2 degrees of freedom The finger and thumb were oriented in opposition to facilitate cylindrical grasp and tip pinch. Silicone finger pads were added to provide increase friction for grasping activities. A rotation mechanism placed on the wrist allowed full pronation and supination, and a pivot system with internal components allowed wrist rotation without twisting the line. The rotation mechanism of the wrist consisted of an inner circular disc/shaft with a center opening. A circle of embedded magnets with matching polarity was placed around the disc. A bi-valve circular sleeve with embedded magnets aligned to match the disc magnets, was placed over the disc. The magnets were placed with opposing polarity to assure mutual attraction. The disc and sleeve rotate independently and were stabilized in various positions by the attraction of the magnets. The magnets were sealed in a protective sleeve for safety. Elbow flexion and extension can be performed using a simple hinge mechanism. A BOA dial tensioner system allowed the regulation of the tension of the cables controlling the finger flexion. A Velcro strap secured the prosthesis to the arm and harnessing was not needed for suspension. Gripping can be assisted through the use of two proximally-mounted linear actuators; this allows for modulation of required elbow range of motion for gripping as well as grip strength.

1.1 Mechanical design

One notable issue with the existing transradial, body powered 3D printed prostheses is the difficulty in object manipulation and force production due to factors including short residual limb length, object manipulation height, muscle fatigue and excess trunk involvement. These factors have been reported by users and observed by the researchers as barriers to effective and long-term use of the prostheses.

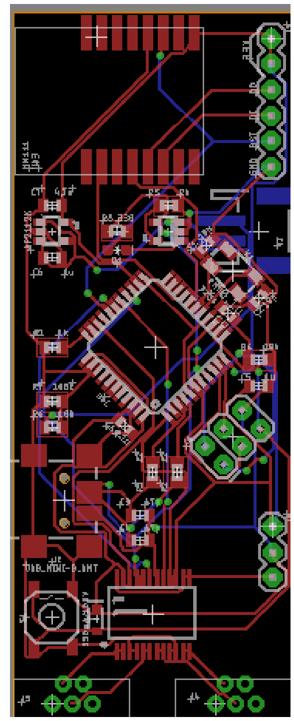
The proposed solution to this limitation of the current design is to incorporate simple, linear actuator-based variable tensioner system. By introducing an independently controlled tensioning component, both required range of motion and force production can be significantly enhanced. By placing the shafts of the linear actuators perpendicular to the cord path, their travel linearly increases or decreases tension in the cord. The reduced cord travel required while the actuators are extended leads to a lower required elbow and trunk range of motion to complete a gripping task, allowing for the relief of difficulties introduced by object manipulation height and excess trunk involvement. If the actuators are activated during the act of gripping, the grip force on the object can be enhanced, thereby reducing torque requirements of the user (especially important for users with short residual limbs) and alleviating muscle fatigue.



In order to minimize the bulkiness and optimize efficiency of the actuators, the motors were placed on the ventral side of the most proximal area of the prosthesis. Motor shafts were aligned perpendicular to the tension cord path, and placed so that, when fully retracted, the actuators had no interference with the cord (in this condition the prosthesis functions in the same manner as the original design). (Figure 1) When extended, the motor shafts then exert force to shorten the cord path, effectively reducing needed cord travel and applying external force simultaneously.

1.2 Electrical design

The driving motors used are the PQ12 linear actuators, which are capable of 40N at 6mm/s with the 100:1 gear ratio, which was the version used. Their stall current hovers around



210mA, while its active current draw without load has been experimentally found to be around 100mA. With their full stroke length of 20mm, we have found success using them to control the designed prosthetic arm.

The designed control system integrates an ATmega32u4 microcontroller to allow for USB based firmware uploads and is clocked at 8MHz with an external crystal oscillator with a system voltage of 3.3V. It is paired with the HM-11 Bluetooth Low Energy module flashed with the MyoBridge firmware to allow communication between the MyoBand and microcontroller. To enable portability a lithium-polymer battery and integrated charging circuit were implemented, the battery voltage being regulated down to 3.3V using the AP2112K 600mA LDO. Industry standard design considerations were implemented including 0.1uF bypass capacitors on both the digital and analog power supplies to suppress RF emissions as well as a secondary diode and 100nF bypass capacitor on the reset line to suppress noise and protect the pin from overvoltage. In addition, series 22Ω resistors were added on the USB differential lines to suppress ringing and 47pF bypass capacitors were added on the same lines for stability.

Five pin FPC connectors were used for the PQ12 motor connections. The motor voltage of 12V is achieved using a simple three pin boost converter from Pololu which can achieve around 85% efficiency at 3.3V. The TB6612 motor driver is used to drive the two motors with 1.2A maximum driving current.

This configuration has been shown to be successful with our prototype boards and we are currently in the process of ordering this design to test.

1.3 3D Printing Specifications and Materials

The most common 3D printing method for 3D printed prostheses is fused deposition modeling. Fused deposition modeling is a form of additive manufacturing that involves melting thin layers of plastic over each other to form a 3D structure. The two most common 3D printed filament materials used to manufacture upper limb prostheses is polylactide filament and acrylonitrile butadiene styrene filament. Polylactide filament has similar properties to a thermoplastic and permits minor modifications through targeted heating once the device has been 3D printed. Acrylonitrile butadiene styrene filament however, does not offer homogenous thermoplastic properties making post-processing modifications difficult. Thus, the preferred material for 3D printed prostheses is polylactide filament given the ability to perform post-processing modifications that may be required during assembly or clinical fitting.

