Re-design and Evaluation of an Energy Storage and Return Ankle-Foot Orthosis for the Rehabilitation Centre for Children

Final Design Report

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Executive Summary

Team 5 has been charged with improving the design and/or manufacturing process of the Energy Storage and Return Ankle-Foot Orthoses produced by the Rehabilitation Centre for Children. The fitting process for these devices is performed via trial and error, requiring a significant time investment on the part of the clinicians, limiting the number of patients who may be treated.

The most important deliverable is a method to improve the data available for analysis. A Microsoft Access database was developed to track the characteristics of patients and their prescribed devices. Another component of this deliverable was the design of a device that can empirically measure the stiffness of issued devices.

The second deliverable is an Excel spreadsheet to analyze the information collected with the database. Using the XLSTAT add-on, the spreadsheet uses a comparison of a patient's anthropometrics and the stiffness of their ESR AFO to predict the required ESR AFO stiffness for future patients.

Finally, the stiffness prediction will be used to manufacture a modular ESR AFO. By designing the device so that the spring is a discrete part, a number of springs of different stiffness may be quickly swapped in and out. These implementation of these four tools will serve to reduce the workload and length of time required to produce an ESR AFO.

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Nomenclature

AFO	Ankle-Foot Orthosis
ESR	Energy Storage and Return
ETC	Et cetera
RCC	Rehabilitation Centre for Children
σ	Stress
ϵ	Strain
FEA	Finite Element Analysis

1 Introduction

The Rehabilitation Centre for Children (RCC) designs and fabricates prosthetics and orthoses to help their patients overcome physical and developmental challenges. One of these orthoses is an Energy Storage Return (ESR) type Ankle-Foot Orthosis (AFO). This device assists patients in walking by storing energy loaded by the patient's weight during the beginning of the gait cycle and returning it to the wearer during the midstance. This enables patients with little to no muscle control of their ankle to perform the motions required during ambulation.

This report describes the final design to the problem presented by the RCC as well as the design process employed by Team 5, New Leaf, hereto after referred to as "the team."

1.1 Project Objectives

The requirement for this project is to reduce the amount of clinician time spend on the fitting of ESR AFOs to allow for more patients to be treated, while reducing or maintaining the current cost.

The team's objective was to design a system which solves the issues as described in the problem statement.

1.2 Background

The RCC designs and develops assistive technology for children with disabilities. These technologies include custom wheelchairs, school desks, prosthetics, and orthoses. The specific focus of this project is the ESR AFO. AFOs are a lower leg, ankle and foot support device for patients who have difficulties with their gait or require corrective action for deformities.

AFOs can help with the following areas of patient care: “Preventing the onset or progression of foot and leg deformities, aiding in correction of foot and leg deformities, augmenting function that may be absent, controlling joint motion, and increasing balance and gait efficiency.” [1]

There are several types of AFOs such as solid shown in Figure 1, articulating shown in Figure 2, and ESR shown in Figure 3 [1].

Figure 1. Solid AFO [1]

Figure 2. Articulated AFO [1]

Figure 3. ESR AFO [1]

Solid AFOs are rigid and restrict any motion of the ankle and foot in relation to the lower leg [1]. A solid AFO is used for slowing or preventing the progression of a deformity and preventing spastic movement of the calf and foot. These devices are useful for younger children as they are simple and less bulky.

Articulated AFOs consist of two rigid pieces with a joint at the ankle to allow dorsiflexion (upward movement of the foot), limiting the plantarflexion (downwards movement) to 90 degrees from the lower leg. Articulated AFOs are common for conditions with spastic muscle movements, such as cerebral palsy, where slight sensory triggers can cause the calf muscle to flex involuntarily, which causes toe-walking and tripping. An articulated AFO limits this movement and supports ankle rotation in the frontal plane.

An ESR AFO stores energy from the load applied to the posterior strut when the foot dorsiflexes during the midstance [1]. The energy stored in the strut is released when the weight is transferred to the patient's other leg at approximately 10 to 12 degrees of flexion between the ground and the patient's fibula, thereby providing propulsion. ESR AFOs allow a limited amount of joint movement, in between what is allowed by the solid and articulated AFO types. Since ESR AFOs must be carefully calibrated to the patient at the time of fitting, they require more follow up for refitting or replacement due to changing patient weight, height, and activity levels.

1.3 Current Process

The manufacture of an AFO starts with casting the patient's leg, which is in turn scanned to create a 3D model of the limb. A mold is then created using either a CNC cutter or plaster, an example of which is shown in Figure 4.

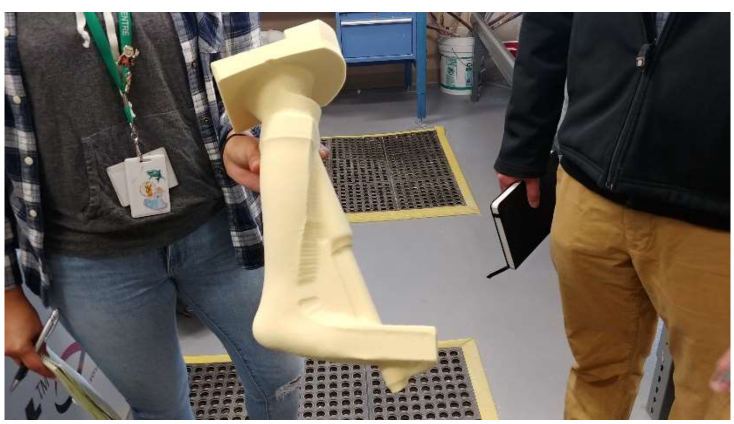

Figure 4: Machined foam mold

The mold is then modified to allow for any corrective shaping the patient may require, and provide room for padding. A technician will then manufacture the AFO using high temperature vacuum forming with layers of differing types of thermoplastic such as polypropylene, copolymers, polyethylene, and Pro-Comp. There are no quantitative guidelines for which materials to use, so the choice is based on the clinician's judgement. Figure 5 shows an AFO undergoing vacuum forming on a mold.

Figure 5. AFO during the high temperature vacuum forming stage [2]

The AFO is then removed from the mold and cut to a rough approximation of the final shape before being ground down and sanded to ensure all edges are smooth. The technician then attaches the padding and straps to holding the AFO to the patient. The process is outlined by the flowchart in Figure 6.

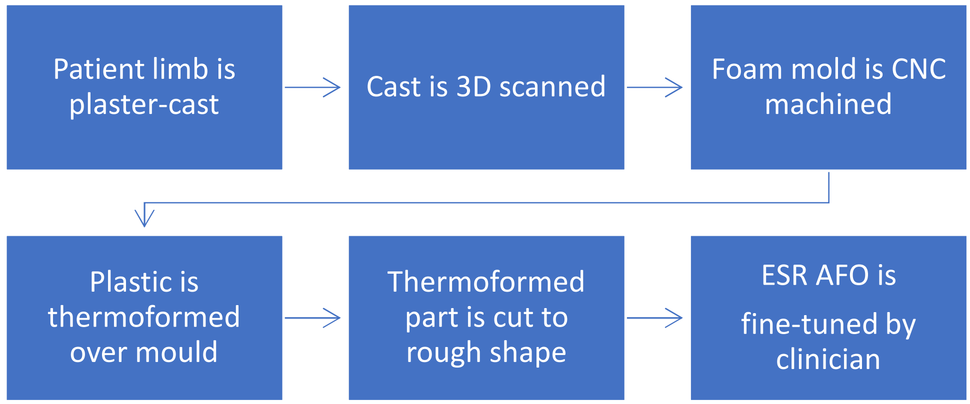

Figure 6: Manufacturing flow chart

For ESR type AFOs, clinicians then fit the orthosis on the patient and test if the strut is sufficiently flexible. The problem with the existing design and process is apparent during this stage. If the device is too stiff, the strut must be ground down and then refitted to the patient, often taking several iterations before an ideal stiffness is found. This need to custom tailor each orthotic iteratively to a specific patient requires a large time commitment from the patient and the clinician, with a device requiring 15-20 hours of clinician and technician time from patient intake to finished product. In addition, there is no reliable and convenient way to increase the stiffness, so adjustments must be done in small increments so as not to remove too much material. There are approximately 400 orthotic clinicians in Canada, with only 30 in Manitoba [1]. This lack of credentialed professionals means that clinician time is at a premium and finding a way to reduce the fitting time of ESR AFOs is of high importance.

1.4 Project Needs

Project needs were developed internally then weighted through discussion with the RCC.

A summary of client needs along with the relative importance of each (100 points distributed through all categories) is provided in TABLE I.

TABLE I. ESR AFO REDESIGN NEEDS

#	Need	Description	Weight
1	The AFO allows customization for fitting and kinetics	The AFO design and manufacturing process must be able to accommodate each unique patient's needs.	10
2	The AFO allows for consistent manufacturability	Production must be performed in-house as much as possible to allow the RCC control over fabrication.	10
3	The AFO promotes user independence	The AFO should play a role in developing a child's independence.	8
4	The AFO enables comfortable fitting	An AFO is meant to be worn during all active hours and must not provide discomfort.	4
5	The AFO is receptive to aesthetic changes	The AFO must be able to have its aesthetics altered to the patient's choosing.	9
6	The AFO is durable	The AFO must be able to withstand daily use and meet the requirements of ISO standards.	9
7	The AFO has a lower or equal cost than the current design	The cost of the redesign cannot exceed $900 *CAD* per unit.	8
8	The AFO design reduces manufacturing time	The solution must have a short lead time to allow patients to receive their AFO shortly after consultation.	10
9	The AFO is suitable for growing children	The AFO must be able to accommodate some degree of growth, as they are meant to be used for up to a year.	6
10	The AFO is lightweight	The AFO must be as light as possible to minimize energy expenditure of the patient.	6
11	The AFO has a low negative impact on daily life	The AFO should not present any additional challenges to the patient's daily life.	2
12	The AFO design reduces clinician time	The solution must reduce the amount of time a clinician spends fitting and readjusting an AFO.	9
13	The AFO enables stable ambulation	The purpose of an AFO is to allow non-ambulatory patients to regain their mobility and independence.	9

1.5 Project Constraints and Limitations

The problem as explained by the RCC is of an open-ended nature, so the constraints and limitations were identified early to make the most of the available time. Constraints were applied to the design space based on discussions with the client.

- The final design must not exceed the per unit price of an existing orthosis, approximately $900 *CAD* when factoring in labour cost.
- The design should aim to utilize as many RCC resources as possible. Outsourcing is done on a limited basis, but it is not preferred as it increases both the lead time and cost of the ESR AFO.
- The design should avoid complex carbon fiber components. The client does not have the ability to produce complex carbon fiber components in house, so these parts necessitate a third-party supplier, or implementing new tooling for manufacturing.
- The design must conform to medical standards for materials and processes used in its construction, personnel responsible for its creation, and quality management.

Considerations outside of those described by the client further limited the scope.

- The project has a short duration, with final submissions due on December 5th, 2018. This restricted the team to short-term testing.
- There is little consensus among the research into correlation between patient condition and orthosis stiffness. This constrained the team in terms of timeline since there was limited foundational knowledge.
- The team is limited to the equipment available to the University of Manitoba and the RCC when fabricating and testing any designs.

- There are no detailed records concerning the distribution of AFO types issued by the RCC, nor records concerning the physical size and weight of the patients to which they were issued. This limits the team to analyzing whatever data can be collected within the project timeline.

2 Concept Selection

Before the concept selection began, the team noted that the problem had several avenues through which it could be approached. Concepts were categorized by which of these avenues they fell in to. These categories are: device redesign, manufacturing improvements, theoretical predictions, and physical predictions, which are explained in Appendix A.

For the first iteration of concept selection, the concepts were scored relative to the existing ESR AFO design and manufacturing process using a simple 'better, equal, worse' method. The concepts that made it through the first pass were then scored on a series of weighted needs provided by the client. The two top scoring concepts in each category were then presented to the client for feedback. Further information on this process can be found in Appendix B.

To generate concepts the team research existing alternative designs and stiffness correlation methods, which are shown in Appendix C.

Based on client feedback, the team elected to move forward with four concepts:

1. A database to store information about the AFO properties and pertinent patient information.
2. A stiffness testing device manufactured to determine the stiffness of physical ESR AFOs.

3. An Excel based neural network to predict the required ESR AFO stiffness of future patients based on the information stored in the database.
4. A modular design of ESR AFO in which a spring component may be easily swapped to adjust the stiffness based on the excel predictions.

To prioritize the deliverables, the concepts were ranked by importance, and the amount of time spent by team members was distributed accordingly. The database was deemed most important, as the other concepts rely on the database's information to function. The stiffness testing device was considered to be a derivative of the data collection deliverable and was likewise prioritized.

The needs and metrics were continually developed as the team gained greater understanding of the problem and its implications. As such, the team's initial set of metrics became obsolete as the project's scope was finalized, resulting in the creation of a new set of metrics. Manufacturing changes relied heavily on the redesign itself, so these were compared in conjunction with redesign metrics and grouped into the AFO redesign category. Since each of the final deliverables fell under a different category (physical testing, data processing, and an AFO redesign), a range of metrics were constructed for each individual deliverable. It must be noted that because the final deliverables were chosen through discussion with the RCC, this final set of metrics was mainly used as a guideline to ensure the design of each deliverable met client needs. TABLE II, TABLE III, and TABLE IV show the metrics used for evaluating concepts in the stiffness testing, data collection, and modular redesign categories respectively.

TABLE II. STIFFNESS TESTING DEVICE METRICS

#	Metric	Description
1.1	Ease of use	A measure of the knowledge required to operate and understand the device.
1.2	Manufacturability	The overall complexity and time required to construct and implement the stiffness testing device.
1.3	Mobility	The ability to move the stiffness testing device to different benches, stations, etc.
1.4	Accuracy	The accuracy of stiffness measurements provided by the stiffness testing device.
1.5	Cost to implement	The cost of implementing the stiffness testing device.

TABLE III. DATA COLLECTION METRICS

#	Metric	Description
2.1	Accessibility	The end-user's experience in terms of use and understanding of the program.
2.2	Cost to implement	The cost of purchasing and/or implementing a data collection system.
2.3	Adaptability	The ability to adapt the data collection system to account for new inputs, outputs, or other applications.

TABLE IV. MODULAR REDESIGN METRICS

#	Metric	Description
3.1	Manufacturability	The overall complexity in manufacturing the modular AFO.
3.2	Clinician time	The amount of time a clinician must spend assessing and/or adjusting the stiffness of an AFO.
3.3	Manufacturing time	The amount of time spent manufacturing the modular AFO.
3.4	Material cost	The cost of materials used to manufacture the modular AFO.
3.5	Labor cost	The cost associated with technician time spent manufacturing the modular AFO.

3 Final Design

The final design encompasses four different deliverables which each contribute to creating a system that reduces clinician time spent fitting a new ESR AFO. The database is populated from patient data acquired through routine check-ins and new patient intake procedures. This data is a combination of basic patient measurements, as well as the stiffness of their ESR AFO. Since this must be determined empirically, the stiffness is found using a stiffness testing device. The stiffness testing device is able to calculate the stiffness of an ESR AFO manufactured either using the existing method employed by the RCC, or with the team's new design. Once the stiffness value is found, it is used to continually update and train a neural network. This neural network is able to predict the ideal patient stiffness from the patient data measured during their intake procedure. This allows the clinicians to have a more accurate initial guess for patient stiffness required, and quickly tune the device using a modular design which accommodates carbon fiber struts of different stiffnesses and is amenable to quick, non-permanent adjustments. The following sections discuss the advantages of each of the four solutions, their development process, and their implementation in the RCC's existing patient care framework.

3.1 Data Collection

The team used Microsoft Access to implement a database as the RCC already uses the software for other applications. Since Excel is being used for the neural network analysis, it was desirable to use another Microsoft Office application which allows for easy integration between the two systems.

Once information has been input into the Access database it is much easier to organize, search, and analyze patients as a group. This process will take a comparable amount of time to logging the information on paper. As there is no current digital repository for information of this type within the RCC, this database allows for easier analysis for future studies related to patients and can be used to find trends and correlations between similar pathologies.

3.1.1 Utilization

The information stored within the database is based on the patient parameters listed on paper documents currently used by the RCC [3], along with additional ESR AFO specific information. The user will input information through a pop-up form similar to the existing document.

3.2 Stiffness Testing Device

To make the most of the database, the physical properties of the ESR AFO issued to a particular patient must be recorded. An empirical method for testing the stiffness is desirable for its reliability, accuracy, and simple implementation. An analytical or numerical method of stiffness prediction would necessitate additional measurements and assumptions, and would require expertise in stress analysis to analyze and evaluate new geometries and special cases. A physical testing rig will only add a short amount of time to each patient cycle, which will be offset by the time saved through using data to predict future requirements.

