

A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION

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*This study was presented at the 36th Annual Scientific Assembly of the Eastern Association for
the Surgery of Trauma, January 17-21, 2023 in Lake Buena Vista, Florida.*

All JTACS disclosure forms have been submitted and are provided as supplemental digital content (<http://links.lww.com/TA/D418>).

AUTHOR CONTRIBUTIONS

RV: literature search, study design, experimental procedures, data collection, data analysis, data interpretation, writing, critical revision.

TY: study design, experimental procedures, data collection, data analysis, data interpretation, writing, critical revision.

GG: study design, experimental procedures, data collection, data analysis, data interpretation, critical revision.

PP: study design, experimental procedures, data collection, data analysis, data interpretation

KO: study design, experimental procedures, data collection, data analysis, data interpretation

DFM: critical revision.

KC: data interpretation, critical revision.

LJK: data interpretation, critical revision

JLP: literature search, study design, data collection, data analysis, data interpretation, writing, critical revision

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BACKGROUND

Over the past decade, intraosseous (IO) device insertion has become increasingly utilized in emergent settings to secure vital vascular access when intravenous cannulation is not an option (1). Based on the success rate and ease of insertion, IO placement also occurs in the inpatient setting for emergency rescue, establishing access more rapidly than central venous catheterization (CVC) (2). Unlike CVC insertion – a procedure commonly guided by ultrasound – IO insertion remains landmark based and essentially “blind”. Accordingly, IO insertion may be technically challenging and fail in those whose body habitus differs from the average adult (3). Such misplacement can place the device tip in muscle or adipose, where a high-pressure infusion can lead to an acute compartment syndrome, or in the extreme, the need for amputation (4) (5).

We therefore sought to modify a commercially available and commonly utilized IO device to eliminate device tip position uncertainty and ensure accurate placement. We hypothesized that coupling simple sensors with existing IO device electronics would reliably alert the operator of cancellous bone cannulation, and remove the subjectivity of IO insertion.

METHODS

Hardware

A commercially available IO access device (Arrow EZ-IO System, Teleflex Inc., Wayne, PA) was dismantled to identify potential opportunities for user interface expansion (Figure 2). The optimal path of an IO needle was conceptualized as sequentially traversing three distinct tissues: soft tissue (skin, adipose, muscle), cortical bone, and cancellous bone (Figure 1A, B).

Because each tissue type would exert a different impeding force to drill tip revolution, we selected two metrics to reliably distinguish between the three tissues in the drill path: drill needle revolutions per minute (RPM), and the reaction force exerted from the tissue back onto the drill (force) (Figure 3 & 4).

Revolutions Per Minute (RPM)

The current Teleflex IO driver uses a brushed DC motor, and the speed of the rotating drill (RPM) may be directly correlated with the density of the material into which the drill needle is being inserted (e.g., less RPM in more dense tissue [cortical bone] and faster RPM in porous materials [cancellous bone]). To measure RPMs, we used a Hall sensor (A3144, Allegro Microsystems, Manchester, NH) and magnet (2mm x 1mm, FINDMAG, China) to track close proximity magnetic field strength via the switch-like properties of the sensor. By embedding a magnet into the rotating drill bit and affixing the Hall sensor onto the stationary casing of the DC motor, the number of rotations can be counted, and by tracking the time between rotation counts, RPM values may be calculated (Figure 4).

Force

The second sensor we utilized was a force sensor where the force applied by the user onto the drill and bone (action force) is met by a measured counterpart reaction force exerted by the tissue onto the drill as dictated by Newton's Third Law. Stiffer, more dense tissues will exert a greater force while softer tissues will exert a weaker force. The reaction force was measured by attaching an extremely stiff spring (SPB-05002, Newst, Zhongshan, China) onto the base of the

pre-existing DC motor and to a force sensor (GHF10, Uneo, New Taipei City, Taiwan). (Figure 4).

Software

The measurements obtained by the two sensors are a direct surrogate of the density of the tissue the drill bit is penetrating. Due to its compactness, affordability, and processing speed, the Raspberry Pi Pico Microcontroller (Raspberry Pi Foundation, Cambridge, England) was used to integrate both sensors' data and run an algorithm that *only* turns on a Red LED (LTL-4221N, Liteon Optoelectronics, New Taipei City, Taiwan) when data from either sensor confirms transition from cortical to cancellous bone.