After selecting the printing material, the files need to be sliced and nested before 3D printing. Slicing can be performed using open-source software (see Table 1). Slicing is the process that converts 3D models into a format understood by 3D printers. The model is "sliced" into 2D cross-sectional layers which can be placed by the extruder. The slicing software often develops a G-code which is a set of numerical values representing positions in the system-based reference frame in which the extruder needs to follow to trace and recreate the design.

Furthermore, nesting is the process of organizing the printed parts in the building platform in an effective and efficient manner. Most consumer desktop 3D printers provide access to software that allows the user to set the preferred parameters. These parameters include percentage of infill and pattern (i.e., hexagon pattern), print speed (mm/s), temperature of the heated bed (°F/C), shell thickness (mm) and the option of using rafts and supports to ensure printing feasibility. Most 3D printed prostheses can be manufactured using low-cost desktop 3D printers (Ultimaker 2, Ultimaker B.V., Geldermalsen, The Netherlands) or industrial grade 3D printer (Uprint SE Plus, Stratasys, Minnesota, USA). In general, the digital files of any upper-limb prostheses for children available on the internet can be 3D printed with a minimum building platform of 28.5 cm L x 15.3 cm W x 15.5 cm H. When using desktop 3D printers, the recommended settings are 40% infill (hexagon pattern), 35 mm/s print speed, 150 mm/s travel speed, 65°C heated bed for acrylonitrile butadiene styrene filament (room temperature for polylactide filament), 0.15 mm layer height, and 1 mm shell thickness. Rafts and supports are always recommended to avoid misprints. Furthermore, the application of light adhesive (e.g., glue stick) or painter's tape over the building platform of desktop 3D printers can aid in improving the adherence of the first plastic layer and facilitates removal of the printed structure. For industrial 3D printers, this may not be necessary since the building tray is often disposable and provides sufficient adherence.

Due to the inherent anisotropic characteristics of fused deposition modeling, orientation of the different 3D printed prosthesis components over the building tray can play an important role in the durability of the prosthesis. As characteristics and mechanical properties of 3D printed parts are dependent on printing orientation, it is important to consider the direction of operational loads on each component. 3D printed parts using fused deposition modeling are much more likely to delaminate and fracture when placed in tension in the direction of build height compared to the orthogonal axes. For this reason, it is recommended to print 3D printed prostheses using a horizontal axis. There are only few exceptions to this rule specific to the layer height and dimension of the printed part. Lower layer height (higher resolution) typically results in a part being printed with smoother surfaces and less likelihood to delaminate or fracture. In the case of the palm section of the 3D printed Prosthesis Cyborg Beast 2 using a 0.15 mm layer height, we have experienced no adverse effects in the durability of the palm component of the prosthesis when subjected to real-world use. The duration of the print depends on the size of the prostheses, infill, layer height (resolution) and orientation of the printed part. For example, the printing time of a partial hand prosthesis for a 12 year-old child can be between 6 and 8 hours when using the recommended settings.

Title: Hybrid-Drive Upper Limb Prosthesis

Tagline: Cyborg prosthetic arm has wirelessly controlled motors to enhance functionality and prevent muscle fatigue

Bullet points:

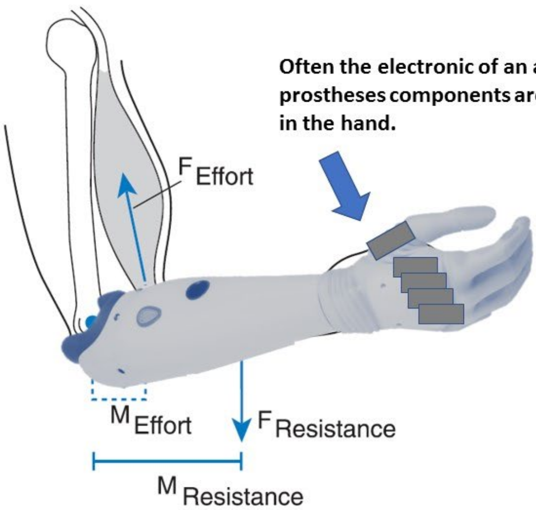
- Lightweight, ergonomic prosthetic arm
- Grip is primarily controlled by elbow or shoulder flexion
- Grip strength can be enhanced or even maintained by wirelessly controlled motors
- Reduces muscle fatigue
- Increases functionality

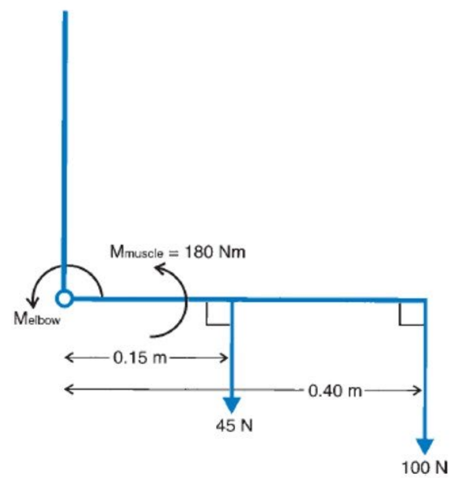
Summary:

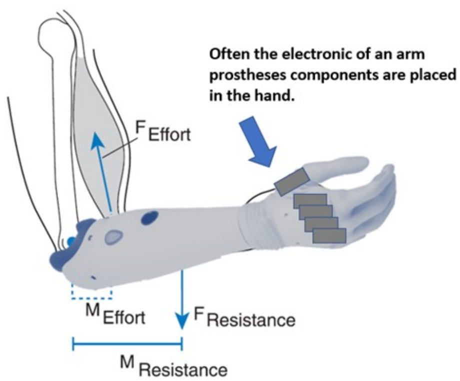
A new cyborg prosthetic arm design brings prosthetics one step closer to replicating anatomy. Traditional electronically-powered prostheses have two common downfalls: heaviness and a lack of manual, body-powered control. To solve these universal issues, a research team at UNO Biomechanics led by Dr. Jorge Zuniga designed this novel prosthetic arm to have the best of both worlds: the lightweight feel of a body-powered prosthetic and the improved functionality of an electronically-powered device. Utilizing a body-powered prosthetic base, this hybrid arm still provides manual control. Manual motor control is a very important feature because it permits the development of healthy and strong muscles in children who would normally abandon the use of their affected limb, which leads to long-term weakness and even postural problems like scoliosis. To reduce weight and enhance ease of use, fewer (and lighter-weight)

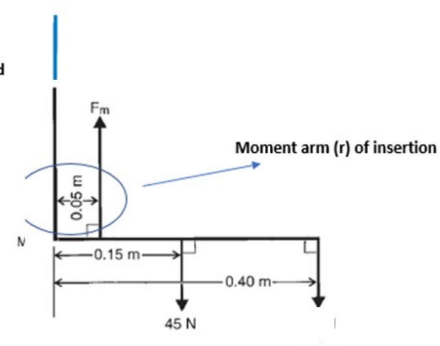
motors are used. Rather than developing all of the force needed to grip objects, the motors in this hybrid design are intended to augment the user's strength to make using the prosthetic easier and to encourage them to use what strength they have.

Calculations









The moment due to the weight of the arm and hand is:
Tarm-hand = 45 N $\times$ 0.15 m = **6.75 N-m**

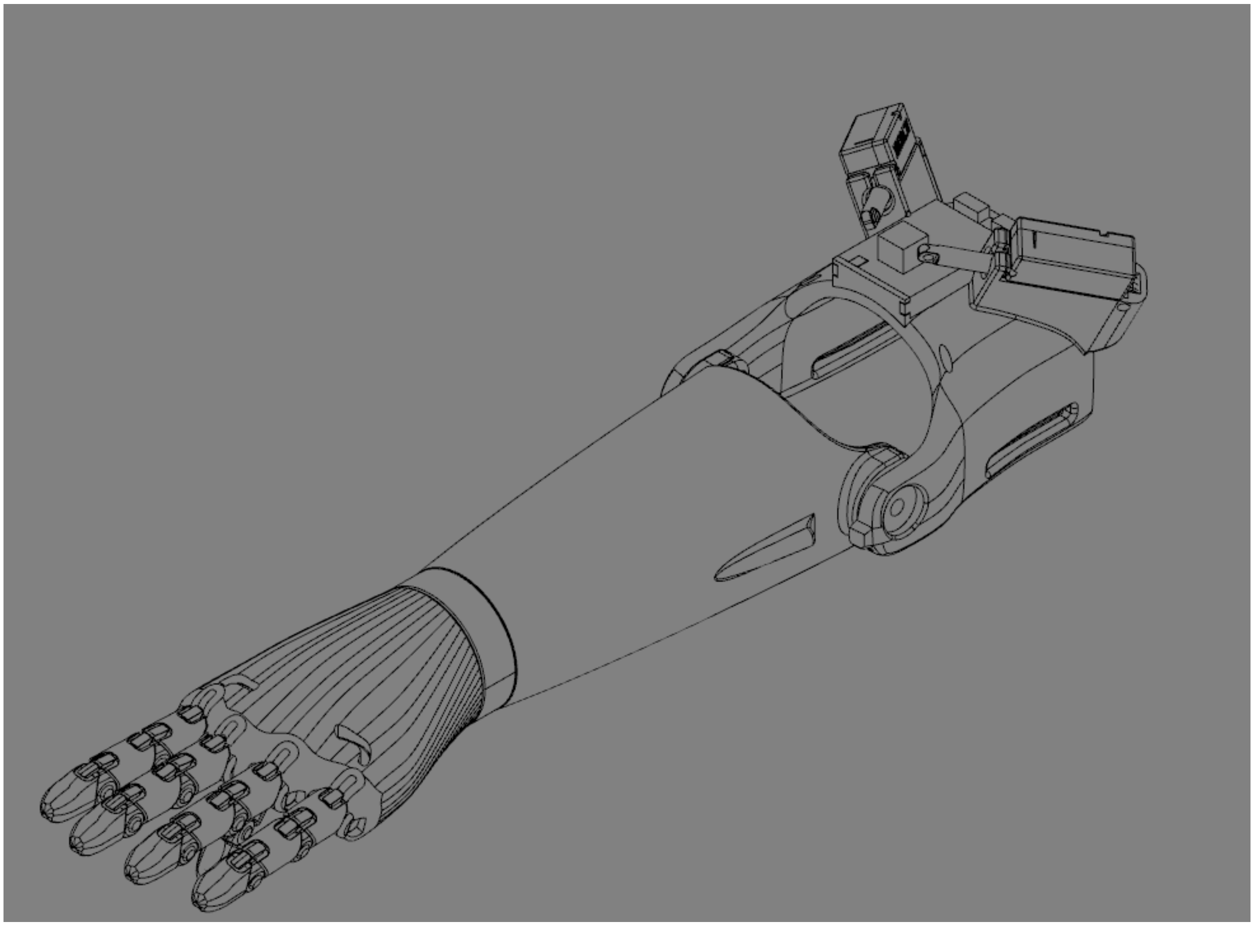
and the moment due to the barbell is:
T of electronics= 100 N $\times$ 0.4 m = **40 N-m**