The testing apparatus consists of one fixed and one free arm, as illustrated by Figure 7. Included in the physical design but not shown are a scale affixed to the eye-bolt, and a protractor attached to the free arm.

Figure 7. Stiffness testing device

3.2.1 Requirements

The team identified a number of requirements for the stiffness testing device:

- Must be able to accommodate any shape and size of ESR AFO. For example, an ESR AFO for a patient who exhibits toe walking would locate the ankle much higher than a patient who walks flat footed and may be difficult to firmly clamp in place.
- Must not require any modification to the ESR AFO. Since the ESR AFO will be measured just prior to final delivery, the test must not leave any marks or require any additional fixtures.
- Must be manufactured by the client at minimal cost.

This design of a stiffness testing device meets all these requirements, while also being relatively inexpensive and using readily available materials.

3.2.2 Detailed Design

The stiffness testing rig was designed to be as simple as possible and to make use of readily available material that could be found in any hardware store.

The design presented below is the second iteration of the stiffness testing device. The first iteration delivered to the client exhibited several shortcomings which were addressed by the client's modifications. These modifications have been incorporated into the CAD models and drawings for the final design.

The upper arm simulates the calf applying load on the ESR AFO as it bends forward, while the lower arm mounts wing bolts with rubber pads attached which press into the bottom of the ESR AFO to prevent the heel from lifting when the load is applied. A scale attaches to the eyebolt on the top of the upper arm and measures the load. A protractor is likewise mounted to the upper arm to measure the angle to which the ESR AFO has been deflected, and an optional stopper may be placed at the joint to prevent the vertical arm from traveling past a certain angle.

To ensure that the lever pivots at the same height as the patient's ankle joint, the operator may adjust the number of spacers on the bolts that attach the device to the base plate, as shown in Figure 8.

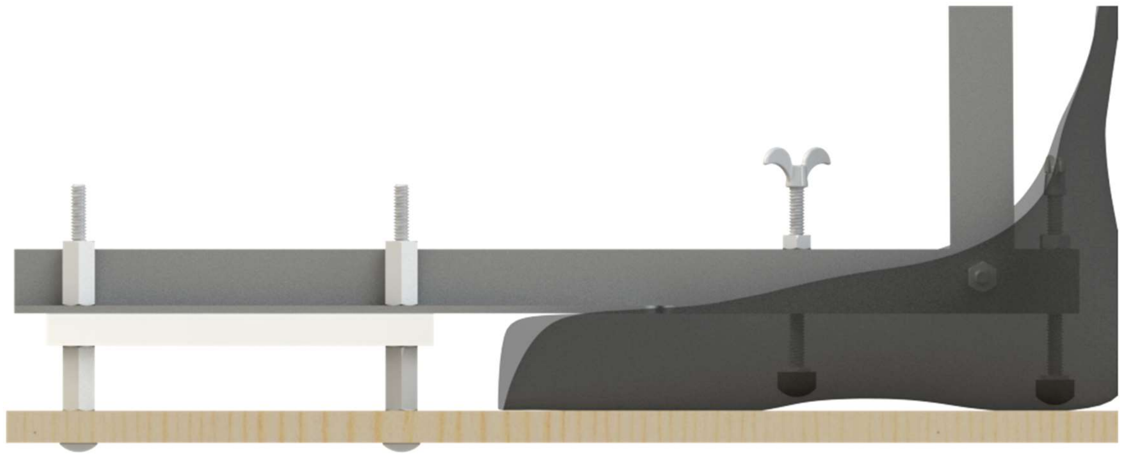

Figure 8. Detail of joint-height adjustment and clamping

The wing bolts that clamp the ESR AFO in place are sufficiently long to fasten an ESR AFO when the testing rig is set up with the maximum number of spacers. This method of adjusting height keeps the horizontal bar level at all times, so when the upper arm is pulled all the way to the stopper, it will always be the same angle from vertical.

Wing bolts were chosen for this application to eliminate the need for additional tools during testing. Any clinician will be capable of performing this test using only the equipment affixed to the stiffness testing rig. Rubber pads were mounted on the bottom of these wing bolts to prevent any damage or marking to the ESR AFO during testing.

The team used SolidWorks CAD to design the device and sent preliminary engineering drawings to the client for their approval and manufacture. All necessary hardware was sourced from a local Home Depot apart from a luggage scale which was available at Canadian Tire. The drawings and a detailed bill of materials of the first iteration of the design can be found in Appendix D, which resulted in a total cost of $119.05. Certain components, such as the baseplate, were left to the discretion of the client since they have a stock of material which could be used for this purpose.

3.2.3 Assumptions

Several assumptions were made in the design of the stiffness testing device.

- The moment applied by the bending arm is negligible when compared to the applied load.
- The friction of the hinge is negligible.
- The foam insert transfers load to the ESR AFO similar to a patient’s calf.

3.2.4 Implementation

The operator will apply a load by pulling the scale handle, until the desired angle of 10 degrees has been reached, which can be determined using the magnetic protractor. At this point, the load value will be recorded in the database. To establish a baseline data set, this test can be performed on existing patients and their ESR AFOs as they return to the RCC for routine follow-up meetings. As standard procedure, this test will occur after the clinician and patient have found a suitable stiffness of ESR AFO, but before the patient leaves. If an adjustment is required, the new ESR AFO stiffness will be measured and the previous value overwritten.

This tool will be also used to empirically verify the stiffness of the carbon fiber struts used in the ESR AFO redesign. Struts with matching fiber direction and layers which correspond to a given stiffness will be grouped together for quick access by clinicians when fitting a patient.

3.3 Neural Network

Neural networks offer the ability to train an algorithm to predict outputs based on any number of inputs, given an existing trend between them and that a sufficiently large training data set is available. This approach was desirable for the team since it generalizes all ESR AFO styles into a single case (i.e. a single approach can be taken for predicting the stiffness, regardless of the ESR AFO design). In addition, there is the opportunity for refinement as additional data is added to the training data set. This allows the predictions to become more accurate even after active development has ceased. Finally, it is relatively straightforward to design, implement, and train technicians to use.

This neural network will not be used for actual patient stiffness prediction since it is not currently trained for actual patients. This is because there is no algorithm to predict the stiffness from the training data. If this was known, there would be no need for a neural network. However, once a sufficiently large data set has been obtained using the stiffness testing device, the neural network will be implemented. The work done up to this point demonstrates proof of concept.

To begin development of the neural network, the team researched existing modular ESR AFOs and customization services. A summary of this research can be found in Appendix D. The four most important patient factors in determining the stiffness of an ESR AFO provided by these services are: height, weight, foot length, and fibula height (fibula head). These factors are measured as shown in Figure 9.

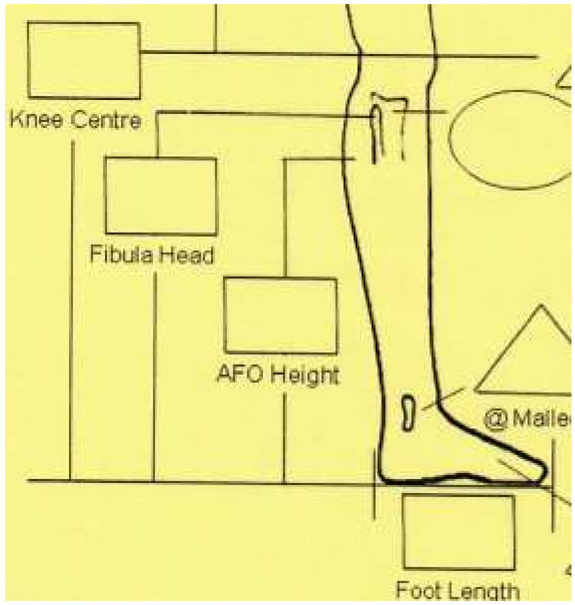

Figure 9. Detail of RCC patient intake chart [3]

The most significant barrier to creating a functional neural network was the lack of training data, so the team generated a simulated data set to test the neural network. Once the data set was complete, the team used a commercially available software, XLSTAT, to design and train a neural network. The results from this analysis were then loaded into a sheet independent of XLSTAT, so single patients can be quickly entered and their required stiffness predicted using the weights previously determined without retraining the entire network. The following sections further explain each of these steps.

3.3.1 Training Data Set

The team created a simulated data set to validate the performance of a neural network in predicting accurate ESR AFO stiffness values based on the aforementioned input parameters. According to research by Statistics Canada [4], the average Body Mass Index (BMI) of Canadian children aged 6 to 11 is 17.8 kg/m^2, and 22.5 kg/m^2 for children aged 12 to 19. In a sample of over 4,000 people, Penman and Johnson [5] found the mean BMI of Mississippians to be

27.7 with a standard deviation of 6.12. This information provided a starting point to generating a sample of patients with a standard distribution of BMIs. To generate random patient data, the average BMI was set to 20 kg/m^2 with a standard deviation of 4 kg/m^2. The purpose of this data was not to recreate a perfect representation of the general population, but a roughly realistic data set for testing. The heights of samples were bounded between 90 and 180 centimeters. Similarly, fibula height and foot length were bounded between 20 and 40 centimeters and 15 and 30 centimeters respectively. These values were estimated based on existing patient measurements and spread out to cover a wide range of patients to account for extreme cases.

The spreadsheet first generated a random patient height. Then, using a NORM.INV function, selected a BMI along the standard distribution curve. The height and BMI were used to calculate a corresponding weight. The fibula height measurement was randomly selected along a standard distribution curve and weighted with the height to maintain proportionality. The foot length was then calculated in a similar manner to the fibula height.

Correct answers must be provided for a training data set to function. The "required stiffness" was defined as the ESR AFO stiffness that a particular patient would find the most comfortable and help most in correcting their gait. Since realistic values for stiffness were not known, an arbitrary function multiplied and divided the parameters to obtain units matching the desired output, followed by an added element of randomness. This added random spread accounts for both personal preferences of the patient, and all other factors that affect the required stiffness but are not included as inputs.

With these functions complete, a sample data set of 300 patients was generated. The same methodology was used to generate another data set for which the neural network would attempt to predict a series of suitable rigidities. A sample of the training data generated can be found in Appendix E.

3.3.2 Neural Network Parameters

The software used, XLSTAT, has a "neuralnet" function which requires at least two input data series:

- Independent variables of training data set
- Dependent variables of training data set

In addition to these, the team added a series "Independent variables of prediction data set." This tested the neural network using a non-training data set. The independent variables correspond to the measurements of the patient, while the dependent variable is the required stiffness of an ESR AFO.

With four inputs and one desired output, the team selected two hidden layers, the first with three neurons and the second with two. The software used a seed to randomize the starting weights of each connection, and automatically added weighted biases to each connection.

3.3.3 Neural Network Execution

Once the training data set was selected, the software was run over 5 iterations to find the ideal weights for each connection. Figure 10 shows the final neural network for a given random data set.

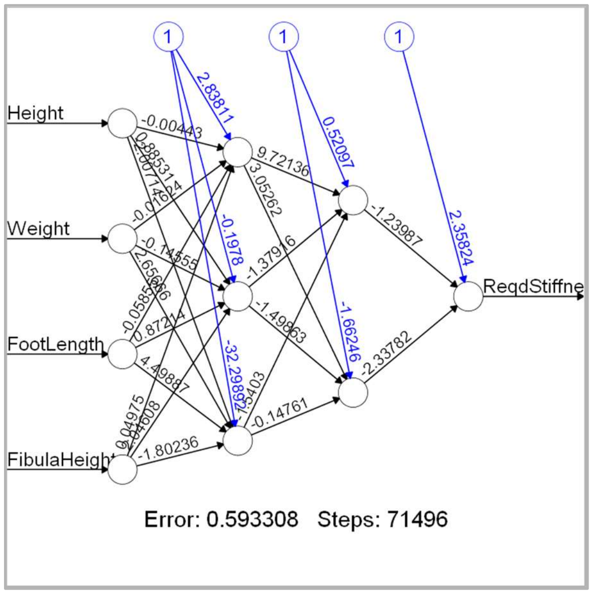

Figure 10. Neural network

The height, weight, foot length, and fibula height are input into the first layer of neurons. The values in the subsequent layers are the values of each neuron in the previous layer multiplied by the connection weight and summed, then "activated" using an activation function. This function can be selected in the XLSTAT software package, and the team has had success using both the logistic and tangent hyperbolic functions.

To verify that the neural network performed as desired, the software plotted the correct results from the training data set against the neural network's predicted results for the same data set. This plot is shown below in Figure 11.

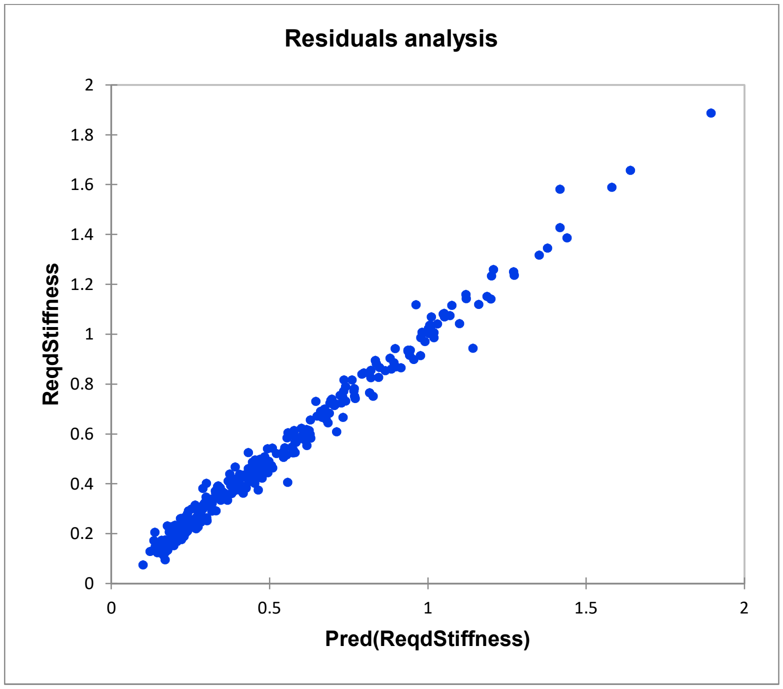

Figure 11. Comparison of stiffness required against predicted stiffness

This trend shows a prediction model accurate to within ±0.2 Nm/° over a full-scale range of 2 Nm/°. This corresponds to an uncertainty of 10%, which is to be expected given the weight of the random term in the governing function. In actuality, this function is most likely much more complex, and so the team verified how the neural network would perform if this function had a larger element of randomness or unknown variables. As shown in Figure 12, increasing the weight of the randomly generated term increases the spread of the results, however the trend remains the same.

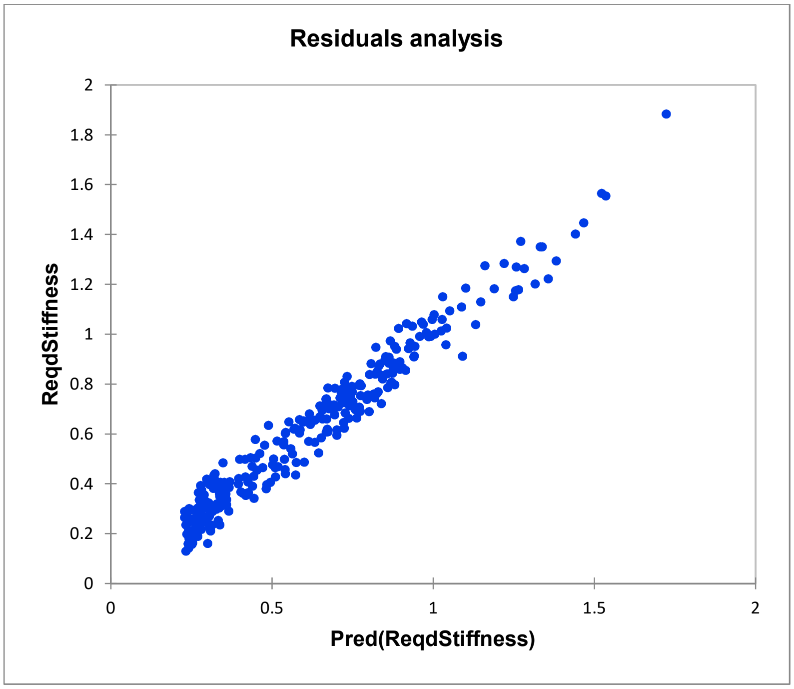

Figure 12. Comparison of stiffness required against predicted stiffness with higher random term weight

This shows that if the ESR AFO stiffness is a function of the four variables identified, the neural network will determine weights which can accurately predict the output to an uncertainty limited by variations in patient preference and other factors not included as inputs.