Correct IO insertion should demonstrate a predictable force and RPM signature (Figure 5) including a high RPM/low force in soft tissue, low RPM/high force in cortical bone, and medium RPM/medium force upon cancellous bone entry. This algorithm is adaptable to each patient as it does not use specific force or RPM values to identify tissue transition. Instead, the RPM and force of the initial cortical bone entry serve as a baseline, and RPM and force ratios are used to identify when the drill bit penetrates cancellous bone. Secondly, the algorithm has a built-in redundancy. By using two sensors and a set of “or” conditions, if one sensor fails, the algorithm and guidance system defers to the other sensor and LED lighting will occur as anticipated upon cancellous bone entry. To ensure the LED as activation as quickly and appropriately as possible, the system was programmed for LED illumination based on the first sensor to meet the triggering conditions. Future algorithms will further differentiate entry in cancellous bone from entry into muscle or soft tissue that will be useful in the unique situation

where IO entry from soft tissue into cortical bone but skiving back into muscle will be specifically indicated to the provider.

Integration of Components

The microcontroller, sensors, and LED were connected through a custom-designed printed circuit board (PCB) (Sunstone Circuits, Mulino, OR), and all additional components were housed in unused space within the drill body and behind the motor (Figure 3). The drill motor, needle assembly, and injection tubing for the prototype remained identical to the ones used in the commercial device.

Prototype Testing on Bone and Statistical Analysis

To verify the double-sensor prototype device, we used two experimental models: commercial synthetic bone model (SKU3401, Sawbones, Vashon Island, WA) (n=50) and fresh goat tibia bones (Makkah Market, Philadelphia, PA) (n = 25) wrapped in bovine muscle (Makkah Market, Philadelphia, PA). The microcontroller was connected to an external monitor via USB while drilling, allowing collection of drill force and RPM readings in real time for each of the three major regions (muscle, cortical bone, cancellous bone). Mean \pm SEM readings obtained while directly visualizing cross-section drill tip entry from soft tissue to cortical bone, and from cortical to cancellous bone were compared with ANOVA and post hoc Tukey-Kramer testing.

Each trial was digitally recorded (iPad 10.2, Apple, Cupertino, CA) focusing on the cross-section of the model being used. Correlation of LED illumination with needle entry into cancellous bone was assessed with direct observation, and the insertion accuracy was defined as the simultaneous observation of the tip of the needle exiting cortical into cancellous bone and LED illumination.

RESULTS

In commercial synthetic model bones, RPM was highest in muscle and lowest in cortical bone ($p < 0.001$) (Figure 5A). Muscle RPM (1444.9 ± 9.2 rpm) was also significantly higher than that of cancellous bone (1409.8 ± 5.57 rpm, $p < 0.001$). Force measurements followed the same pattern with the highest force observed when within the cortex (312.5 ± 7.0 N) and lowest, when in muscle (87.2 ± 9.3 N, $p < 0.001$)

Goat tibias demonstrated similar results to those of synthetic models with highest force/lowest RPM in cortical bone, and lowest force/highest RPM in muscle (Figure 5B). Muscle values of both measured parameters also differed significantly with those of cancellous bone.

Insertion accuracy in synthetic bones was 94.0%, (47/50) and 92.0% (23/25) in goat bones.

DISCUSSION

Herein, we describe the novel development of a dual-sensor (RPM and force) modification added to a commercially available IO device. The addition of a compact microcontroller able to integrate and process the data of both sensors allowed for illumination of a signaling LED to alert the operator of successful cancellous bone access. Regardless of synthetic or goat bone used, RPM and force measurements varied predictably and consistently from soft tissue to cortical to cancellous bone, and the certainty of correct tip placement upon LED illumination was nearly uniform.