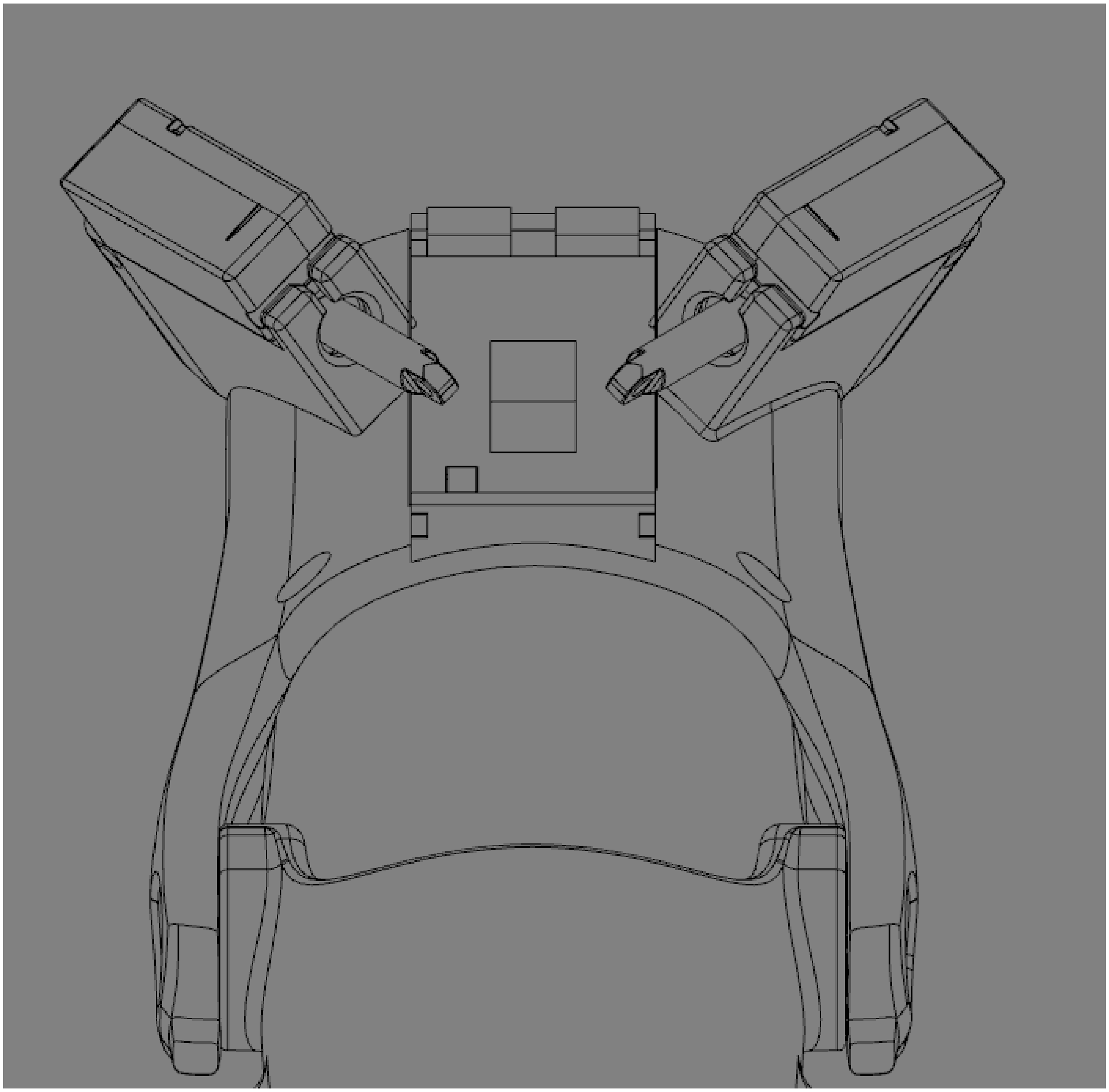
How much force would the muscle have to exert to keep the elbow at 90 degrees?