3.3.4 Implementation

Using the connection weights output from XLSTAT's "neuralnet" function, the team was able to create a seperate function which accepts the four patient parameters as inputs and outputs a predicted stiffness. The database is integrated into the function which will automatically predict a stiffness once the requisite inputs have been entered. To improve the accuracy of the prediction, the sheet is able to accept a table of weights computed by XLSTAT, and then generate a new function. This means that as more patients are added to the training data set, the neural network can be improved, and the results integrated into the existing database and standalone prediction function.

For clinicians to view the results of the neural network, they need to access the Excel workbook with the neural network. This will automatically pull information from the Access database and use this data to select a strut of appropriate stiffness. To further refine the algorithm, clinicians will use the stiffness testing device prior to final ESR AFO delivery to the patient and enter this data into the corresponding patient's file. The neural network can be set to either automatically update after each new entry is received or wait to be manually retrained with the new data.

3.4 Modular AFO

Once work had been completed on data collection and processing, a preliminary redesign of the ESR AFO was performed to utilize the neural network prediction. This redesign fills several client needs, such as reducing clinician fitting time, allowing customization for fitting and kinetics, and consistent manufacturability. One of the main issues the team identified with the current ESR AFO design is that the complex geometry of the ESR AFO limits the applicability of analytical stiffness calculations, making it difficult to properly size an ESR AFO using predicted stiffness. The team performed research into various ESR AFO designs in use by various institutions, a summary of which may be found in Appendix D. The team determined that a simplified modular redesign of the ESR AFO was the optimal solution to meet client needs.

3.4.1 Redesign Benefits

The chosen solution was a modular redesign inspired by the 3D printed AFO designed by researchers in New Zealand, which is comprised of 3D printed calf and foot plates joined to a composite carbon fiber spring, as shown in Figure 13 [6]. The benefits of the 3-part ESR AFO are that the spring stiffness is controlled via the swapping of composite springs, as well as the availability of manufacturing resources already in place at the RCC to build ESR AFOs in a similar manner. Additionally, an initial stock of springs can be procured or manufactured enabling both clinicians and technicians to quickly modify an ESR AFO's spring properties, thus reducing both manufacturing and clinician fitting time.

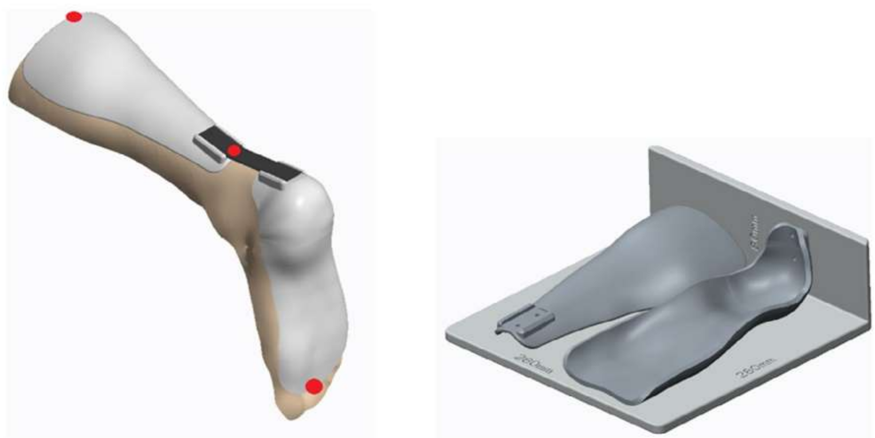

Figure 13. 3D printed modular AFO with composite spring [6]

3.4.2 Adapting RCC Resources

Currently, the RCC manufactures ESR AFOs and articulating AFOs through similar vacuum forming processes. The main difference when manufacturing articulating AFOs, however, is that dummy parts are placed within the thermoplastics in order to mold the body of an AFO to provide space for certain features, such as hinges. The team recognized that such a process could be adapted for the manufacture of a modular AFO, using custom-designed dummy parts to mold a channel for a composite spring within said AFO. With this approach, the RCC maintains control over the manufacturing process, as all forming and cutting is performed in-house.

3.4.3 Incorporation of Data Collection

While the redesigned ESR AFO improves the fitting process on its own, the new design also plays a role in improving data collection. Research provided a starting place for designing the composite spring. However, when paired with the team's data systems, ESR AFO stiffness can be predicted and tuned to each patient with greater accuracy, again increasing as more data is collected. Additionally, redesigned ESR AFOs can be tested via the team's stiffness testing device to empirically verify numerical results. This measured value will then be entered into the database to further the amount of data available for ESR AFO stiffness assessment.

3.4.4 Design Assumptions

During the redesign process, a number of assumptions were made to create a straight-forward system for calculating the spring stiffness of the modular ESR AFO. The first, was that the composite spring will behave as a beam in bending, with fixtures at the locations which the spring is joined to the foot and calf plates. The second assumption was that the foot and calf plates of the ESR AFO would be much stiffer than the composite spring. Assuming that the foot and calf plates are rigid (relative to the composite spring), simplifies the system such that the only area of interest is the ankle spring when considering bending.

3.4.5 Detailed Design and Manufacture

The new modular ESR AFO is similar to that of the existing ESR AFO design, as the modular redesign is based on the RCC's current designs and manufacturing methods. The key difference, however, is that the modular ESR AFO focuses all bending action on the composite spring, rather than along the length of an ESR AFO. The benefit to approaching ESR AFO design in such a manner, is that spring stiffness can be tuned by adjusting only the ankle section of the ESR AFO, or in this case, the composite spring. The main issue with said approach, is that in reality, an ESR AFO bends along the entirety of the strut. To account for the bending of the foot and calf plates of the modular ESR AFO, a reinforcement layer composed of polypropylene will be added along the outside of the ESR AFO while forming to provide extra rigidity. A similar process is used by the RCC already, when a clinician deems it necessary for standard ESR AFOs.

The new composite spring in question is a carbon fiber composite plate that is joined to the foot and calf plates of the ESR AFO. A carbon fiber composite was chosen mainly due to the strength/weight ratio of carbon fiber, though fiber-reinforced composites come with the added benefit of controllable strength and stiffness via alteration of fiber orientation. Controlling stiffness through fiber orientation also allows the composite springs to be held at a constant geometry, further improving modularity and eliminating waste produced from cutting bespoke struts to size for each patient. The team performed preliminary analysis using stiffness data gathered from existing research to determine the appropriate dimensions of the composite spring [7]. Additional material properties such as the elastic modulus was acquired from Rock West Composites, Inc. were used to guide this analysis [8].

To create the channel which holds the composite strut, a dummy part will be placed between the base layers and the mold itself, running along the ankle to the calf. This dummy part will be of similar dimensions to the composite strut, and will be removed once the thermoforming process is completed. After the channel has been formed, a continuous section of material is to be removed from the ankle section of the ESR AFO, as extra material between the ankle and calf will negate the purpose of having a modular composite spring. The disassembled ESR AFO is shown at this stage in Figure 14.

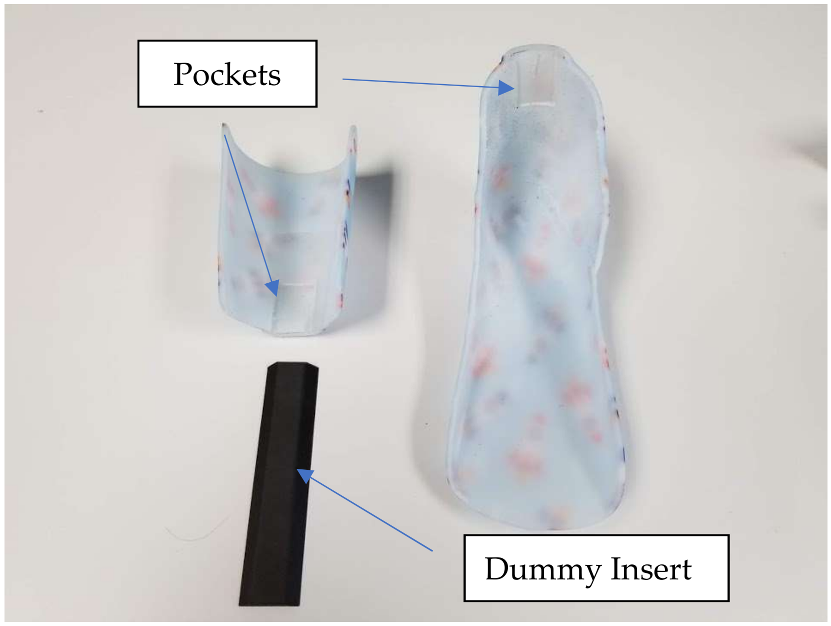

Figure 14: Modular AFO prior to assembly

Following the removal of material at the ankle, holes are to be drilled through the channel for threaded inserts and bolts necessary to hold the composite strut in place. Finally, the composite strut is to be placed into the channel and secured using the aforementioned inserts and bolts. The team found during initial prototyping that a flat, stiff insert between the base layer and the mold was required to prevent warping of the dummy insert.

4 Recommendations

The team has designed a set of deliverables which will reduce clinician time during the patient assessment and delivery phases. These items standardize predictions between clinicians by quantifying all variables used in prediction and using an algorithm to dictate an ideal stiffness, rather than relying on experience and judgement. However, there are additional avenues which were not explored either due to time constraints or being beyond the scope of the project which could potentially have a positive impact on the operation. The following sections detail the team's suggestions for possible alternative approaches to solve the problem, further research in the field, and continuous improvement methods moving forward.

4.1 Alternative Approaches

To obtain more accurate results for the stiffness of ESR AFOs from the testing device, the design could be altered to incorporate strain gauges on the ESR AFO itself, with a data acquisition system to precisely monitor the results. These improvements would be expensive and time consuming to implement, as well as extend the actual measurement process, but these additions would be suitable if the client desires more accurate data or needs to reduce uncertainties for the purposes of a clinical study.

In addition to empirical testing to determine ESR AFO stiffness, analytical or numerical approaches could be pursued. OpenSim, created by Stanford University, is one such software specializing in biomechanics analysis and could potentially offer a way to size ESR AFOs through analysis of all forces acting on the device during the gait cycle. In addition, finite element analysis could be used to numerically obtain the stiffness of an ESR AFO which has been modelled in the analysis software. These prediction methods would allow the staff at the RCC to design a device that conforms to patient requirements with minimal need for adjustment after manufacturing.

4.2 Additional Study

More accurate prediction may be obtained if additional factors are identified, quantified, and incorporated into the inputs. For example, the activity level of a patient may affect their preferences for the rigidity of an ESR AFO. If this were scored on a numeric scale and factored into the neural network training data set, the client may be able to obtain more accurate results. It should be noted that as additional inputs are added, the previous training data set becomes significantly less useful as it will not account for the new variable added. If the client wishes to integrate additional inputs, it is recommended that they first build up a data set which incorporates the new variable before replacing the active algorithm.

Due to the time constraints of the project, a clinical study of the design was not initiated. However, undertaking a thorough study comparing the existing client assessment and fitting process to the proposed methods would allow the client to quantify the improvements made and identify the degree to which the new methods aid in patient treatment. This study could also investigate the effect that patient preference has on ESR AFO stiffness. Surveying multiple users and asking them to quantify their activity level and preferred stiffness may allow the client to incorporate these parameters into the prediction algorithm.

A future study into the performance of ESR AFO designs in terms of spring stiffness may be performed using numerical FEA tools to improve the overall accuracy of the modular strut design. Since the proposed redesign assumes the thermoplastics are rigid relative to the composite spring, variations between theoretical and actual ESR AFO stiffness values will occur. A numerical study will provide insight into the actual performance and requirements of the composite spring, thereby improving the accuracy of the redesigned struts.

4.3 Continuing Work

The team recommends purchasing a Biomed license of XLSTAT software used in the analysis. The team downloaded a trial version for all preliminary work, which has since expired. To incorporate new patient data into the neural network, a full license must be purchased.

The team recommends continuing development of the data collection system with a custom database program or integrating the database into the RCC's existing database software. This increases the security of the patient data as well as helping to prevent data loss. A custom database could also streamline the intake process as well as the analysis by integrating the Excel functions into the software. This would improve the ability of users to enter new data as well as analyze the data already contained by the system. The time spent waiting while the database generates reports or work orders for fabricating ESR AFOs could also be reduced by creating a custom database.

To further increase the data set, collaborative initiatives with other health care facilities which prescribe and manufacture ESR AFOs could be undertaken. This would allow multiple institutes to share data and quickly improve the algorithm, as well as achieve a more diverse range of patients to ensure accurate data may be predicted for all patients.

5 Conclusion

Team 5 has undertaken a rigorous process to ensure that the needs of the client were met as best as possible. By spending the opening weeks of the project defining the problem and expanding understanding of it, the team was able to ensure that the proposed solution met the client need of reducing the time investment in fitting ESR AFOs.

A multi-faceted solution has been proposed to improve the process by which ESR AFOs are designed. Establishing a foundation for data collection not only allows for trends and patterns between patients to be assessed, but also provides future projects with reference material for further development in this field.

By using an Excel based neural network to analyze the information contained within the database, the team's solution reduces the need for experienced clinicians in sizing the orthosis. By analyzing the trend in patient and ESR AFO parameters with a tool, the process of design will be more systematic and less prone to institutional memory loss. The proposed solution also preserves the opportunity for clinician experience to affect the final result, and learn from this knowledge.

Finally, the modular strut design of the redesigned ESR AFO allows the overseeing clinician to choose an appropriately sized spring off the shelf. Despite the neural network predictions for stiffness becoming increasingly accurate, there will remain a variation in patient ESR AFO stiffness due to individual preferences and needs. The modular design will reduce the time required to adjust the stiffness, while also being semi-permanent so that later check-ups are quick and stiffness can be increased without remanufacturing the device.

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Appendix A Concept Selection

During the concept generation phase, approximately 40 concepts were proposed, across a number of distinct categories. As the problem statement allows for many different avenues of solution, these categories were identified early in the project to guide concept generation. These categories are ESR AFO redesign, manufacturing changes, theoretical prediction, and physical prediction. Categorizing the concepts also limited redundant ideas and allowed the team to compare and combine similar concepts and select the best from each section.

A number of brainstorming meetings were held. Prior to these meetings, each team member was assigned to focus their efforts on two categories, and generated several concepts for each.

A.1 Concepts

Concepts were categorized into one of four sections and compared against other concepts in their category. The following sections detail each concept.

A.2 ESR AFO Redesign

The team describes a redesign of the ESR AFO as a change to the way the device functions, the material used, or additions to the existing design. Some of these concepts necessitate additional changes in other categories, such as manufacturing.

A.2.1 Utilizing Alternate Materials

Alternate materials, such as composites and metals, can provide a greater stiffness for an equivalent mass to the thermoplastics used in ESR AFOs now. By incorporating alternate materials into the design, it would be possible to produce a more durable and low-profile device.

A.2.2 Utilizing 3D Printing

A 3D printed strut created to fit over a conventionally vacuum formed thermoplastic would provide the customizability and precise stiffness control that a 3D printer offers, while maintaining the ergonomic shape that is obtainable by using a mould of the patient's limb. Most of the stiffness would come from the 3D printed strut, thereby reducing the bulk of the ESR AFO as a whole. This concept would also allow for different shapes of struts to be easily designed around different pathologies.

A.2.3 Spring outside at the bottom

A metal coil spring would use instead of the thermoplastic leaf spring to provide the energy storage and return. A spring located on the back of the AFO, connected from the heel to the brace at the top of the device, would allow a clinician to swap the spring for one of a different stiffness and reduce calibration time. This design also has the advantage of being non-permanent, so the stiffness could be increased or decreased during subsequent visits. The AFO would be manufactured in a similar way to the existing device, however the ankle would hinge so that the stiffness is only a function of the spring. The concept is illustrated by Figure 1.

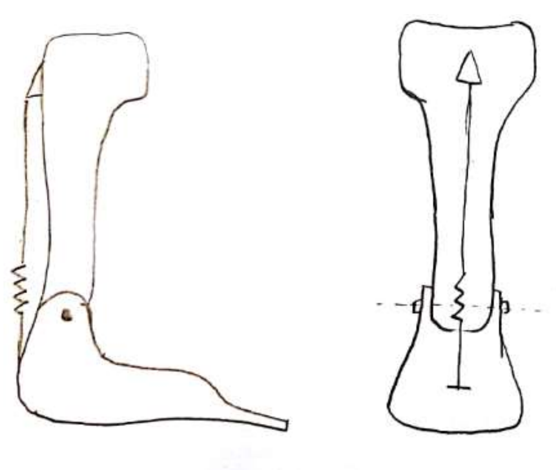

Figure 1. Spring at the bottom concept

A.2.4 Torsion spring under ankle

In this concept, a spring is used to store and return energy to the patient. Instead of a linear spring, a torsional spring is used. While the previous 'spring outside at the bottom' concept puts the spring in tension, this concept would mount a torsional spring to the back and pull it more tightly together when the leg moves. This set-up is demonstrated in Figure 2.