The inability to cannulate a peripheral vein, particularly in the prehospital or austere environment is not uncommon as the peripheral venous system is often collapsed in patients *in extremis* due to shock. In military and prehospital settings, IOs have been used as the optimal alternative to obtain vascular access (1). Today, even inpatient urgent vascular access in the emergency department (ED) or during in-hospital rescue (e.g. cardiac arrest), prioritizes IO catheterization over central venous access. Within the ED, this approach has existed for over a decade in patients presenting with hypovolemia, shock, or other emergent conditions (6). IO access has recently been shown to be easier and less risky to perform than central line placement (7). Indeed, IO access can be performed by a wider range of lesser-trained medical and paramedical personnel who may not have the specialized training required to place a central line (8).

Reviewing the video recordings on patients arriving to the trauma bay in shock and in need of rapid vascular access, Chreiman *et al.* demonstrated that the success rate of IO insertion was 1.5 times higher and four times faster than that of any central venous catheterization (2). The rapid IO access time and ease of use flanked by the known ability of IO boluses to reach the central circulation in less than 3 seconds (humeral access) makes IO insertion an appealing and dependable method of gaining non-collapsible vascular access even during cardiac arrest (9).

Despite the proven value of IO access, optimal fluid and medication delivery through this approach has several challenges (4). Even when following manufacturer recommendations and standardized protocols, operators currently cannot be certain if the IO device correctly accesses medullary cancellous bone. The angle and depth of insertion may vary from operator to operator. After patient positioning and bony landmark palpation, the operator activates the drill after establishing drill tip skin contact. With pressure and drill revolution, the tip passes through soft tissue, cortical bone and then enters cancellous bone, an event that is accompanied by characteristic auditory and tactile cues. Unfortunately, many experienced operators who routinely insert IOs report the absence of the characteristic cues, perhaps reflecting cue subtlety that may be readily missed in a chaotic and time-pressured resuscitation setting (10). Thus, the inability to consistently confirm if the IO needle tip into a cancellous location may ultimately miss an pressurized infusion in soft tissues, potentially causing tissue extravasation, compartment syndrome, and limb morbidity; requiring ultimate limb amputations (5). Relatedly, precise IO placement in cancellous bone can be challenging in pediatric, muscular, and obese patients. as larger muscle mass or adipose layers impede bony landmark palpation of or accessing bone despite longer needle length (3). In pediatric patients, small bony dimensions -

especially at the humerus - may be misjudged with regard to trajectory and depth (11). While post-placement imaging or marrow aspiration may confirm cancellous bone placement, this is cumbersome and introduces an obligate time delay (imaging) and pain (marrow aspiration) (1).

There are diverse examples illustrating the benefits of using simple engineering principles to transform and optimize existing, and widely used medical and surgical instruments and devices (12). For example, sensor-based magnetic field tracking improves the placement accuracy of nasogastric tubes by providing definitive confirmation of intra-gastric positioning (13). New bi-stable mechanism changes in cranial drills enable transcranial drilling without risk of cerebral parenchymal injury by retracting the drill bit upon dural penetration (14).

A significant advantage of being able to modify a widely utilized device is that it preserves device familiarity, space allocation, and the key aspects of device utilization. These principles apply to our IO device modifications and require quite little training to adapt medical personnel to a more precise and safer device insertion drill system. As the design of this prototype is refined, algorithmically identifying unique situations such as skiving from soft tissue into cortical bone and back into soft tissue will be addressed. Having herein demonstrated how both RPM and force differ statistically and significantly in the three distinct tissues (soft tissue, cortical bone and cancellous bone) future iterations of the algorithm will be able to reliably discriminate between an improper cortical to muscle transition and a proper cortical to cancellous transition and further remove virtually all uncertainty in IO placement.

CONCLUSION

Simple engineering modifications of a commercially available IO device can help ensure proper positioning without changing the current insertion process. Operationalizing this modification will require industry support, but more importantly defines an approach that may be useful for a broad array of devices used across multiple disciplines and settings.

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LEGEND OF FIGURES

Figure 1: (A): Cross-section of a humerus with the standard path of the drilled needle (dotted line). The thickness of cortical and cancellous bone significantly varies with individual characteristics including body habitus and age. (B) Magnified schematic of the proper drill path.