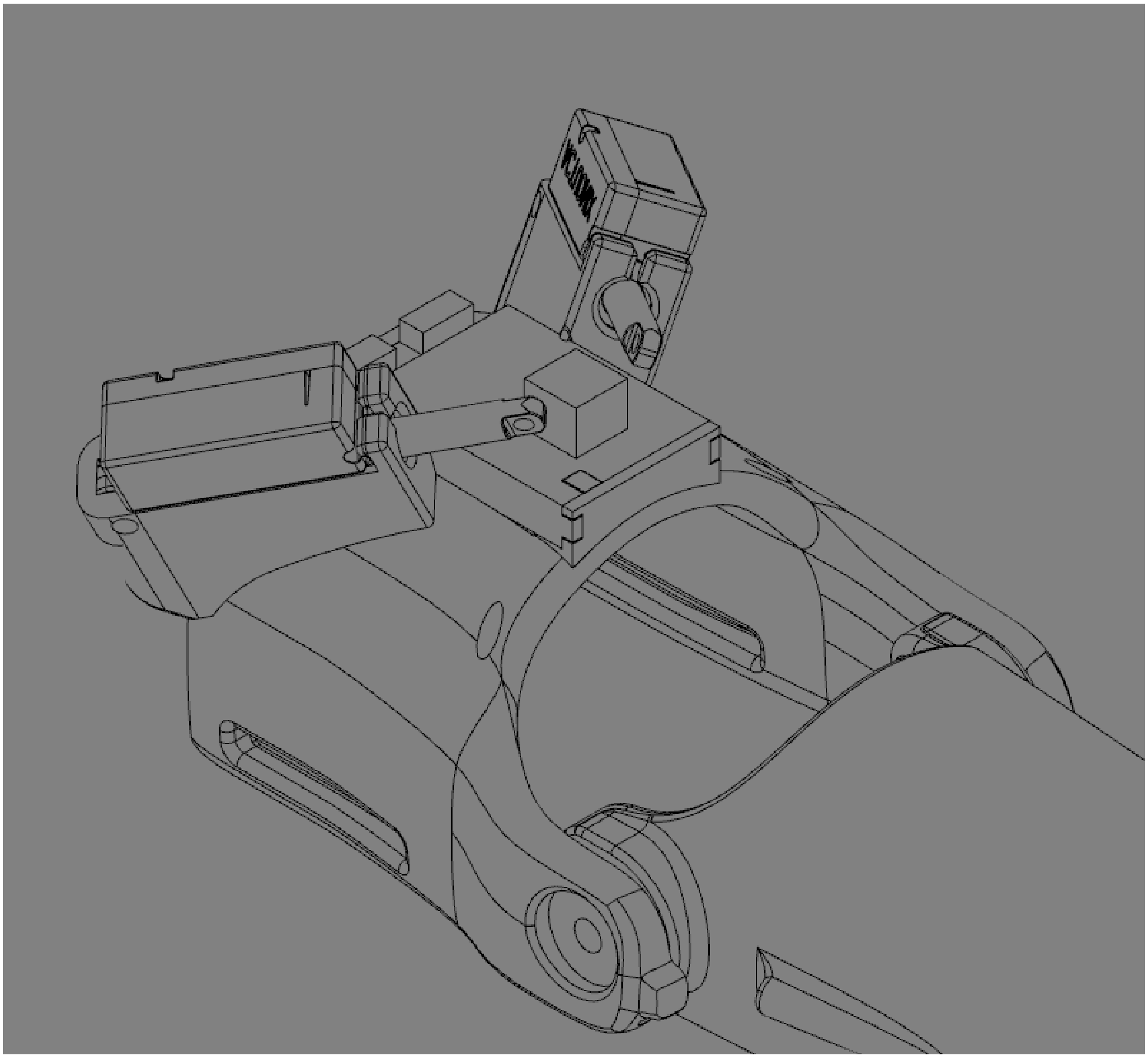
The moment due to the muscle force can then be calculated as:
Tmuscle − Tarm-hand − T of electronic = 0
Tmuscle − 6.75 N-m − 40 N-m = 0
Tmuscle = 6.75 N-m + 40 N-m
Tmuscle = **46.75 N-m**