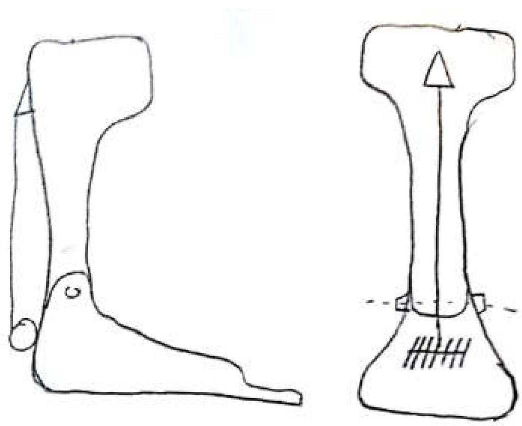

Figure 2. Torsion spring under ankle concept

A.2.5 Torsion springs located alongside the ankle

In this concept, a torsional spring is located alongside the ankle, so that the bottom foot plate and calf brace are connected by the torsional spring, in a similar manner to an articulated AFO which is hinged at the ankle. This concept would differ from the other spring concepts by placement of the spring, as shown in Figure 3.

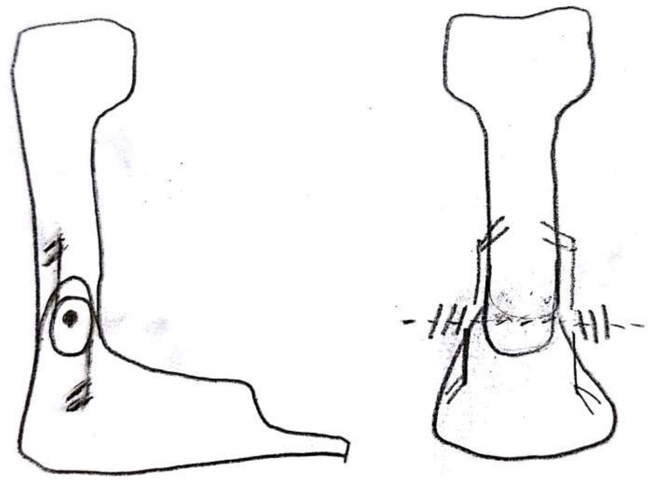

Figure 3. Torsion springs alongside the ankle

By placing the spring along the side of the device, it may be able to fit better within the patient's clothing, and offer less restrictions on daily life.

A.2.6 Modular Strut

A modular AFO consists of three distinct parts: a foot plate, a calf brace, and a strut of known stiffness connecting them. This design would reduce the time investment for adjustment, as instead of shaving down the strut, a different stiffness strut would simply be installed instead, as demonstrated by Figure 4.

This design would require that the RCC build up a stock of struts, so that they have material on hand to quickly adjust the device.

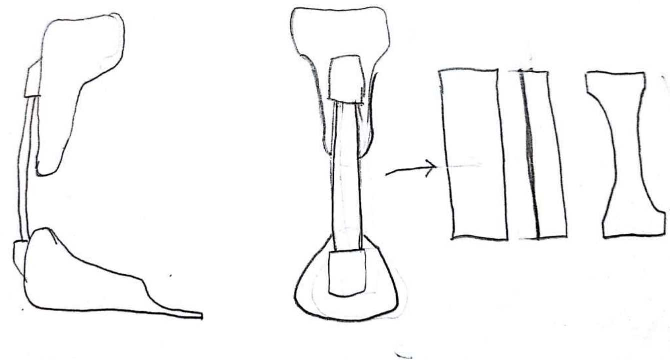

Figure 4. Modular AFO with different struts

The footplate and calf brace may be thermoformed using the existing process, as this method is able to reliably fit most patients. The exact nature of the strut may vary from a simple piece of layered thermoplastic of known stiffness, to a series of carbon fiber rods. Instead of different struts with varying stiffness's, similar rods could be used, and stiffness altered by adding or removing reinforcement rods.

A.2.7 Pocket with Strut Insert

The pocket concept requires that an additional layer is manufactured along the strut, which is sized for fitting a predetermined strut reinforcement. The stiffness comes from the insert placed in the pocket instead of from the thermoplastic leaf spring, as shown by Figure 5. The device is then adjusted by swapping out inserts of differing stiffness. This concept functions similarly to the Modular Strut concept, but maintains the ergonomics enabled by the existing manufacturing method.

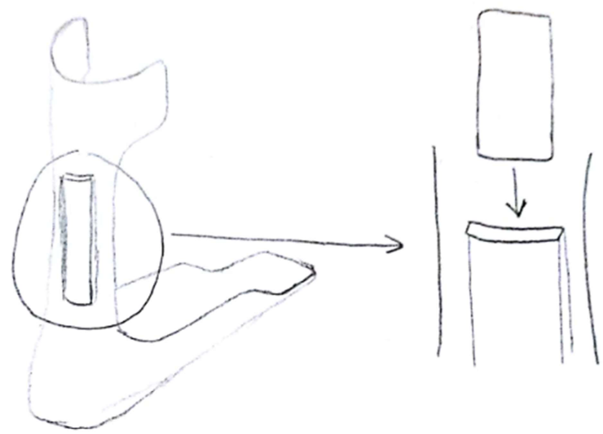

Figure 5. Pocket with strut insert concept

A.2.8 Smaller Strut Section

The current device is designed such that the entire rear of the device constitutes the spring. This concept would change shape of the device so that only a small section of the orthosis will experience the majority of the bending action. This will reduce work required when a clinician must adjust the stiffness, as the workload is minimized making adjustments.

A.2.9 Trapezoidal Strut

A trapezoidal strut is known to be the best shape for the ESR AFO strut. This is because the strut is thicker where the bending moment is greatest, and it thins out as the moment decreases, resulting in a more uniform bend. This in turn means that the stiffness is easier to predict. This shape is already preferred by the RCC for these reasons, however the pathology of the patient frequently means that this shape is not achievable. The shape is shown in Figure 6.

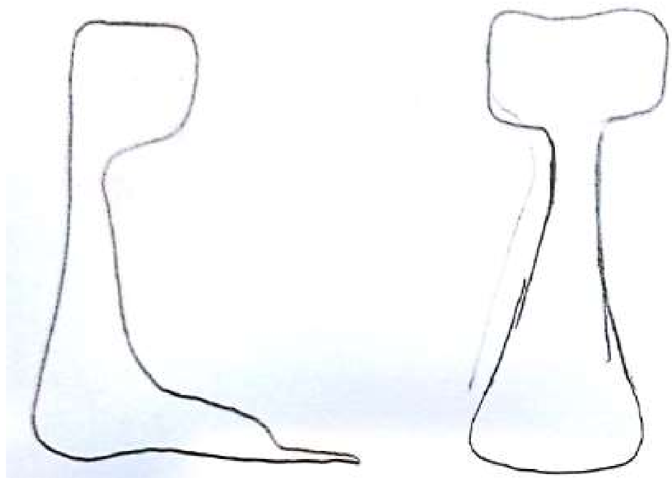

Figure 6. Ideal trapezoidal strut

A.2.10 Add-on Piece

When adjusting the stiffness of an ESR AFO by way of removing material, the clinician must err on the side of caution. If too much material is removed, the device will not be stiff enough to function, and a new ESR AFO will have to be manufactured. By creating an add-on piece, the clinician may ‘patch’ understrength devices, and therefore will be able to adjust stiffness through larger iterations. They will also be able to reinforce an ESR AFO as a patient grows, and their needs change, without the need to issue an entirely new ESR AFO. The premise is explained in Figure 7, where an under-strength ESR AFO is reinforced with additional material.

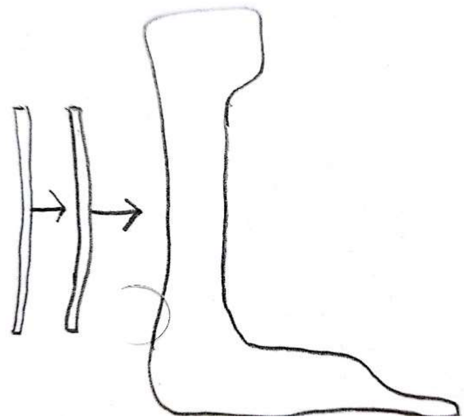

Figure 7. Additive AFO reinforcement

A.2.11 Oil Damper Joints

Following research into current work in the field [1], the idea of using a hydraulic spring/damper system was generated, similar to Concepts 3-5, except using a damping element instead of springs, as shown in Figure 8.

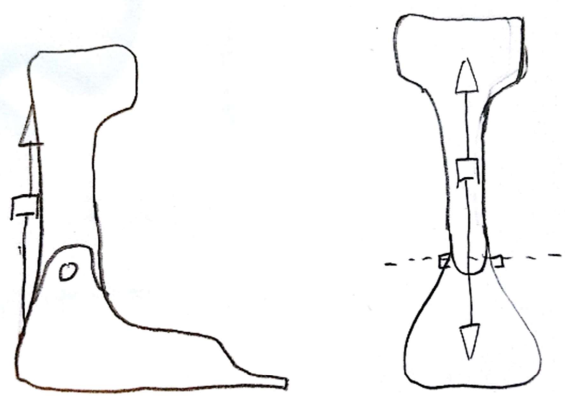

Figure 8. AFO with damper

By providing the damping with a hydraulic system, the device would be suited to patients with cerebral palsy, who experience muscle spasms that can impede their ability to walk properly. Due to its hydraulic nature, this system would be more easily adjusted than the thermoplastic leaf spring, at the expense of increased bulk, cost, and complexity. However, this would not provide the same propulsive effect as a spring system, and therefore would require additional components to achieve its primary goal of aiding propulsion.

A.3 Manufacturing Changes

Manufacturing changes are considered distinct from 'redesign' concepts, as they are only concerned with the method of fabrication and have little bearing on the design of the ESR AFO itself. Some designs would be prohibitive, or indicative of the manufacturing method used, and conversely some manufacturing concepts are only applicable to certain designs. The team generated the following manufacturing change concepts.

The current manufacturing process begins with the creation of a plaster cast of the patient's lower limb. This cast is then scanned to create a 3D model and a mould is carved out of foam using a CNC lathe. This mould is trimmed and sanded to remove excess material, then placed on a mandrel for vacuum thermoforming. In this process, plastic sheets are heated then draped over the mould and a vacuum creates a seal to form the sheets to the mould. After cooling, the ESR AFO is trimmed and sanded to an approximate shape. Then, the clinician and patient work iteratively to test the ESR AFO and reduce the stiffness by grinding until it is suitable for the patient.

A.3.1 Shell on Bone Base

Implementing a standard leg shaped piece (the bone) through which the mandrel passes and adding a thinner carving of the patient's details (shell) to the base could save time. Currently, the CNC machining procedure is limited in its ability to trim down the ESR AFO mould since the mandrel location must be considered and trimmed off by hand after machining. This design is shown in Figure 9.

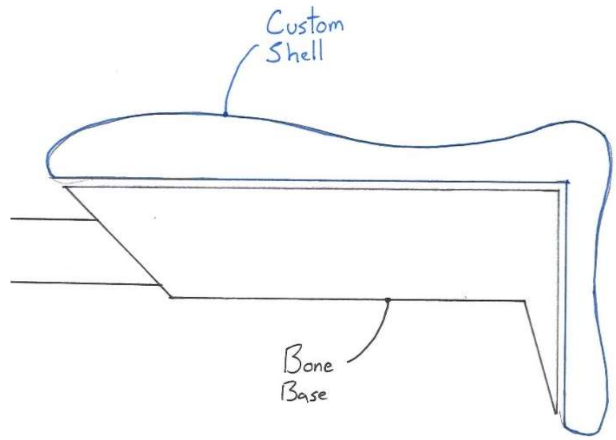

Figure 9. Shell on bone base

A.3.2 CNC Machining

Cut-out dimensions for the ESR AFO could be programmed into the same CNC machine used for carving the foam moulds. The ESR AFO would then go directly into the CNC machine to be shaped and reduce the amount of clinician time spent trimming the ESR AFO. This method could be applied to either trim an ESR AFO after being thermoformed with the current method or used to carve an ESR AFO from a block of material.

A.3.3 3D Printing

The ESR AFO could be 3D printed with fiber reinforcement. This would allow for accurate and repeatable ESR AFOs, albeit with limited options for trimming if they are too rigid. Reinforcements could be implemented then added or removed after 3D printing to allow for more customizability. Due to the low melting point of 3D printed plastics, it would be relatively simple to heat a localized area and plastic weld reinforcements on, albeit with the risk of deformation. The RCC's current production 3D printer is unreliable for mass production and relying on this device to create a prototype could be a significant risk.

A.3.4 Cut-out Template

A printed sheet with predetermined trim guidelines based on patient height, weight, and limb shape could be overlaid onto the material to guide technician trimming. The sheet would be applied after the ESR AFO has been formed to the mould and is cooled. This would allow the technicians to trim the ESR AFO exactly to shape either based on computer modelling of strut shapes or initial guides for later trimming. Clinician judgement plays a large role in determining the initial shape of the ESR AFO and they will often be the ones trimming rather than the technicians. Reducing the workload on the clinicians by creating accurate guides for the technicians to follow would allow the clinicians to focus their time more effectively. A disadvantage of this design is that it would be difficult to accurately place trim lines on a planar surface to be printed then wrapped around a complex shape, as shown in Figure 10. In addition, typical body reference points which clinicians are accustomed to referencing would not be present when laying out the lines, so a custom computer program would be required to adjust for the complex geometry transformation.

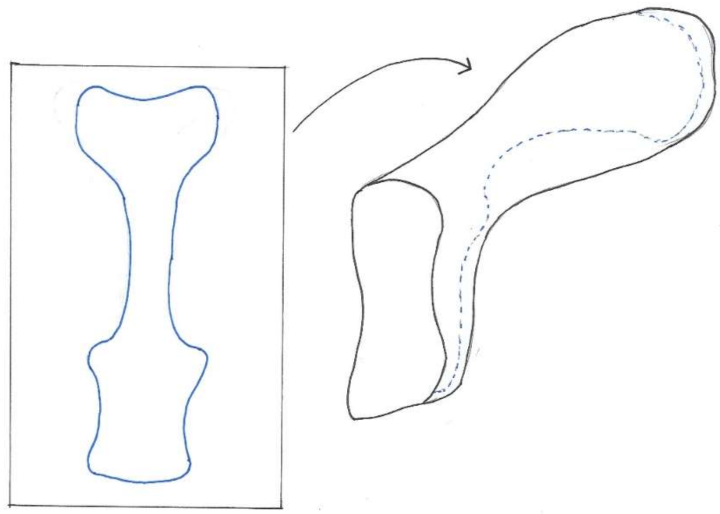

Figure 10. Cut-out template

A.3.5 Vary Strut Thickness

Rather than altering the shape of the strut by trimming, the thickness of the strut could be changed by sanding along the inside or outside of the strut as shown in Figure 11. This would allow for more comparable analysis between ESR AFOs and reduce the clinician time required for fitting. However, this method would impose either an alteration to the aesthetics of the design (when sanded externally) or an alteration in the fit (when sanded internally).

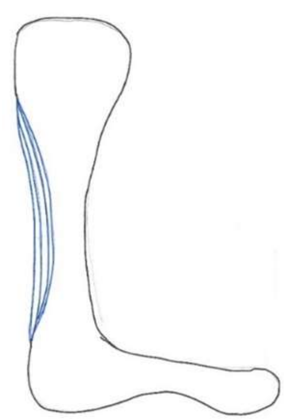

Figure 11. Vary strut thickness

A.3.6 Optimize Manufacturing Methods

When the patient is assessed, an algorithm will consider their limb shape and condition, which will then dictate whether their ESR AFO should be made using the conventional method or one of the other means identified. However, it may be more practical to manufacture especially small, large, or complex ESR AFOs using alternate manufacturing methods. For example, the 3D printer used by the RCC has a roughly 20 cm x 20 cm x 20 cm print bed which could fit ESR AFOs for smaller patients, but taller patients would require the traditional method. It may also be practical, once a patient's limb length exceeds a certain limit, to alter the design to a modular or other ESR AFO.

A.3.7 Double Thermoforming

A pair of ESR AFOs could be manufactured at once rather than one at a time if oriented in such a way that two male moulds could be manufactured side by side, as shown in Figure 12. This would allow for more consistency between either sides of a pair of ESR AFOs, and help maintain a symmetrical gait. In addition, this could potentially save on material costs by reducing wastage during trimming.