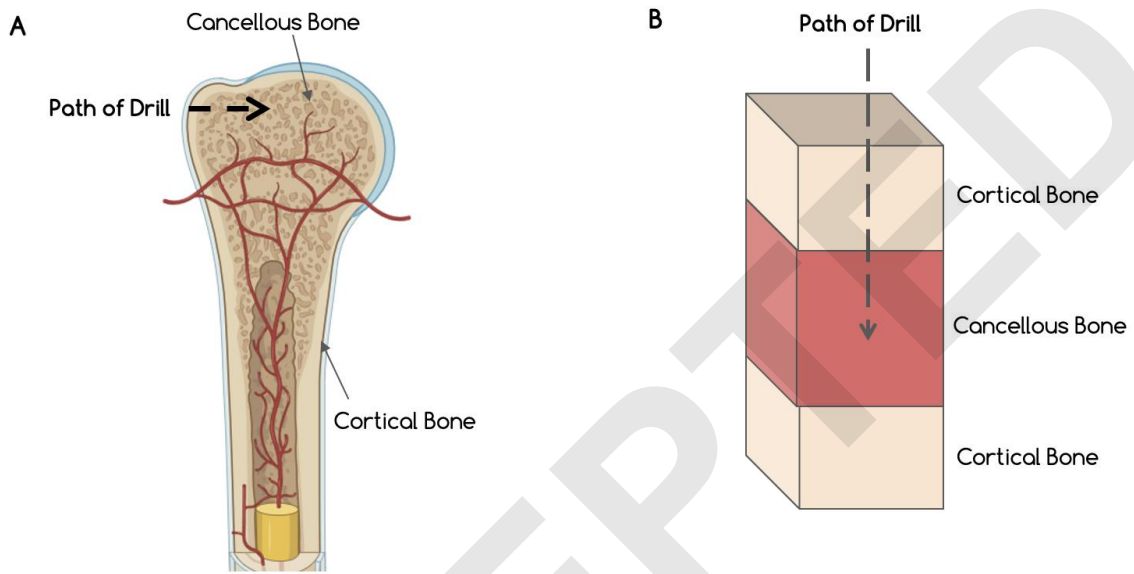
Figure 2: Commercially available Teleflex EZ-IO Drill. The major components are the DC Motor and six 3V batteries (18V total). Not pictured is a circuit board that controls the power to the drill and also indicates a low-battery light. There is significant unused space behind the motor and above the batteries that was used for alterations.

Figure 3: A rendering of how the proposed guidance system integrates with existing Teleflex driver with new features denoted in red. The total battery voltage remains unchanged (18V), but the new system uses two, 9V batteries instead of six, 3V batteries to preserve space.

Figure 4: Schematic demonstrating the drill and its sensors interfacing with soft and bony tissues using a humeral insertion site.

Figure 5: Force and RPM signatures for the commercial bone and goat models are displayed. The relevant pairwise comparisons in each data set and model (cortical vs cancellous, cancellous vs muscle, and muscle vs cortical) showed significant statistical differences. (#: $p < 0.001$ vs Muscle, *: $p < 0.001$ vs Cortical, Ψ : $p < 0.001$ vs Cancellous).