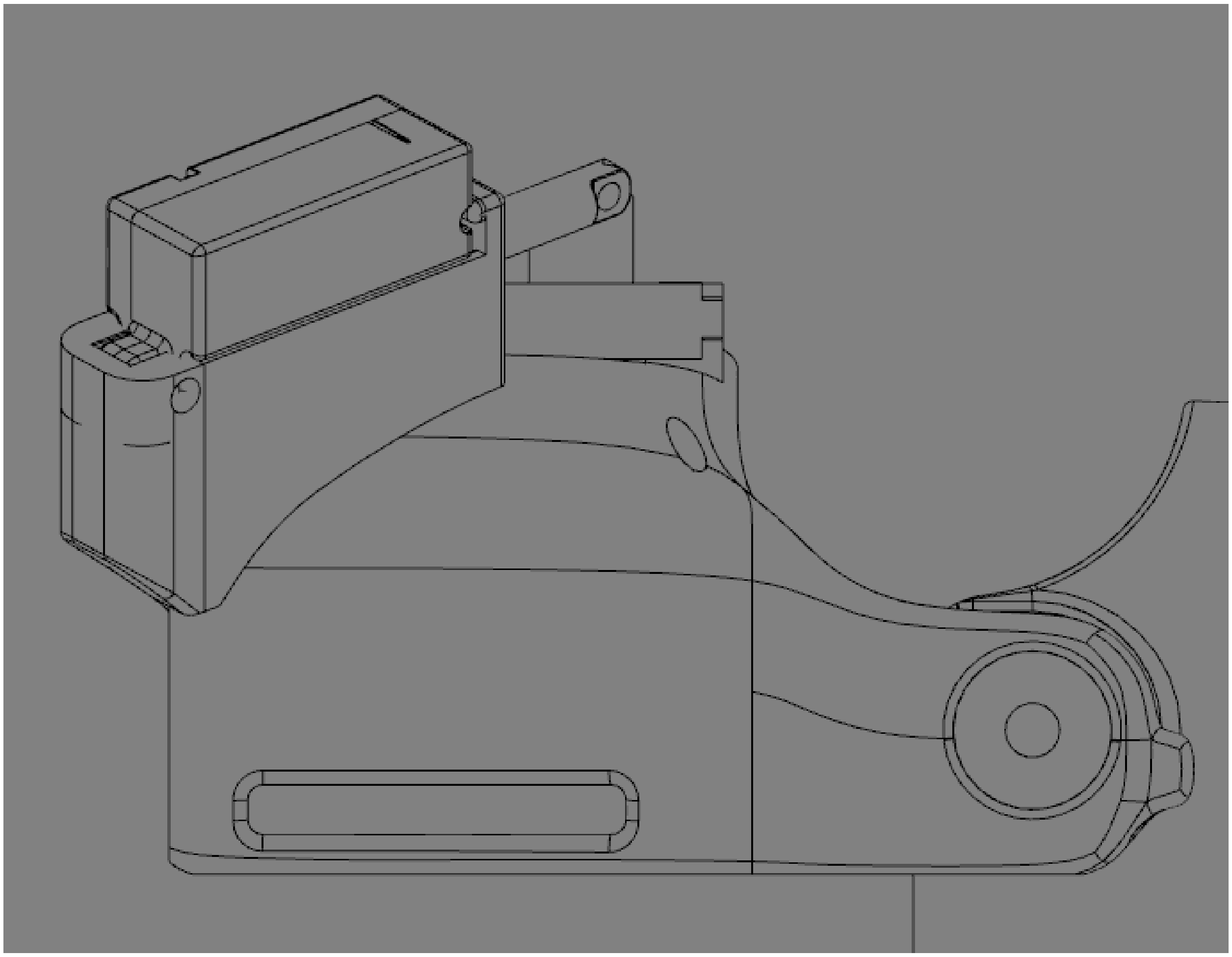
$Force_m$ = Tmuscle/Moment arm

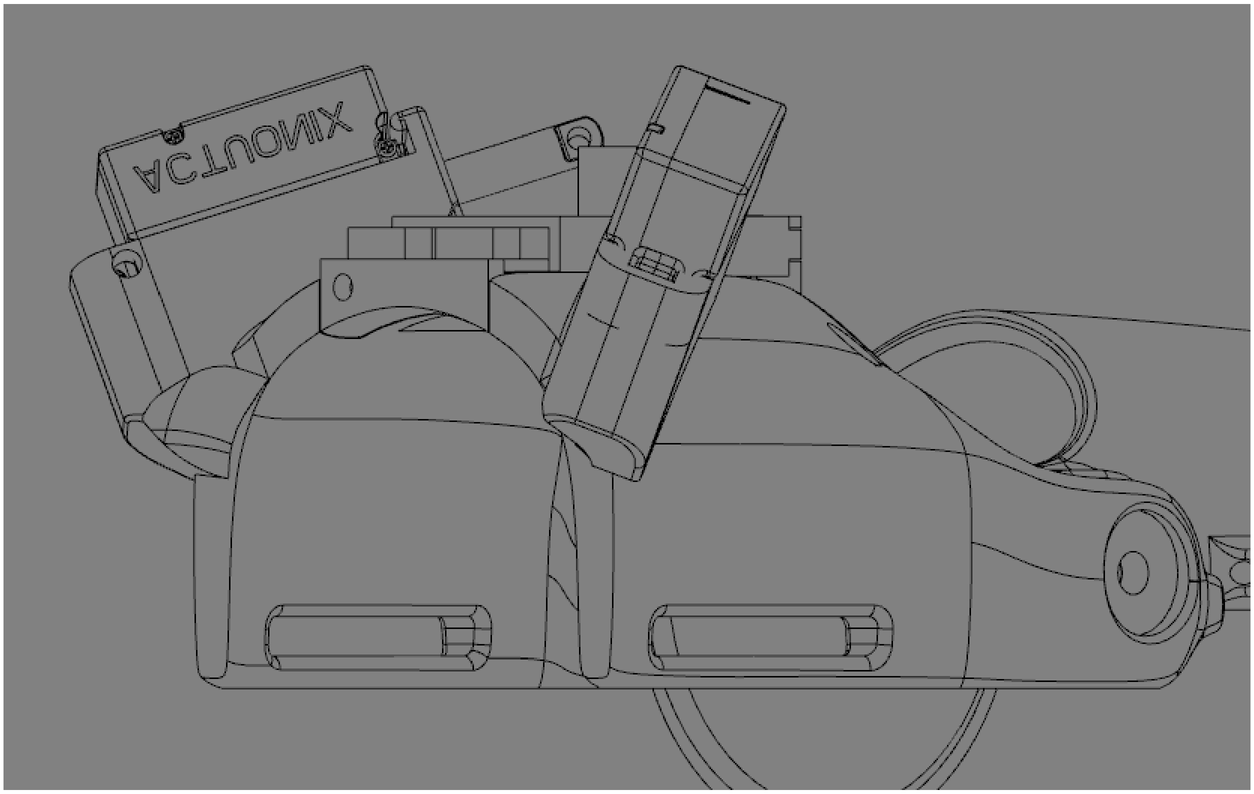
$Force_m$ = 46.75 N-m/0.05 m
$Force_m$ = 935 N







