Distal Targeting of Interlocking Screws in Intramedullary Nails

Jacob D. Long[1], Collin E. Hawes[1], Christopher D. Smith[1], Kayla S. Stoeffler[1], John T. Patton Jr., Ph.D.[1]
[1]Bock Department of Biomedical Engineering, Trine University, Angola, Indiana 46703

Introduction

Intramedullary nailing is a surgical technique that involves the insertion of a nail into a long bone (femur, tibia, humerus) to secure fractures and promote healing. At the proximal and distal end of the nail, there are holes in which screws are drilled into for interlocking, nullifying forces that act over the fracture line [1].

Current techniques rely on X-ray imaging for identifying where the holes are located within the bone, which not only exposes staff to radiation but also increases time in the operating room. Another challenge is the difficulty in drilling the screw to the hole due to deflective forces acting on the nail.

OrthoPediatrics seeks a new targeting system that can locate the screw holes without the use of ionizing radiation. This will assist orthopedic surgeons with intramedullary nailing procedures and mitigate the negative impacts of X-ray imaging, coupled with reduced surgical time. It will also allow for higher accuracy and precision when drilling into the holes.

Design Criteria

Requirements and Constraints

Requirement / Constraint	Description	Significance
Locates distal screw holes in any size PediNail	The ability for the device to find all distal screw holes in OrthoPediatrics proprietary nails	Essential
Compatible with OrthoPediatrics proximal targeting device	The device should be able to be used in conjunction with OrthoPediatrics's current jig for proximal targeting	Essential
Reduced radiation exposure	The device should expose the patient and surgeon to less X-ray radiation than the current method of "perfect circles"	Critical

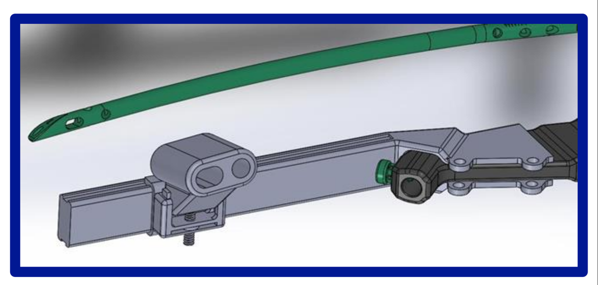
Technical Specifications

#	Specification	Target Value	Measurement Method
1	Weight	< 25 lbs	Imperial Scale – ANSI/AAMI ST77:2006 [2]
2	Ability for Sterilization	Yes/No	Autoclave – Steam Pressurization – ISO 17665 [3]
3	Left and Right Compatibility	Yes/No	Fit Testing (Qualitative Observation)
4	Complete or Significant Reduction of Ionizing Radiation	Yes/No	N/A
5	Reduce Operating Speed Compared to Perfect Circles Technique	< 240 seconds	Mock Surgery Testing- No ISO Standard Available
6	Maintain Precise Drill Alignment	< 2mm misalignment	Mock Surgery Testing- No ISO Standards Available

Design Process

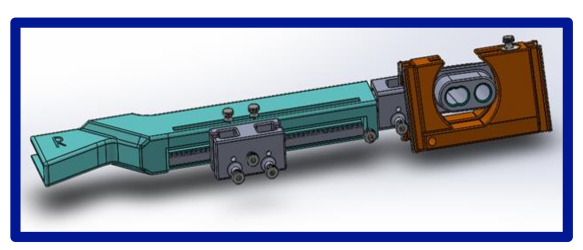
Prototypes were modeled using SolidWorks CAD software and 3D printed from PLA filament.

First Prototype



The prototype used a sliding collar system to adjust the horizontal position of the targeting guide. The targeting guide could be moved vertically to align with the screw holes.