Figure 1



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Figure 2

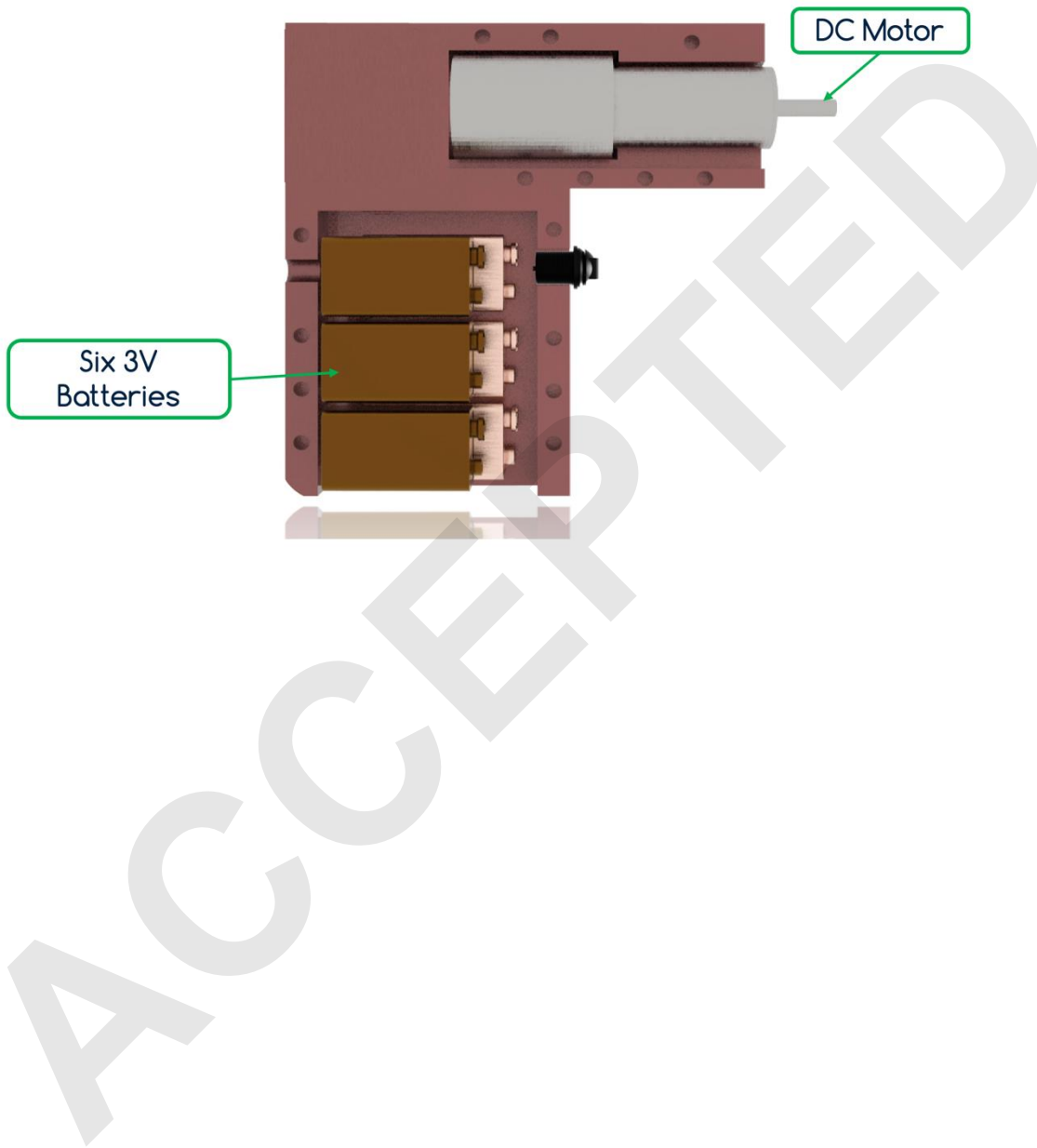
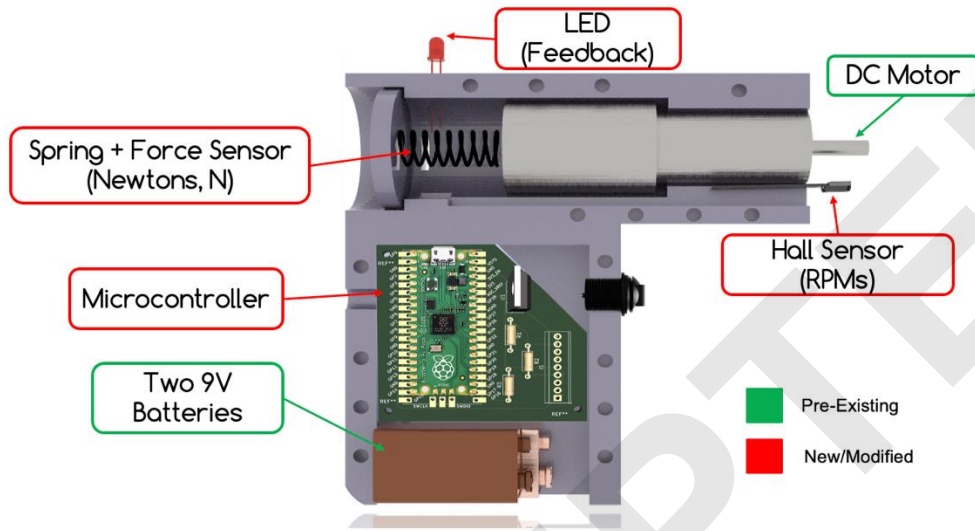