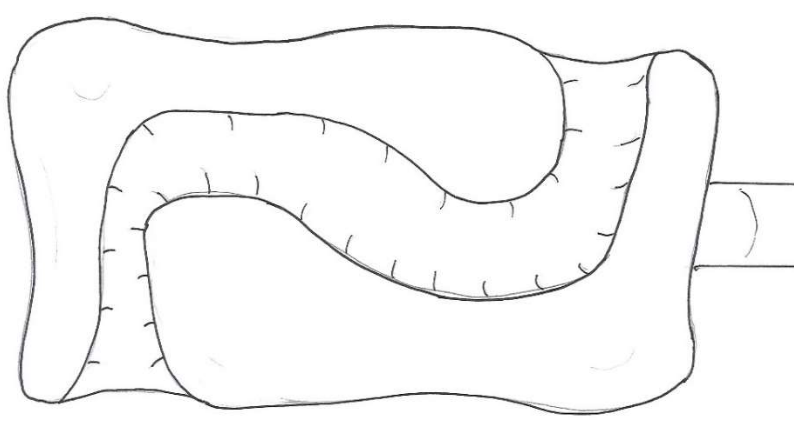

Figure 12. Double thermoforming

A.3.8 New Vacuum Forming Process

An alternate method of vacuum forming is a vacuum thermoforming table. Instead of the thermoplastic sheet being wrapped around a male mould which slides onto a mandrel, the material is held taught and heated with space above and the mould below. When sufficiently hot, the bottom chamber is evacuated as the mould is pushed upwards. This process is shown in Figure 13. This would not easily allow for multiple layers of different material, but benefits may be derived through the lower complexity and reduction in employee time to form since this process would only require a single individual and multiple ESR AFOs could be formed simultaneously.

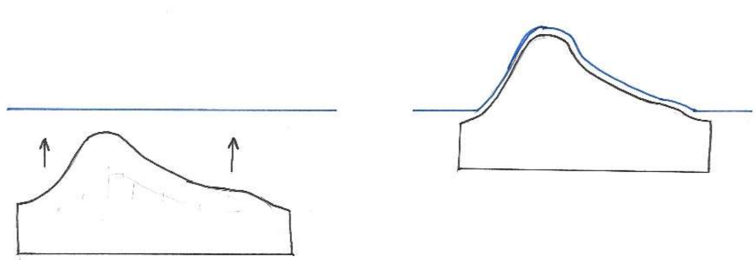

Figure 13. New vacuum forming process

A.3.9 Sonic Welding of Thermoplastics

Standardized shapes and reinforcements could be welded onto the ESR AFOs after manufacturing to either alter the stiffness or after vacuum thermoforming the ESR AFO. Coupled with other methods, this could potentially allow for multiple ESR AFOs to be formed simultaneously from the same sheet of material, then fine-tuned with reinforcements.

A.4 Theoretical Prediction

These concepts focus on the application of data to create a theoretical prediction of either what the patient requires in terms of stiffness of an ESR AFO, or how stiff an ESR AFO would be based on design, strut cross-section, material etc. These theoretical predictions would then be used to improve the initial form of the ESR AFO and lessen the amount of optimization required by the clinician and patient. Theoretical prediction can take either the empirical or numerical approach. Empirical approaches to theoretical predictions directly involve the use of patient data to select an ESR AFO based on theoretical trends. Numerical approaches to theoretical prediction make use of patient data to numerically determine ESR AFO properties, or to numerically design an entire ESR AFO.

As per the RCC, most patients, regardless of pathology, require an ESR AFO stiffness that roughly correlates with their weight and height.

A.4.1 SOLIDWORKS Model

SOLIDWORKS can be used to create a model which automatically updates its dimensions based on input from patient measurements and complexities. Additional information from testing jigs or other sizing tools can assist in modifying the orthosis to allow for complex patient limb structure. Additionally, SOLIDWORKS FEA tools can be applied to optimize geometries for specific ESR AFO requirements based on patient data.

A.4.2 Excel Spreadsheet

This spreadsheet would generate a stiffness for the posterior strut at a predetermined weak point to define the spring stiffness of the entire rear strut. This spreadsheet would accept inputs from a clinician based on the patient height, weight, complexity of the limb structure, complexity of the condition, and other variables.

A.4.3 MATLAB Code

This concept uses MATLAB in a similar way to the Excel spreadsheet concept to assist in the creation of the model. This concept has the advantage of very powerful visualization and plotting tools, as well as simulation capabilities.

A.4.4 Trend from Existing Data

Using existing data collected from patients, such as height, weight, complexity of condition, and stride length, the team will create a database to interpolate the relationship between this data and the ESR AFO designed for the patient to assist in the design of future ESR AFOs. This would be created as a standalone project without further data input unless combined with a data collection system.

A.4.5 Trend from Testing Data

Physical testing of current materials and ESR AFOs to find and verify a model of the stress-strain curve for these materials and ESR AFO designs. This will improve accuracy of predictions for future ESR AFO design and develop an understanding of how stiff these AESR FOs are and how that stiffness changes with modifications to the strut cross-section and materials used.

A.4.6 Biomechanics Analysis

This concept will use analysis from clinicians, research papers, and other sources to determine the relationship between the force resulting from running and walking, and body dimensions and weight. Then, use this data to improve the design of the AFO and develop a close first guess for the stiffness of the spring-strut to limit the time needed to optimize the stiffness for each patient and clinician.

A.4.7 Data collection

A data collection system which allows easy input from all clinicians and technicians. This database would analyze data and find trends between patient characteristics and ESR AFO stiffness to be used for the prediction of future patient's ESR AFO dimensions. With enough data points, an accurate trend could be developed which would significantly reduce clinician time spent fitting.

A.4.8 SimTK Biomechanics Analysis

SimTK is a project database for the biomedical industry to share software, data, models, and other resources [2]. Using OpenSim software, and models, both found on the SimTK website to develop a numerical model to predict the forces experienced in the foot, ankle, and lower leg to produce a closer first guess for creating the orthosis geometry and its stiffness.

A.4.9 Test Rig Stiffness into Sizing Script

A testing rig would gather measurements from a physical testing rig for patients to determine the stiffness particular to that patient. This data would then be analyzed using a finite element software or a similar code to the MATLAB or Excel examples above to find the optimal geometry of the AFO. Using this type of analysis would allow for modifying the design to fit around possible uncommon shapes of the patient due to their condition.

A.4.10 Mo-cap Gait

Motion capture allows clinicians to study the gait of patients both with and without an AFO. This allows for a better understanding of what the patients gait is like without needing to study it in real-time and allows for motion studies to find if the gait cycle for each patient could be improved further. It also allows for this type of data to be used to determine an improved starting point for the manufacturing of an ESR AFO.

A.5 Physical Prediction

The concepts within the physical prediction category make use of a testing set-up to determine the preferred ESR AFO stiffness for each patient. By testing the patient before manufacturing a bespoke ESR AFO, the exact needs of the patient would be known, reducing the guesswork involved in the adjustment process. Each of these concepts suggests some way of creating an AFO whose stiffness can be adjusted on-the-fly to suit patient needs.

A.5.1 Different Sizes of Testing AFO

Various testing ESR AFOs can be produced with known stiffness values and sizes to fit different patients. The ESR AFO stiffness can further be modified by using testing rods to gather information to enable the clinician to make a better initial estimate. Testing AFOs of this type will require production of a wide range of AFO sizes and shapes in order to accommodate the variations in patient pathology.

A.5.2 Device to Measure Foot Pressure Points

A device used to measure the pressures exerted by the foot onto an AFO to assist in shape and stiffness design. This device may assist a clinician's ability to add padding and reinforcement to an AFO in a CAD model and on the final AFO itself.

A.5.3 Different Methods of Measuring Strain

Different methods of measuring the strain experienced by a testing AFO include axial strain dials, strain gauges and a physical dial pushed by the AFO as it rotates. These dials and gauges can be placed on different locations of the AFO strut, either on the sides or on the back, to measure strain and deflection. The strain data can then be applied to a numerical model to design a new AFO, or to select an AFO with a known stiffness to best fit the patient.

A.5.4 Adjustable Hinges on Testing AFO

A testing jig which is fitted with hinged sides to secure the calf and foot, enabling the testing AFO to fit a wider range of patients. This is shown in Figure 14. Adjustable hinges on testing AFO solid components allow more rigidity compared to Velcro to secure the patient's leg.

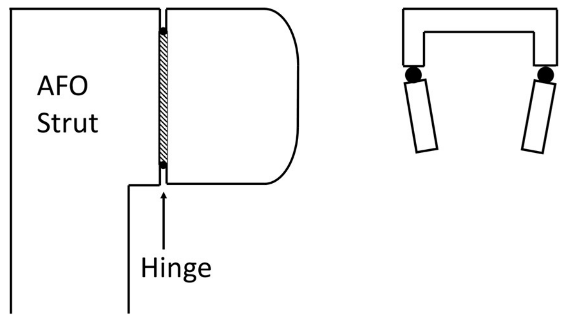

Figure 14. Adjustable hinges on testing AFO

A.5.5 Elastic Testing Rig

Elastics are affixed on posts at the calf and heel as shown in Figure 15 and provide the stiffness of the AFO, rather than the thermoplastic. Using an elastic setup allows for an inexpensive and easy-to-operate solution that a clinician can use to determine AFO fabrication requirements. The elastics can be added or removed from a testing jig to adjust AFO stiffness while testing. These elastics will have known stiffness values and will act linearly and in parallel with each other to produce a quantifiable stiffness for the final AFO.

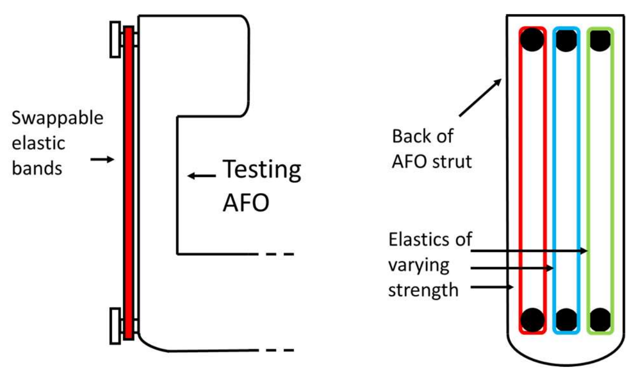

Figure 15. Elastic testing rig

A.5.6 Ratcheting Testing Rig

This concept consists of a simple ratcheting system that is applied to a testing jig to tighten the strut of the jig that affects the bending properties of the jig. This can move the weak point along the calf to modify the stiffness by altering the bending moment as shown in Figure 16. Additionally, the jig can have an adjustable calf height while maintaining stiffness by tightening the strut. Such a device could potentially reduce the amount of testing jigs required, as patient height/calf height can be accounted for via the adjustable strut.

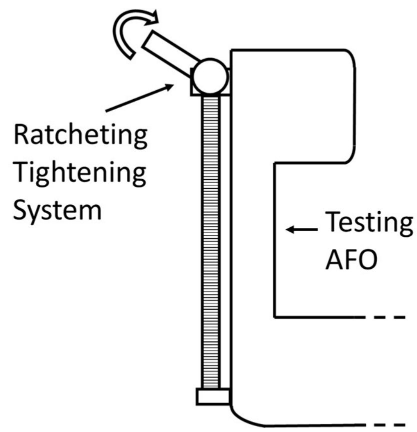

Figure 16. Ratcheting testing rig

A.5.7 Reinforcement Material

Layers of material may be added to the back of a testing jig to modify and calibrate the stiffness for a final AFO design. Figure 17 shows this concept. This method may need to be combined with thermoplastic welding to ensure layer adhesion.

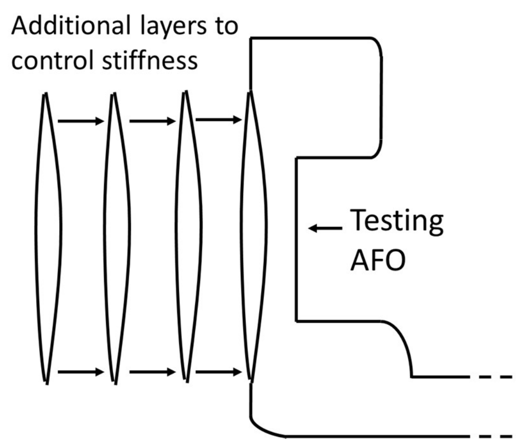

Figure 17. Reinforcement material

A.5.8 Modular Rigidity Calculations

Information regarding the rigidity of reinforcement rods can be acquired either through testing or from manufacturer specifications. Once analyzed, the rods can be placed in testing jigs or modular designs to simplify stiffness calculations. Having a stock of rods with known mechanical properties enables clinicians to quickly swap reinforcement rods for ESR AFO adjustment as shown in Figure 18.

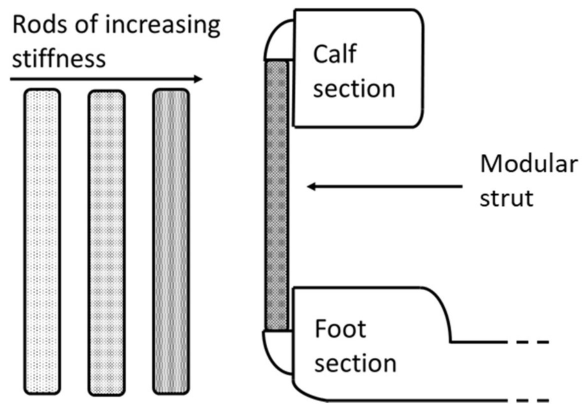

Figure 18. Modular rigidity calculations

Appendix B Concept Selection

The team began concept selection by arranging all concepts into categories based on if they pertained primarily to an ESR AFO Redesign, Manufacturing Changes, Theoretical Prediction, or Physical Prediction. The team then created a concept selection matrix to provide a quick ranking of concepts against the existing design and manufacturing processes. Needs were used since comparing the metrics of many of the concepts would either be impractical or purely guesswork. After this initial selection, the best three results from each category were arrayed into a decision matrix with weights provided by the RCC. Scores were assigned in every category by ranking concepts relative to each other, rather than to the existing design. The winners of each category along, with close contenders, were brought to the RCC for discussion to ensure that pursuit of these selections is feasible.

B.1 First Iteration

The concept selection began with the creation of a concept selection matrix to quickly rank concepts against the existing design and manufacturing processes. The concepts were compared within their category, as the needs and metrics were not equally relevant too each category. After the initial selection, the best three results from each category were arrayed into a decision matrix with weights provided by the RCC. Scores were assigned in each category by ranking concepts relative to each other, rather than to the existing design. The winners of each category, along with close contenders, were brought to the RCC for discussion to ensure that pursuit of these selections is feasible.

All team members individually assessed the performance of every concept with respect to relevant needs and assigned a score of either +1, 0, or -1 (represented as +, null, or -, respectively). A positive score denotes that the concept accomplishes the need better than the current design, a score of 0 represents no change in performance from the current design, and a negative score means that the concept performs worse than the current solution. The sum of scores from each member were concatenated instead of summed, because totals could be misrepresentative of actual votes. For example, a value of ‘0’ in each category could represent either 4 null scores, or 2 positive and 2 negative scores.

In cases where the need was not applicable to the category, a score of 0 was applied.