Second Prototype

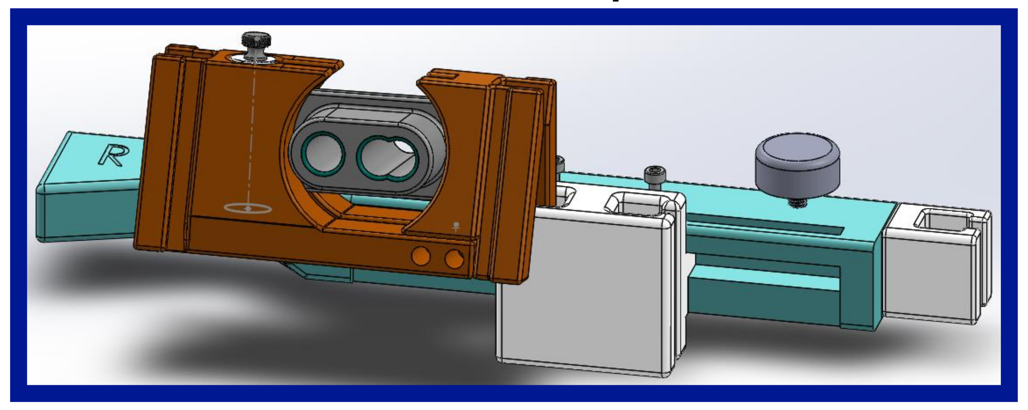


The second prototype used a worm-gear system to adjust the targeting guide angle. A telescoping arm and sliding block mount were added to assist all nail lengths. Gear-driven mechanisms were added to increase adjustment precision.

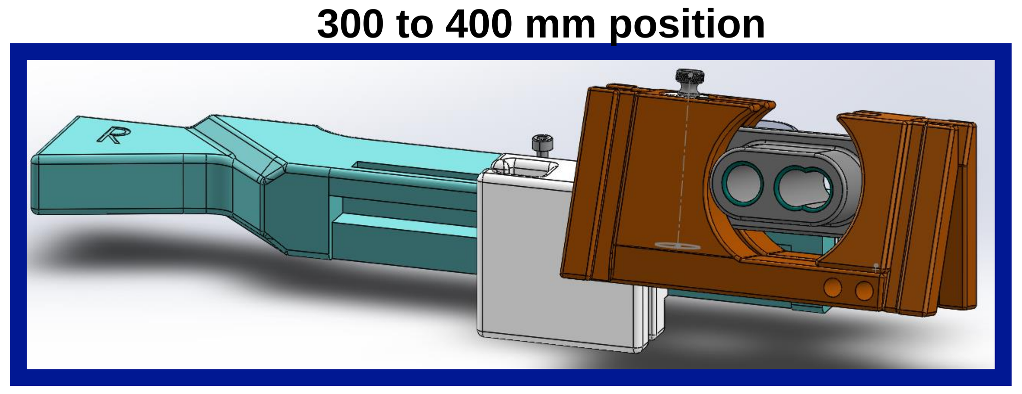
Final Design

The third prototype and final design improves the prototype by increasing the length of the sliding block and moving away from gear-driven mechanisms in favor of tightening bolts for easier user interface. This design is reversible, compatible with left and right leg orientations, is dynamically adjustable for all nail lengths between 220 to 500 millimeters using the three block positions and is user friendly only requiring a few adjustments prior to surgery.

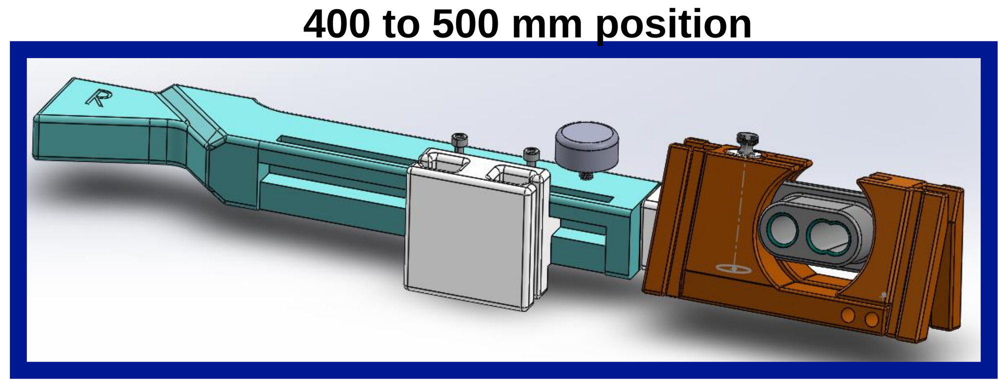
220 to 300 mm position



300 to 400 mm position



400 to 500 mm position



Sterilization Testing

Sterilization trials were performed to observe two distinct characteristics: (1) the ability for heat sterilization without degradation of the material and (2) the effective mortality of any microbial contaminant before surgery.