Figure 3



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Figure 4

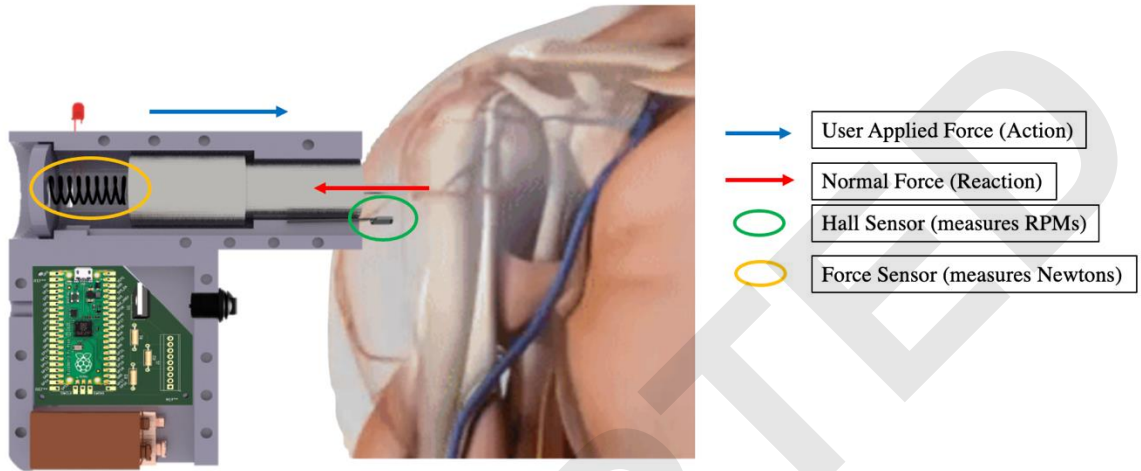
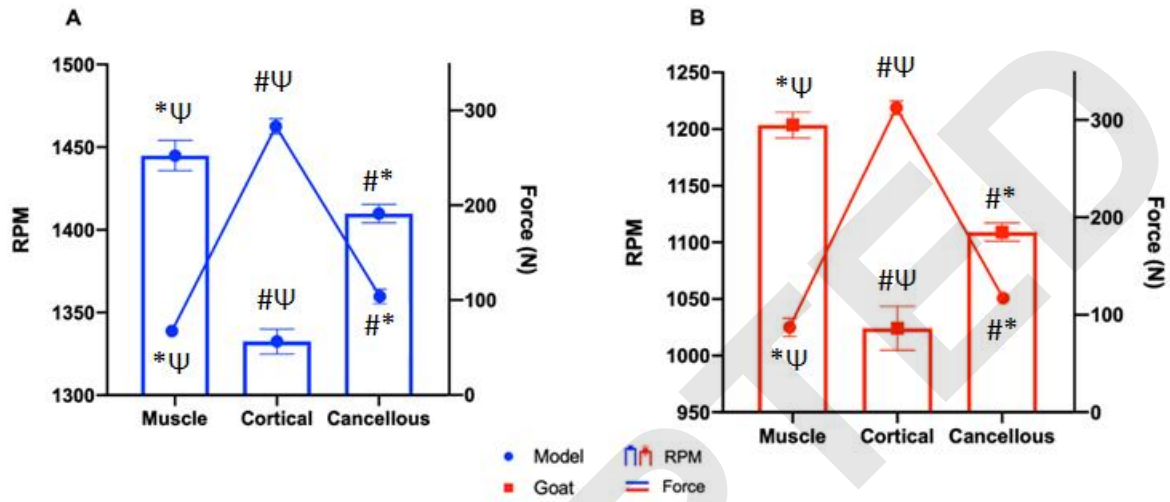