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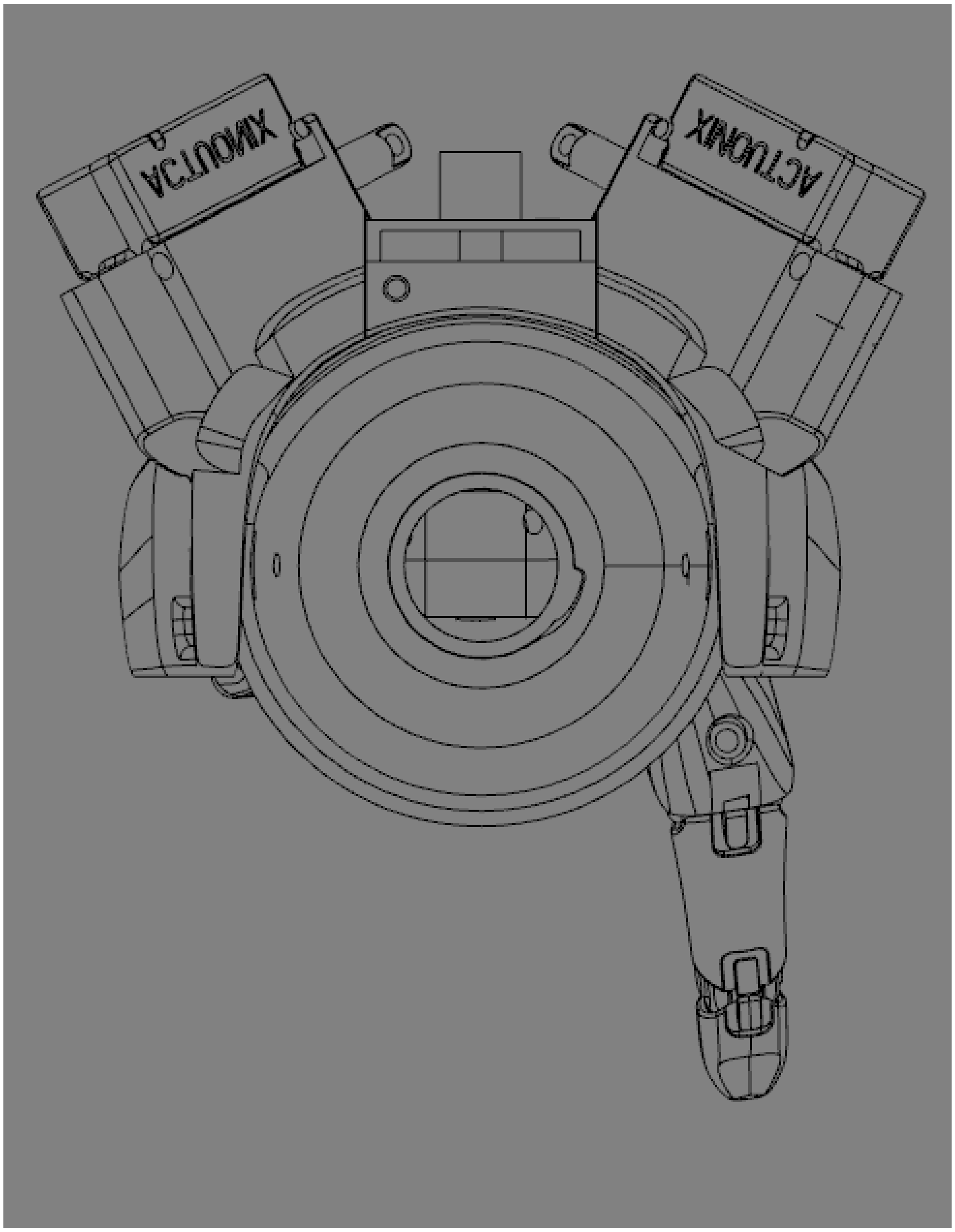
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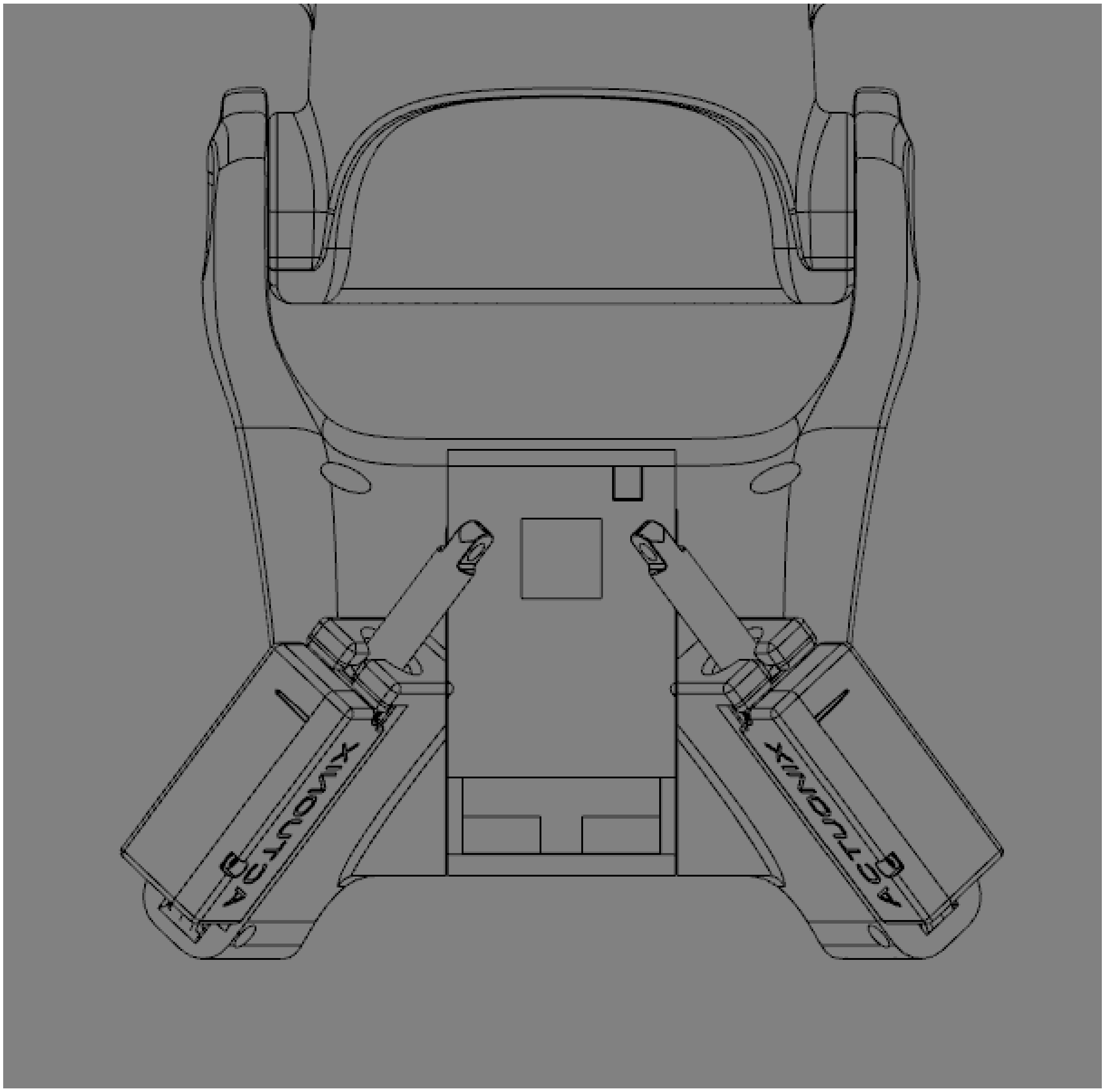