12 trials of sterilization were performed. For each trial, the device was thoroughly scrubbed with microbial contaminants and swabbed to collect control samples on an agar petri dish. After autoclave each autoclave cycle, the device was swabbed again to observe if bacteria would grow in the test area of the petri dish.

All medical devices much reach a sterility assurance level of 1 in a million survivors per item [3][4]. To reach level, calculations were performed with probability functions that incorporate first order reaction kinetics. Effective time of exposure was approximated at 6 minutes at 121 degrees Celsius.

Sterilization Results

It was proven through qualitative observation that the material of the device did not degrade after 12 rounds of autoclave cycles. It was also observed that the device was effectively sterilized, **with an absence of microbes in the test groups, and displayed contaminants in the control as initially proposed.**

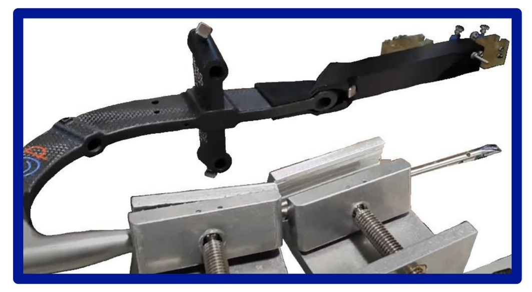
No bacterial growth on the device after sterilization.

Mock Surgery Testing

Mock Surgery Set Up

Mock surgeries were used to test for operating speed and targeting precision. 15 mock surgeries were performed using the 420 mm PediNail.

1) **Mock Surgery Setup**



2) **Alignment Calibration**

3) **Insert Test Bone**

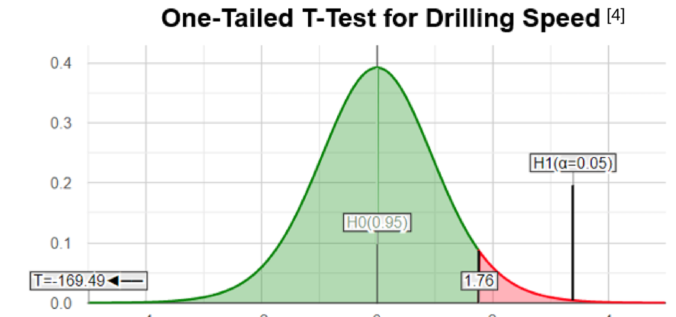
4) **Drill Through Test Bone**

Speed Testing Results

Drilling speed was measured from the moment the drill bit entered the drill sleeve to when the bit breached the opposite end of the test bone.

Distal Drilling Speed Testing	
Trial	Time (s)
1	36.87
2	40.41
3	37.05
4	38.12
5	35.47
6	34.42
7	28.57
8	37.8
9	27.72
10	34.88
11	37.14
12	25.8
13	28.58
14	29.46
15	28.68
Average	33.398
Standard Deviation	4.72

One-Tailed T-Test for Drilling Speed [4]



Statistical analysis showed a significant reduction in drilling speed compared to the average freehand speed of 240 seconds. **The distal targeting system reduced drilling time by approximately 86%**, indicating the device can successfully reduce distal locking time during surgery.

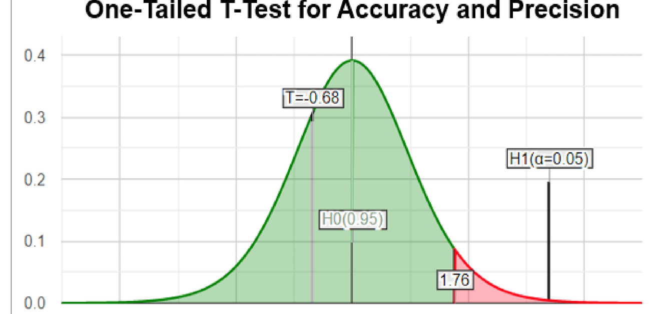
Targeting Accuracy and Precision Results

Targeting accuracy and precision were tested by measuring the distance of the drilled hole relative to the test bone and comparing the value to the position of the targeted screw hole. The targeted screw hole position was measured as 330 millimeters relative to the test bone.