Figure 5



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14	Family Disclosure. Disclose any financial associations involving a spouse, partner, or children	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%;"><tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%; height: 20px;"></td></tr><tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr><tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr></table>							

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In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related or unrelated to the content of your manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g.,	<input checked="" type="checkbox"/> None	

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	

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9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%;"><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></table>							
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12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%;"><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></table>							
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%;"><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></table>							
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CONFLICT OF INTEREST DISCLOSURE FORM

Based on ICMJE Form

Date: 7/31/2023

Your Name: Patrick Paglia

Manuscript Title: **A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION**

Manuscript Number (if known): TBD

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Based on ICMJE Form

Date: 7/31/2023

Your Name: [Kaiser Okyan]

Manuscript Title: **A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION**

Manuscript Number (if known): TBD

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Date: 7/31/2023

Your Name: David F Meaney

Manuscript Title: A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION

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Date: 7/31/2023

Your Name: Kristen Chreiman

Manuscript Title: **A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION**

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		Teleflex	Beginning May 2023
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14	Family Disclosure. Disclose any financial associations involving a spouse, partner, or children	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%;"><tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr><tr><td style="height: 20px;"></td><td></td></tr><tr><td style="height: 20px;"></td><td></td></tr></table>							

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

CONFLICT OF INTEREST DISCLOSURE FORM

Based on ICMJE Form

Date: 7/31/2023

Your Name: Lewis J Kaplan, MD

Manuscript Title: A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION

Manuscript Number (if known): TBD

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related or unrelated to the content of your manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

Participants of an accredited activity must disclose all personal **financial** and **non-financial relationships**, over the previous 36 months with an **ineligible company** (formerly defined as a commercial interest). **Financial relationships** are those relationships in which the individual benefits by receiving a salary, royalty, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest), or other financial benefits, and may affect activity content relevant to products or services of an **ineligible company**, defined as an entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

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The author's relationships/activities/interests should be defined broadly and not only related to the manuscript in question. For example, if your manuscript pertains to the epidemiology of shock, you should declare all relationships with manufacturers of treatments used in shock, even if that form of treatment is not mentioned in the manuscript.

According to federal regulations approved by the US Senate, any amount equal to above \$10 USD must be disclosed. Although disclosure of the total amount is not required on this form. Authors are encouraged to search the CMS Open Payments Database found at <https://openpaymentsdata.cms.gov> and report on the JTACS Conflict of Interest Disclosure form ALL COI, and any other conflicts related or unrelated to the manuscript being submitted to the Journal for the last 36 months/3 years.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials,	<input checked="" type="checkbox"/> None	
			Click the tab key to add additional rows.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	medical writing, article processing charges, etc.) No time limit for this item.		
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input type="checkbox"/> None	
		UpToDate	Royalties paid to me
4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	
		Medical Legal consulting	Monies paid to me
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
		Society of Transplant Surgeons meeting	Travel expenses only

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	
14	Family Disclosure. Disclose any financial associations involving a spouse, partner, or children	<input checked="" type="checkbox"/> None	
<p>Please place an "X" next to the following statement to indicate your agreement:</p> <p><input checked="" type="checkbox"/> I certify that I have answered every question and have not altered the wording of any of the questions on this form.</p>			

CONFLICT OF INTEREST DISCLOSURE FORM

Based on ICMJE Form

Date: 7/31/2023

Your Name: Jose L. Pascual L.

Manuscript Title: **A SIMPLE ENGINEERING ALTERATION TO IO ACCESS DEVICE ELECTRONICS CAN LEAD TO IMPROVED PLACEMENT ACCURACY CONFIRMATION**

Manuscript Number (if known): TBD

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related or unrelated to the content of your manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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1	All support for the present manuscript (e.g., funding, provision)	<input checked="" type="checkbox"/> None	

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3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	Multiple presentations for SCCM Executive No payments
6	Payment for expert testimony	<input type="checkbox"/> None	Multiple firms for plaintiff and defendant Counsel As per standard fee schedule U Penn
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	SCCM, AAST, ACS To cover travel, lodging and registration at conference

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
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10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None SCCM Secretary <table border="1" style="width: 100%;"><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></table>							
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