TABLE I. FIRST ITERATION CONCEPT SELECTION MATRIX

	The AFO	has customization for fitting and kinetics	has consistent manufacturability	promotes user independence	enables comfortable fitting	is receptive to aesthetic changes	is durable	has a lower cost than the current design	reduces manufacturing time	is suitable for growing children	is lightweight	has low negative impact on daily life	reduces clinician time	enables stable ambulation	Sum
	ESR AFO Redesign														
1	Utilizing Alternate Materials	-+	-+-			--	+++	---	---	-	-++	+		+	-1
2	Utilizing 3D printing	+++	++--			++	-+-	---	----	-+-	++		+++		0.25
3	Spring Inside at the Bottom	--++	--+-	-	--	+	-+-	--+-	--+	-+	---		++		-2.25
4	Torsion Spring Under Ankle	-++	--	-		+	+-	---	-+		-		+		-1
5	Torsion Springs Located Alongside Ankle	--++	----	-	+	+	++-	----	-++	-+	-	-	++		-1.25
6	Modular Strut	++++	++++		-+	---	+++	-+	+-+	++++	-+		+++		**4**
7	Pocket with Strut Insert	+++	+-+		+		+++	+-+	-+	++	++		+++		**4**
8	Smaller Strut Section	++++	-++		+		-+	+++	++	+	+		++		**3.75**
9	Trapezoidal Strut	+++	++-		+	-	+++	+	+	+	++		+		3.25
10	Add-on Piece	+++	+--			-	++	--	+	-++	++		++		1.75
11	Oil Damper Joints	-+	----	--	--	-	+	----	-+-	-+	-	---	-++		-4
	Manufacturing Changes														
12	Shell on Bone Base	+++	-+-		-+	+		+++	+++	+			+		**2.75**
13	CNC Machining	++	++++				+	-+--	+-++		+	+	++++		**3.25**
14	3D Printing	+++	++--		-	+-	+	----	---+	-	++		+++		0.25
15	Cut-out Template	+++	++++					-++	++++				+++		**3.75**
16	Vary Strut Thickness	-++	-+--			-	+	--+	--	+	+		++		0
17	Optimize Manufacturing Methods		++					+++	++++						2.25
18	Double Thermoforming		-+++			-		++++	++++						2.25
19	New Vacuum Forming Process		+++			-		+	-++						1
20	Sonic Welding of Thermoplastics	-++	--+-		-	--+-	++	--+	--+	++			+-		-0.5
	Theoretical Prediction														
21	SOLIDWORKS Model	++++	++			+		+++	+	+			+++	+	**4**
22	Excel Spreadsheet	-+++	++					+++	+	+			+++		3
23	MATLAB Code	-+++	++					-++	+				+++		2.25
24	Trend from Existing Data	+++	++	+				+++	++	+			++		**3.5**
25	Trend from Testing Data	++					+	+++	++				++		2.5
26	Biomechanics Analysis	++++	++				+	-++	+				+++	+	**3.25**
27	Data Collection	+						-+					++		0.75
28	OpenSim Biomechanics Analysis	+++	+				+	-++	+				++	+	2.5
29	Test Rig Stiffness Into Sizing Script	++++	++					-++	+				+++		2.75
30	Mo-cap Gait	++	+					--+	+	+			-+	+	1.25
	Physical Prediction														
31	Different Sizes of Testing AFO	+	+					+					+		1
32	Device to Measure Foot Pressure Points	+++	+	-	+		+	+++	+	-+			-++		2.5
33	Different Methods of Measuring Strain	++	++					-++	+				++		2
34	Adjustable Hinges on Testing AFO	++	+					-+	+				+		1.25
35	Elastic Testing Rig	++	++					++	++				++	+	**2.75**
36	Ratcheting Testing Rig	++++	+-		+		-	+-+	+	+			+++	+	**2.75**
37	Reinforcement Material	++++	+					-++	+++	+			+++	+	**3.5**
38	Modular Rigidity Calculations	++++	+						+				+++		2.25

The three highest scores in each category were kept for the next iteration and are shown in TABLE II. For convenience, a reference to each concept's description page has been included.

TABLE II. HIGHEST RANKED CONCEPTS FROM FIRST ITERATION

ESR AFO Redesign	**Page**
6. Modular Strut AFO	A-4
7. Pocket with Strut Insert	A-5
8. Smaller Strut Section	A-6
Manufacturing Changes	
12. Shell on Bone Base	A-9
13. Use CNC Machining	A-10
15. Cut-out Template	A-11
Theoretical Prediction	
21. SOLIDWORKS Model	A-15
22. Excel Spreadsheet	A-15
24. Trend from Existing Data	A-16
Physical Prediction	
35. Elastic Testing Rig	A-19
36. Ratcheting Testing Rig	A-19
37. Reinforcement Material	A-20

B.2 Second Iteration

During the team's internal concept selection, the team sent a list of identified needs to the RCC with a request to distribute 100 points between them. The team used these weights in the second iteration of concept selection to further evaluate suitability of concepts. The weights assigned by the RCC are shown in the top row of TABLE III. Each concept was given a score of 0-3 for each need, with 3 representing the best, 1 representing the worst, and 0 not applicable to that need.

The sum of each is shown on the right, with the highest scored concept of each category in bold.

TABLE III. SECOND ITERATION CONCEPT SELECTION MATRIX

The AFO	has customization for fitting and kinetics	has consistent manufacturability	promotes user independence	enables comfortable fitting	is receptive to aesthetic changes	is durable	has a lower cost than the current design	reduces manufacturing time	is suitable for growing children	is lightweight	has low negative impact on daily life	reduces clinician time	enables stable ambulation	**Total**
Weight:	10	10	8	4	9	9	8	10	6	6	2	9	9	
ESR AFO Redesign														
6 Modular Strut	3	3	2	2	2	2	1	3	3	3	0	3	0	**221**
7 Pocket with Strut Insert	2	2	2	2	3	3	2	2	1	2	0	2	0	190
8 Smaller Strut Section	1	1	3	3	3	1	3	1	1	2	0	1	0	153
Manufacturing Changes														
12 Shell on Bone Base	2	1	0	3	2	0	2	2	0	0	0	1	0	105
13 CNC Machining	3	3	0	1	1	0	1	1	0	0	0	2	0	109
15 Cut-out Template	1	2	0	3	3	0	3	3	0	0	0	3	0	**150**
Theoretical Prediction														
21 SOLIDWORKS Model	0	3	0	0	0	0	2	3	1	0	0	2	1	109
24 Trend from Existing data	0	1	0	0	0	0	3	3	3	0	0	3	2	**127**
26 Biomechanics Analysis	0	2	0	0	0	0	1	2	2	0	0	1	3	96
Physical Prediction														
35 Elastic Testing Rig	2	3	0	0	0	3	3	0	0	3	0	2	1	**146**
36 Ratcheting Testing Rig	3	2	0	0	0	1	1	0	0	1	0	3	3	127
37 Reinforcement Material	1	1	0	0	0	2	2	0	0	2	0	1	2	93

The concepts which best meet the needs in each area are as follows: Modular Strut, Cut-out TemplateCut-out Template, Trend from Existing Data to theoretically predict required stiffness, and an Elastic Testing Rig to obtain a physical prediction of stiffness.

B.3 Results Discussion

Based on the results of the second iteration of concept analysis, the team selected the top two concepts for each objective area. These top concepts were brought forward to the RCC to obtain further input and to ensure there were no unforeseen restrictions that would inhibit the implementation.

The team, in discussions with the client, determined that a modular redesign of the ESR AFO was the preferred solution. This has more functionality than a specific physical prediction rig and is custom fit to each patient, removing the limitations of the physical prediction rig. Redesigning the ESR AFO into a modular style will necessitate manufacturing changes and removes the applicability of that design area.

As the RCC does not currently have an existing database for matching patient data with the specifications of the ESR AFO they receive, this was made a priority. This was decided as going forward the RCC would like to easily review and compare the patient ESR AFO architecture. The RCC is also interested in a theoretical or numerical model to predict the stiffness requirements for each patient. This model was developed using random patient data and can then be connected to the database of actual patient data to be continually optimized. Software restrictions were discussed, with the team and client concluding that developing the data tracking and prediction software with Microsoft Office products such as Access and Excel was easiest to implement, as well as train technicians and clinicians to use. In order to measure the stiffness of existing ESR AFOs, a device was designed and manufactured to determine the load required to deform the ESR AFO to a given angle. These factors were combined to calculate a spring stiffness.

The client was intrigued by the idea of the physical prediction concepts, but ultimately decided against moving forward with it. It was believed that creating a number of generic devices for patients to test would be as impractical and just as time intensive as the existing process. As the patients seen by the RCC exhibit such a wide range of physical impairments, it would be impossible to manufacture generic AFOs capable of serving more than a small pool of patients. This type of solution would provide no benefit to edge-case patients that could not use the reference AFOs.

B.4 Final Selection

For the final selection, the team decided on the top item from each of the categories indicated by the RCC. These items were then prioritized, such that the team would complete one deliverable before moving on to the next.

The implementation of a data collection system was deemed most important in solving the problem presented by the RCC. This system is a foundation moving forward, providing information needed to correlate between patient anthropometrics and ESR AFO stiffness.

The next most important deliverable was pulled from the theoretical prediction category. A way to determine the approximate stiffness required for a given patient will improve the 'first guess' provided by the clinician, therefore reducing the time needed to adjust each ESR AFO.

The final deliverable is the design of a modular ESR AFO to be used in conjunction with the data collection and prediction systems implemented by the team. If a clinician can use the anthropometrics of a patient to determine which pre-determined stiffness strut is required, this system will significantly reduce the time investment on behalf of the personnel.

Appendix C Project Management

The team created a multifaceted project management plan to ensure timely delivery of the products. This included a schedule to plan and track deliverable progress, a Work Breakdown Structure (WBS) to separate deliverables into manageable packages, a communications management plan to gather and disseminate information, and a risk management strategy to evaluate and plan for risks.

C.1 Scheduling

A Gantt chart was created during the Project Definition Phase, and was improved upon during each subsequent phase, based on feedback from the graded reports.

Through consultation with the RCC, holding bi-weekly meetings to confer was deemed sufficient the remainder of the project. Said meetings were held for the team to confer with the RCC about designs, prototype construction, testing, and other project content.

Figure 19 is an updated Gantt chart for the project, with new deadlines and deliverables added from new information and design decisions.

ID	Task Name	Duration	Start	Finish
1	CDR Phase	17 days	Thu 18-10-04	Fri 18-10-26
2	Concept Development Period	8 days	Thu 18-10-04	Mon 18-10-15
3	Individual research & brainstorming period	6 days	Thu 18-10-04	Thu 18-10-11
4	Concept matrix development & concept elimination	2 days	Fri 18-10-12	Mon 18-10-15
5	Client meeting and feedback integration	2 days	Tue 18-10-16	Wed 18-10-17
6	CDR Draft	3 days	Thu 18-10-18	Mon 18-10-22
7	Advisor CDR feedback period	3 days	Tue 18-10-23	Thu 18-10-25
8	Final CDR editing period	3 days	Tue 18-10-23	Thu 18-10-25
9	CDR submission	1 day	Fri 18-10-26	Fri 18-10-26
10	Final Report Phase	31 days	Mon 18-10-29	Mon 18-12-10
11	Develop testing regime and parameters	3 days	Mon 18-10-29	Wed 18-10-31
12	Develop numerical model	5 days	Thu 18-11-01	Wed 18-11-07
13	Prototype development	8 days	Thu 18-11-01	Mon 18-11-12
14	Fabricate prototype parts	3 days	Tue 18-11-13	Thu 18-11-15
15	Assemble prototype	3 days	Fri 18-11-16	Tue 18-11-20
16	Complete testing regime on prototype	7 days	Wed 18-11-21	Thu 18-11-29
17	Final report	7 days	Tue 18-11-27	Wed 18-12-05
18	Final oral presentation	1 day	Thu 18-12-06	Thu 18-12-06

Figure 19: Gantt chart

C.2 Work Breakdown Structure

The project's deliverables have been split into three phases in order to differentiate between the tasks associated with project definition, concept design, and the final design. The Work Breakdown Structure (WBS), shown in Figure 20, displays the decomposition of the project's deliverables.

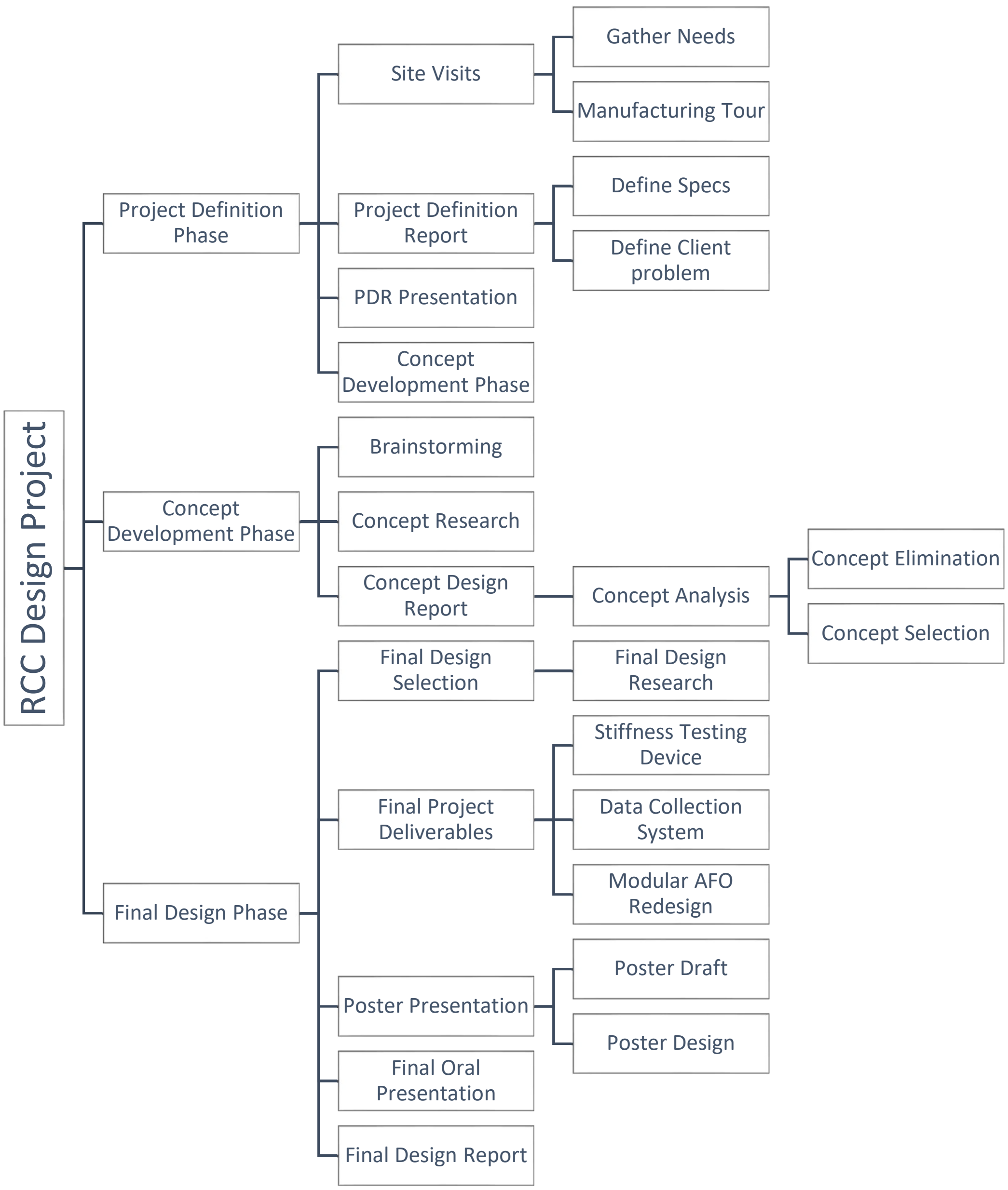

Figure 20. Team WBS

C.3 Communication Management Plan

The team used several different methods of communication depending on the type of information and its audience. A communication matrix, shown in TABLE IV, was developed to explain the different communication channels.

TABLE IV. COMMUNICATION MATRIX

Type	Audience	Medium	Frequency	Purpose
Faculty Advisor Meeting	Team members, Faculty Advisor	In-Person	Weekly	Advisor updates
Client Communication	Client, Team leader	E-mail	As needed	Questions and clarifications
Team Daily Communication	Team Members	Group chat	As needed	Planning and updates
Document Sharing	Team Members	Microsoft OneDrive	-	Sharing information
Team Meetings	Team Members	In-Person	Biweekly	-
Client Meetings	Client, Team Members	In-Person	Biweekly	-

A single team member was nominated to handle all client communication, with all other members being informed.

C.4 Risk Management

Risk analysis was performed at each phase of the project to reduce the likelihood and magnitude of potential problems.

C.4.1 Risk Assessment

Risks were identified through analysis of the course and client requirements. The high level project risks are shown in TABLE V.

TABLE V. RISK ASSESSMENT MATRIX

Number	Description	Project Impact	Cause
1	The team does not submit a report on time	Grade penalty for late delivery	Poor time management when creating technical documents
2	Design does not satisfy client needs	Client dissatisfaction with the project	Failure to consider problem statement when selecting design
3	Prototype not able to be manufactured by end of course	Design not fully tested	Failure to appreciate lead time on manufacture, client schedule
4	The team begins work on deliverables that are not finished for the final report	Time not spent on core project deliverables	Poor scope control

The impact and likeliness of each risk was considered and ranked accordingly. By multiplying these values, the most pressing risks were identified, and response strategies developed.

Qualitative ranks have been assigned to each of the risks identified. A likeliness score has been established, as shown in TABLE VI.

TABLE VI. LIKELINESS RANKING

Rank	Likeliness
5	>95%
4	65-95%
3	35-65%
2	5-35%
1	<5%

The impact of each risk has been assessed qualitatively, on a scale from 1 to 5, shown in TABLE VII.