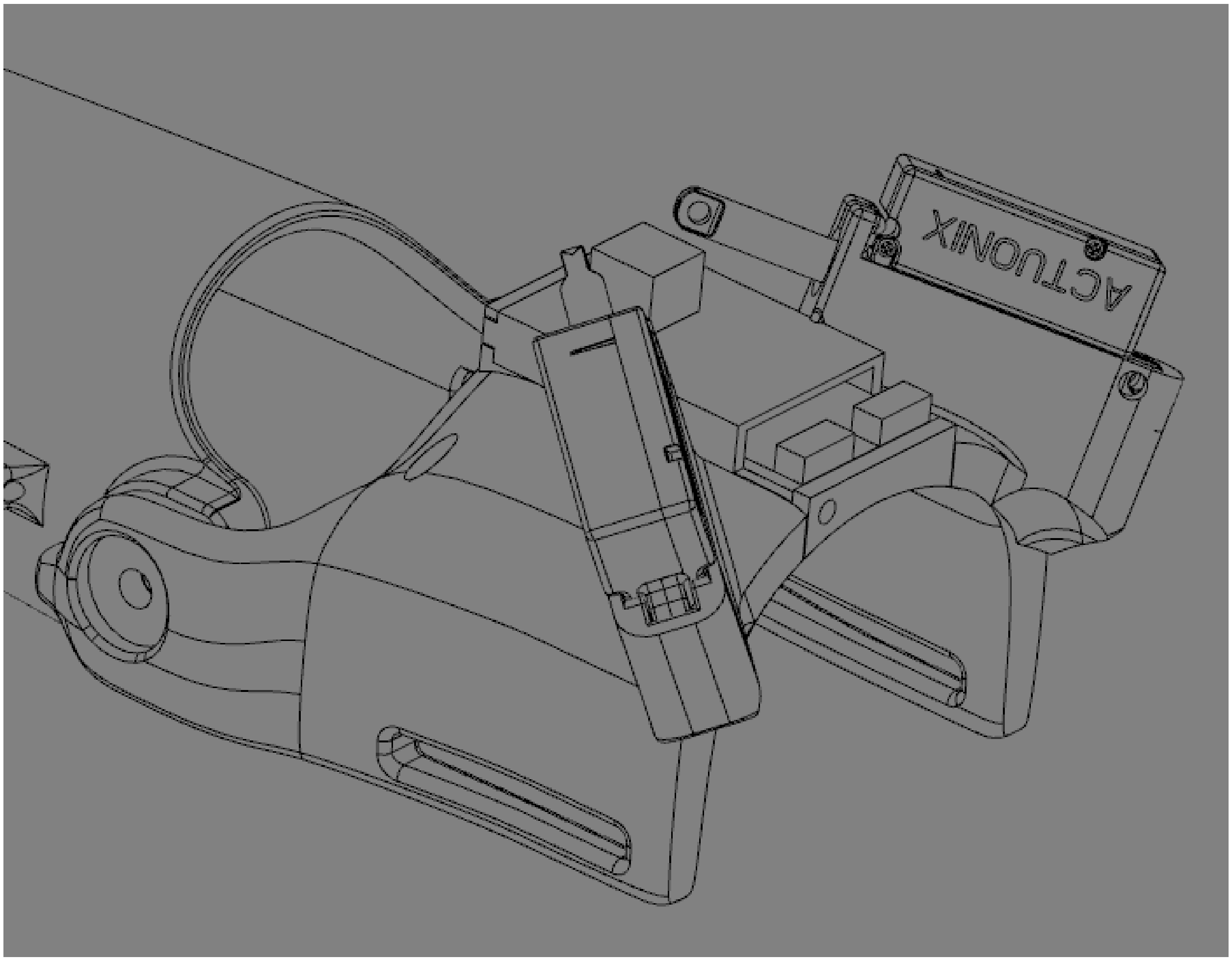
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