The distal targeting system **fell within the acceptable 2 mm tolerance range with an average targeting offset of 1.9 mm.** No statistical differences were found between the trial data and the 2 mm tolerance range, indicating the targeting system meets the technical specification.

Targeting Accuracy and Precision		
Trial	Distance to Drilled Hole (mm)	Drill Hole Offset (mm)
1	329.00	1.00
2	328.50	1.50
3	327.00	3.00
4	329.00	1.00
5	328.00	2.00
6	328.00	2.00
7	328.00	2.00
8	327.00	3.00
9	328.00	2.00
10	328.50	1.50
11	328.00	2.00
12	328.00	2.00
13	328.00	2.00
14	328.00	2.00
15	328.50	1.50
Average	328.10	1.90
Standard Devation	0.57	0.57

One-Tailed T-Test for Accuracy and Precision [4]



The distal targeting system reduces distal locking time and ensures precise and accurate targeting.

Future Design Improvements

Potential improvements include:

- Increasing the size of the knobs used to turn the worm screw and locking the dynamic adjustments to further improve the user interface.
- Manufacturing the components out of carbon fiber instead of Accura 5530 or PLA to increase strength and rigidity, which decreases deflection of the device which can cause misalignment
- Future tests using fluoroscopy and cadaver tissue to determine how different tissues present such as skin, muscle, and bone impact time, precision, and accuracy.
- Adding Micro adjustment reference along the worm gear rotation as well as the sliding block and arm for quicker alignment prior to surgery.

Conclusion

The distal targeting system is designed to locate distal interlocking screw holes during intramedullary nailing operations. The device uses a series of external, mechanical adjustments to target the screw holes, and has achieved the following objectives:

#	Specification	Target Value	Measurement Method	Final Prototype Value	Was Specification Met?
1	Weight	< 25 lb	Imperial Scale – ANSI/AAMI ST77:2006 [2]	0.758 lb	Yes
2	Ability for Sterilization	Yes/No	Autoclave – Steam Pressurization – ISO 17665 [3]	Yes	Yes
3	Left and Right Compatibility	Yes/No	Fit Testing (Qualitative Observation)	Yes	Yes
4	Complete or Significant Reduction of Ionizing Radiation	Yes/No	N/A	Yes	Yes
5	Reduce Operating Speed Compared to Perfect Circles Technique	< 240 seconds	Mock Surgery Testing- No ISO Standard Available	33.398 seconds	Yes
6	Maintain Precise Drill Alignment	< 2mm misalignment	Mock Surgery Testing- No ISO Standards Available	1.9mm	Yes
7	Compatible with OrthoPediatrics' Existing Technology	Yes/No	Fit Testing (Qualitative Observation)	Yes	Yes

Literature Cited

[1] E. Brinkmann *et al.*, "Distal nail target and alignment of distal tibia fractures," *Journal of Orthopaedic Trauma*, vol. 33, no. 3, pp. 137–142, Mar. 2019. doi:10.1097/bot.0000000000001358

[2] *Containment Devices For Reusable Medical Device Sterilization,* ANSI/AAMI ST77:2006, 2010

[3] *Sterilization of health care products*, ISO 17665-1:2006, 2016

[4] Bix, L. (2021, November 15). *Sterilization calculations*. MSU MediaSpace. https://mediaspace.msu.edu/media/sterilization+calculations/1_dbhz3hs8[5] "One Sample T

[5] Test Calculator," One sample t test calculator, https://www.statskingdom.com/130MeanT1.html (accessed Apr. 22, 2024).

Acknowledgements

Contacts

Jacob Long: jdlong19@my.trine.edu
Collin Hawes: cehawes18@my.trine.edu
Christopher Smith: cdsmith19@my.trine.edu
Kayla Stoeffler: ksstoeffler19@my.trine.edu