TABLE VII. IMPACT RANKING

Rank	Impact
5	Extreme. Will guarantee project failure
4	Major. Unlikely that team can overcome issue
3	Moderate. Team may not be able to overcome issue
2	Minor. Team will be able to overcome issue
1	Insignificant. Team can work around issue with minimal effort

The weighted risks are presented in TABLE VIII.

TABLE VIII. RISK MATRIX

Likelihood	5					
	4		3			
	3					
	2			4	1, 2	
	1					
		1	2	3	4	5
	Impact					

The risks are scored in order to rank them by relevance, shown in TABLE IX.

TABLE IX. RISK MATRIX LEGEND

Low	Medium	High
1-5	6-14	15-25

C.4.2 Risk Response

Response plans were made for the highest ranked risks, and are listed in TABLE X.

TABLE X. RISK RESPONSES

Risk	Risk Response
1	Internal scheduling requires that a draft for each major document is completed with adequate time for advisor review prior to submission
2	Rigorous analysis of the problem, including several research trips to the facility. Will require frequent client communication to ensure that the project proceeds per client expectations.
3	Internal deadlines are to be set to provide ample time for client to manufacture prototype. Further, a testing plan is to be created so that the client may test the prototype on their own time.
4	Prioritize work on most important deliverables so that critical elements are completed before 'nice to have' items.

Appendix D Research

D.1 Alternative Designs

The team conducted research into ESR AFO dynamics and applied this knowledge in generating and selecting concepts, as well as in the design of the final deliverables. Webernotes [3] provides an overview of ESR AFO dynamics and shares trends observed when testing various shapes and thicknesses of ESR AFOs. Notably, that a tapered or trapezoidal strut shape will bend uniformly during loading. Comparatively, a straight or filleted strut will tend to only bend at a single location. This uniform bending is more desirable when seeking a gradual, measured response instead of a quick and tight motion. The existing design utilized by the RCC consists of a strut which has been filleted on either side when viewed from the frontal plane.

Alternate designs of the ESR AFO have been prescribed to RCC patients. One of these, the WalkOn Reaction [4], is a carbon fiber design which even has a degree of adjustability since it can be ordered in four different sizes. However, the RCC desires more resolution in their stiffness as well as a wider range than what is provided by the WalkOn Reaction.

A much more tailored ESR AFO is offered by Allard, a company which manufacturers a range of braces and orthoses. Their website offers instructions on how to measure many patient parameters, which are then used to design a custom carbon fiber ESR AFO [5]. The primary disadvantages with this method are the lack of customization for children, the limitation in stiffness adjustment once received, and the expense for an orthosis which will need to be replaced within a year. This resource provided insight into which patient parameters will affect ESR AFO stiffness and how to measure them.

The team obtained a copy of the RCC's patient assessment and measurement form to view the available information which could be used in theoretical prediction methods. Theoretical prediction methods were designed to deliver an accurate result based on this data.

D.2 Stiffness Correlation

Empirical testing of ESR AFOs testing proved to be a necessity and as such, a method for testing an ESR AFO was developed. A study titled, "Quantifying the Spring-Like Properties of Ankle-Foot Orthoses (AFOs)," developed a method to study AFO stiffness in order to determine whether an orthotist could replicate an AFO's performance by fabricating a similar AFO [6]. The study showed that orthotists could reproduce AFO stiffness by using the following testing setup:

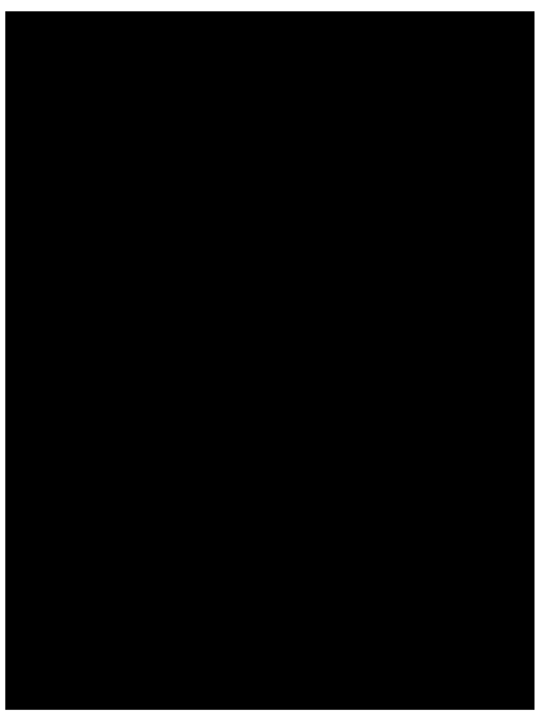

Figure 21. Testing setup used to measure AFO stiffness [6]

The testing system enabled deformation in the sagittal plane and was measured using a motion capture setup [6]. This served as the basis for the team's stiffness testing rig design, with a few notable differences which will be discussed in the detailed design of the stiffness testing rig.

An alternative considered for stiffness testing and prediction was an instrumented AFO, or *i*AFO [7]. This has the ability to both measure and modify the effects of AFO strut stiffness on a patient without numerical prediction. As shown in Figure 22, a diagnostic AFO can be equipped with any number of devices to measure AFO and patient performance, while also providing a means to adjust stiffness by changing parallel springs.

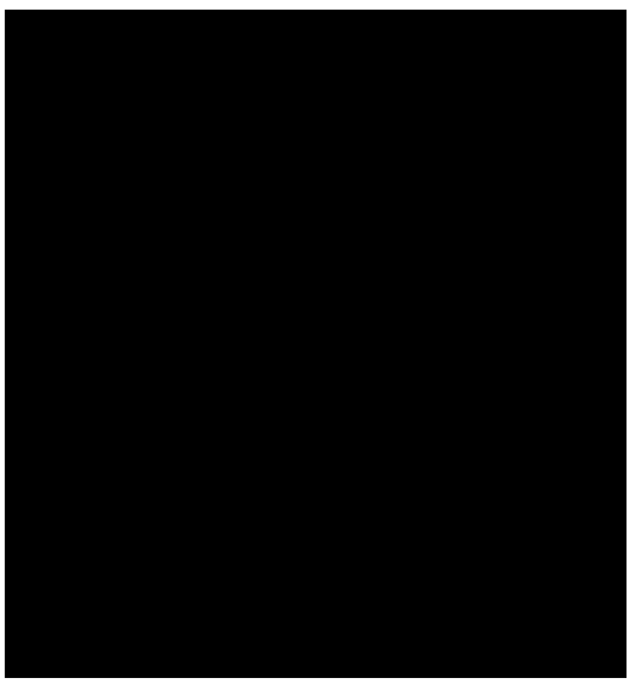

Figure 22. Instrumented AFO for patient study [7]

The metrics measured by this *i*AFO include the ankle joint angle, orthotic torque, planter/interface pressures, EMG, lower-limb orientation and gait states [7].

Another approach to solving for ESR AFO stiffness is to numerically predict or solve the properties of the strut. A study by the University of Oklahoma took this approach by performing Finite Element Analysis (FEA) to determine the stiffness and factor of safety for specific ESR AFO input forces [8]. The result of the study is a patient data-based guideline that has the ability to predict ESR AFO geometry and stiffness and potentially remove the trial-and-error portion of ESR AFO production. While numerical methods were not used in the final designs, this study gave a useful framework for predicting required patient ESR AFO stiffness from a set of patient inputs.

Appendix E AFO Stiffness Testing Device

The preliminary drawings and bill of materials are presented below.

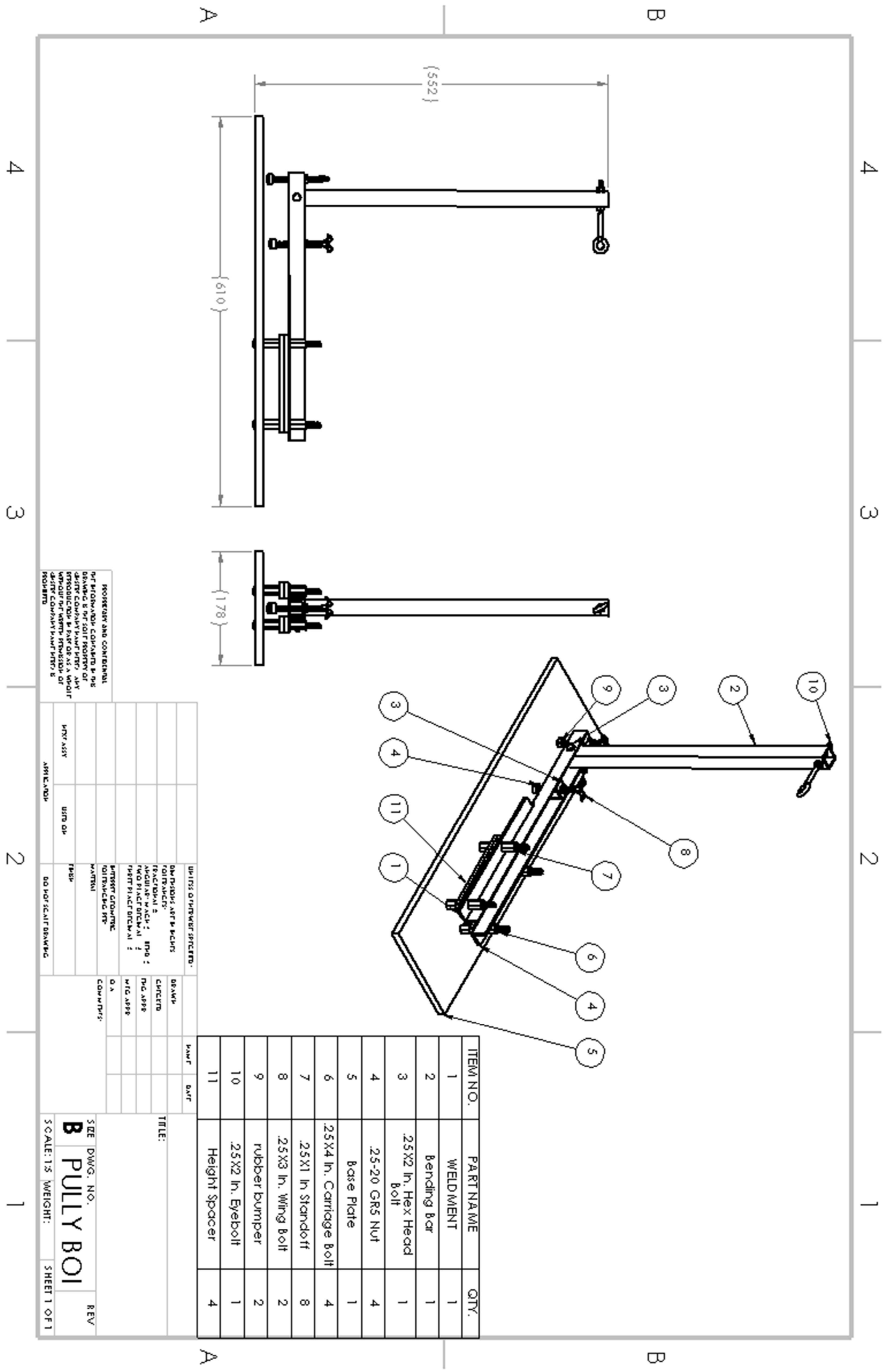

Figure 23. Full assembly drawing of stiffness testing device

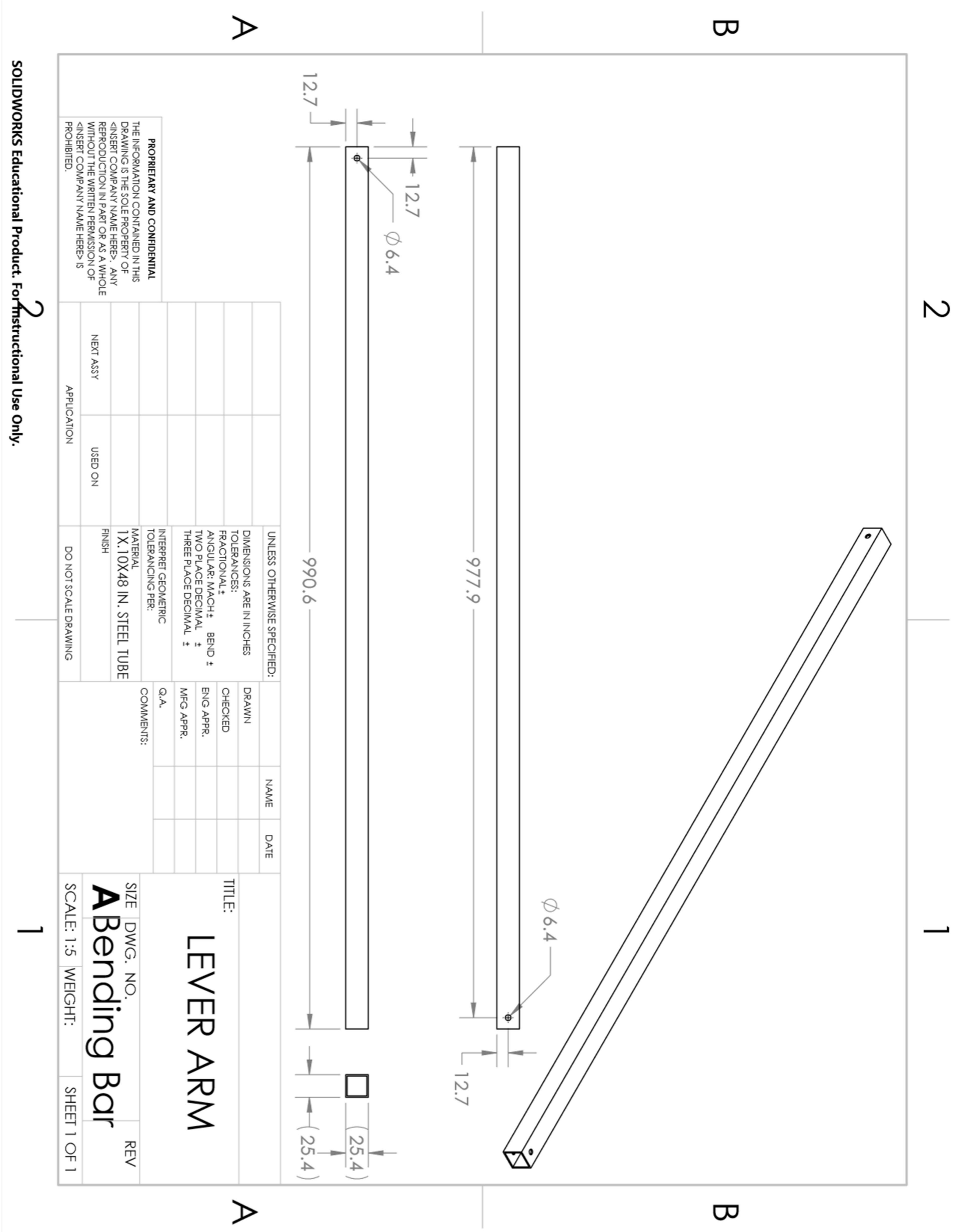

Figure 24. Lever arm drawing

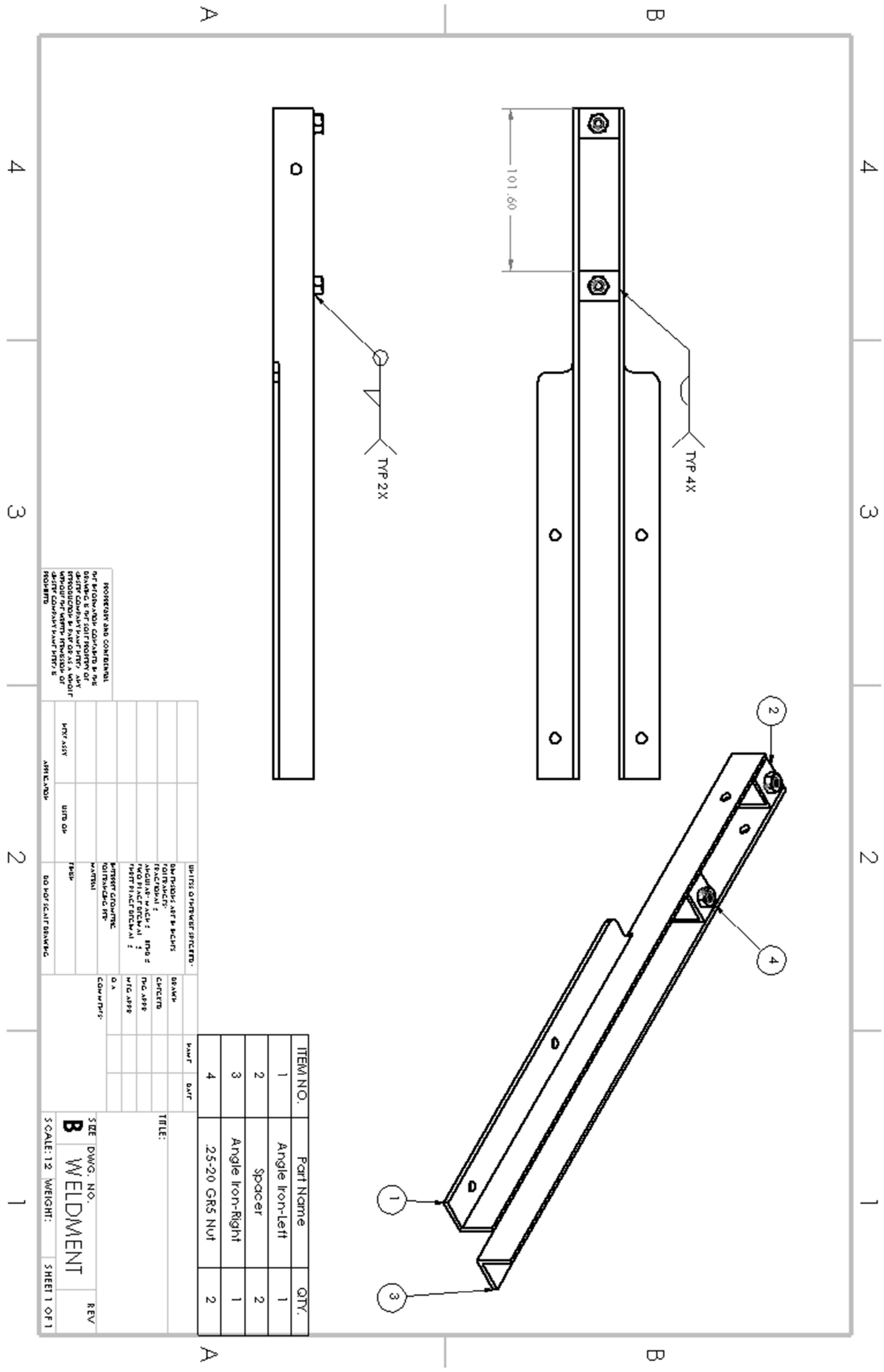

Figure 25. Horizontal weldment drawing

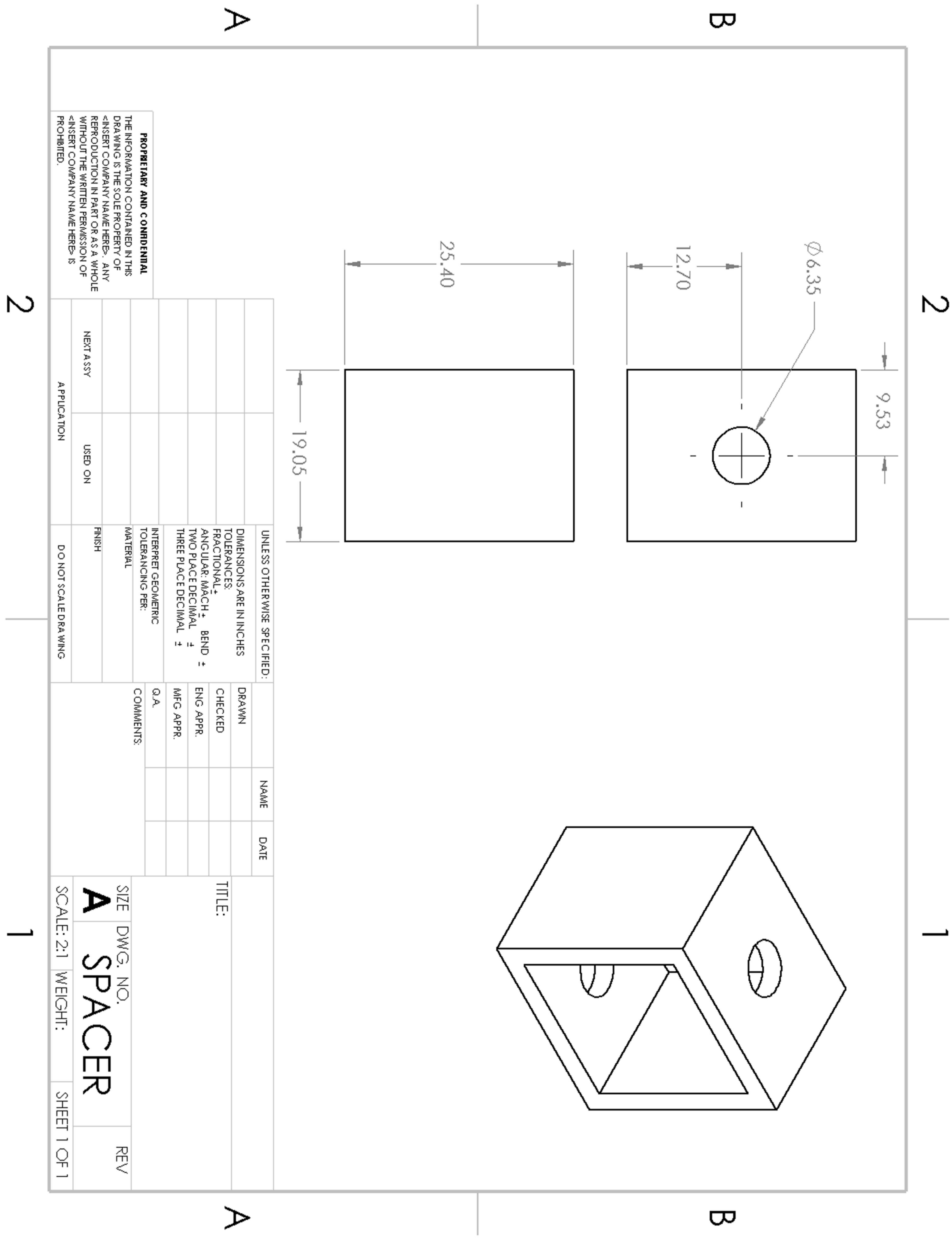

Figure 26: Spacer bar drawing

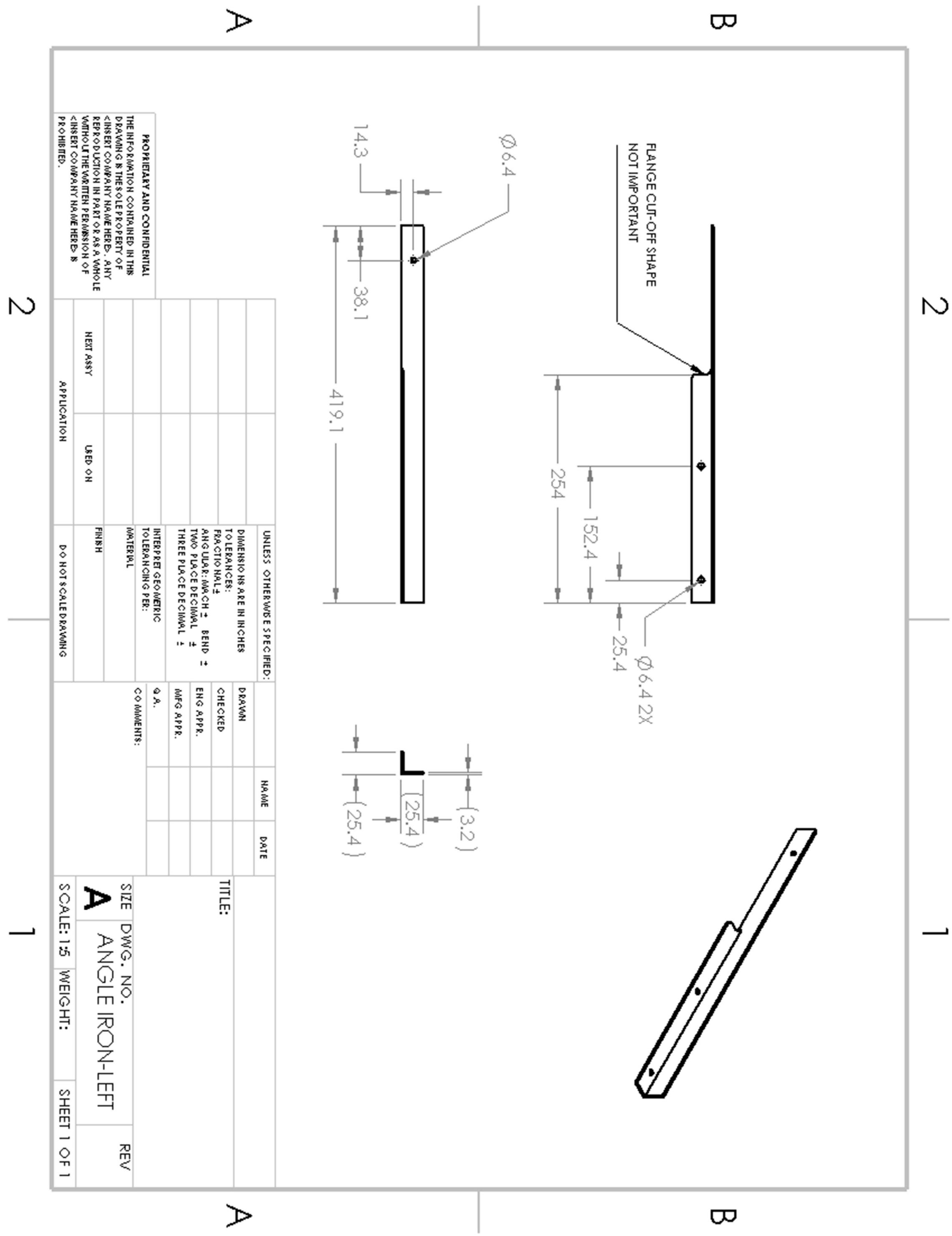

Figure 27: Drawing of left angle iron

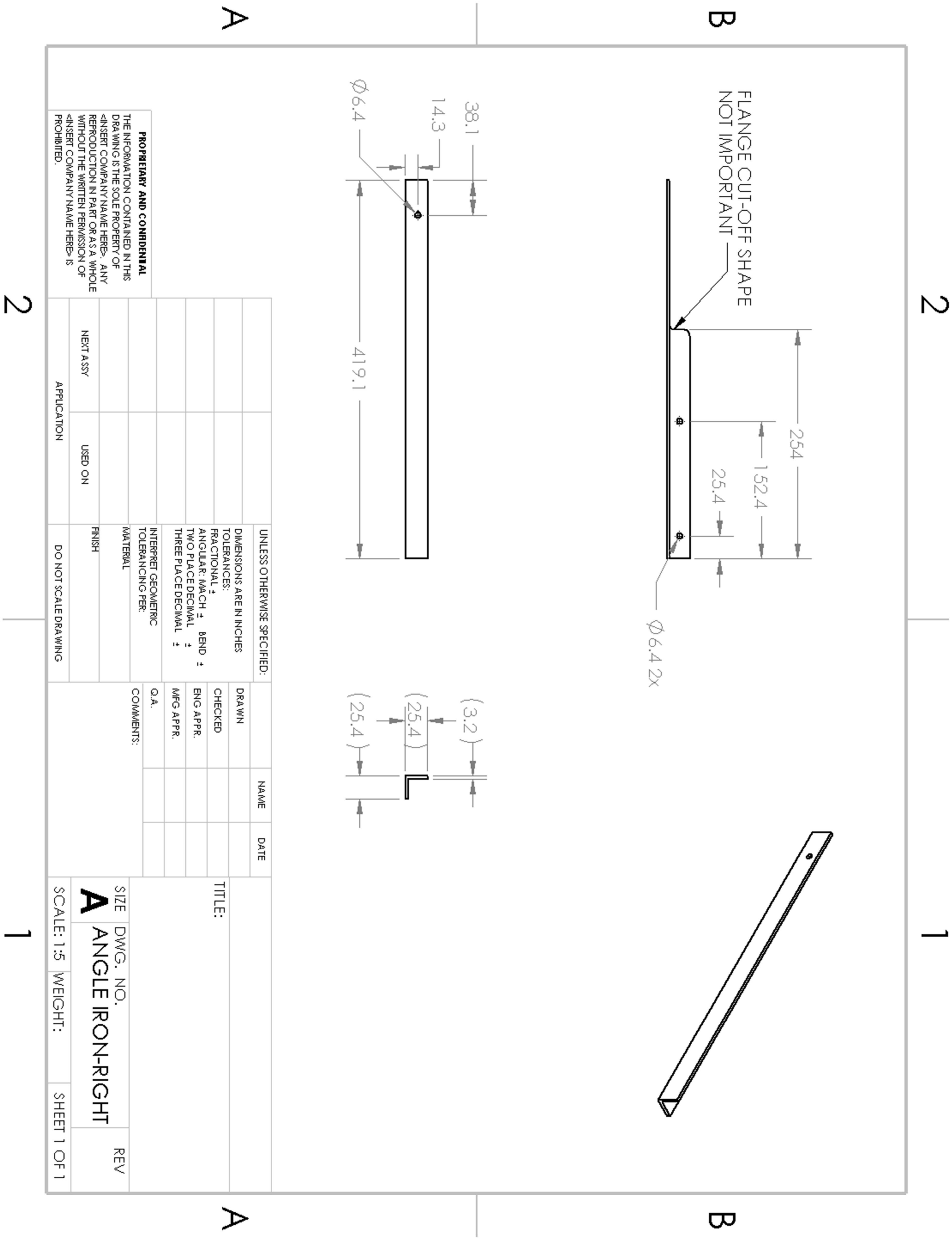

Figure 28: Drawing of right angle iron

The bill of materials required for manufacture is presented below in TABLE XI.

TABLE XI. BILL OF MATERIALS FOR STIFFNESS TESTING RIG ASSEMBLY

Description	Supplier	Supplier Part No.	Quantity	Price ($CAD)
3″ Corner Brace	Home Depot	1000773648	2	3.30
4″ Mending Plate	Home Depot	1000773682	2	1.44
1″X.100″X48″ Square Steel Tube	Home Depot	1000126767	2	23.98
¼″x2″ hex head bolt	Home Depot	1000132277	4	0.84
¼″x1″ hex head bolt	Home Depot	1000122451	4	0.21
¼″X4″ GR2 Carriage Bolt	Home Depot	1000133493	1	0.66
¼″X4″ zinc eye bolt	Home Depot	1000769927	1	0.51
¼″ Nut Nylock	Home Depot	1000122477	8	0.19
Polycast magnetic protractor (or equivalent)	Home Depot	1000812523	1	13.77
¾″x24″x24″ ply (or equivalent)	Home Depot	1000132269	1	26.96
Luggage Scale	Canadian Tire	#076-2874-8	1	13.99

Total: $119.05

Appendix F Neural Network Training Data

Num	Height (cm)	Weight (lbs)	FootLength (cm)	FibulaHeight (cm)	ReqdStiffness (Nm/deg)
1	99	51.1302	19.92826	21.50015	0.327226
2	172	154.3349	19.01141	40.86981	0.712407
3	156	126.9569	28.59697	32.07936	0.883767
4	165	142.0283	22.85968	44.17997	0.668859
5	170	150.7665	30.22183	39.04085	0.909018
6	175	159.7656	24.43345	36.68921	0.889954
7	167	145.4923	20.70892	35.66316	0.753973
8	168	147.24	31.69003	44.52405	0.907843
9	147	112.7306	21.57288	28.82496	0.739881
10	145	109.684	21.43753	38.7172	0.427673
11	92	44.15529	10.23567	14.18888	0.234732
12	140	102.25	18.86411	27.46116	0.439801
13	122	77.64738	15.3007	27.99147	0.390865
14	95	47.08194	16.21835	21.5487	0.238389
15	161	135.2256	26.76807	41.38781	0.728355
16	162	136.9106	27.78531	41.67932	0.79513
17	105	57.51561	14.463	28.84829	0.158848
18	109	61.98122	20.76672	22.86746	0.319415
19	142	105.1923	24.03961	32.85446	0.569466
20	131	89.52611	22.58234	35.1295	0.503897
21	170	150.7665	30.20886	25.71383	1.446301
22	110	63.12371	23.53083	23.93503	0.315215
23	114	67.79799	27.4837	23.43769	0.554277
24	141	103.7159	25.19637	39.87313	0.602412
25	161	135.2256	32.77933	40.94891	0.939818
26	171	152.5455	19.04829	34.94592	0.71843
27	105	57.51561	23.05792	21.65845	0.484108
28	130	88.16452	25.06026	22.59389	0.583932
29	151	118.9491	18.88298	41.18726	0.380312
30	170	150.7665	31.41352	39.57459	1.048965

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