University of Manitoba

Process Improvement for Ankle Foot Orthoses Production

Rehabilitation Center for Children

Final Design Report

MECH4860 Engineering Design

Group 12

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Executive Summary

The goal of this project is to provide a solution to improve the fabrication process of ankle-foot orthoses (AFOs) for the Rehabilitation Center for Children (RCC) Orthotic Department. The client's needs were identified and categorized by the team, and used to create a list of objectives. The recommended process improvement strategy is designed to decrease AFO lead time while increasing productivity and streamlining workflow for the Orthotic Department staff. As productivity increases, the production capacity of AFOs increases accordingly.

The process improvement strategy was generated by using a two-phase system. The first phase investigated high-level operations management strategies. The strategies selected were then used to develop the second phase of methods directly applicable to RCC's needs. These proposed concepts improve AFO production and provide a mechanism for maintaining results of the plan.

The engineered process improvement plan is divided into five concepts, which when used in conjunction will provide the client with expected optimal results. The first concept of the plan is the immediate scanning and modifying the cast after the patient's initial consultation, which eliminates the non-value added wait time currently in the process. The second concept of revising the foam mold cleanup process removes the need for exchanging the molds between the clinicians and technicians by marking up the fiberglass cast with the pad and trim lines. The third concept is the addition of mock pads during the initial casting. This process simplifies the modification of the 3D model by incorporating relief areas during the casting process through the addition of mock pads under the fiberglass cast. The fourth concept of process standardization utilizes pre-cut standard sized pads and cork wedges to pulled off the shelf during AFO production rather that custom-making these items. The fifth recommendation includes all continuous improvement strategies to maintain and sustain these changes and monitor their results. The continuous improvement strategies proposed include organizational involvement strategies, areas where cross-training could improve productivity, and ways to deal with organizational inertia.

The proposed improvement strategy provides methods that will eliminate non-value added time, while streamlining the fabrication process to improve the productivity level in the Orthotics Department at RCC. The recommended improvement plan is projected to increase capacity to 162 AFO devices per month, which is an improvement on RCC's current 115 AFO devices per month. The improved fabrication process has a clinician-to-technician ration of 1:1, while the current fabrication process has a ratio of 3:2. The new ratio matches RCC's current staff levels. The re-engineered process has a minimum lead time of 3 days with an expected lead time of 2 weeks, which is an improvement from the current AFO production lead time of 6 weeks. The design exceeds the optimal metrics and meets all objectives.

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1.0 Introduction

This is the final design report (FDR) for this project, the purpose of which is to provide recommendations to the Rehabilitation Center for Children (RCC) on improvements to the production process of ankle-foot orthoses (AFOs). Detailed information regarding the purpose and definition of the project can be found in the Project Definition Report (PDR), as well as details related to project management strategies used. The concept development methodology is explained in the Concept Definition Report (CDR). This report summarizes both the project definition and the concepts generated. It contains the detailed design of each of the final process changes recommended to RCC, considering both risks and benefits, as well as suggested implementation procedures.

1.1. Background

RCC is a specialized medical clinic that aids children and youth with developmental and physical disabilities. The Rehabilitation Engineering Orthotic and Prosthetic department creates custom orthotic devices specific to their patient's needs. Their orthotics division currently operates with three certified orthotists and three orthotic technicians. The most frequent device fabricated in the orthotics division is the ankle-foot orthosis (AFO), which account for almost all output.

Orthotics are exoskeletal devices designed to externally support a joint [1]. AFOs help in the case of weakness of the ankle [2], and are commonly prescribed to treat many common conditions, including plantar fasciitis, shin splints, iliotibial band tendinitis [3], degenerative and posttraumatic arthritis [4], muscular dystrophy [5], cerebral palsy, equinus [6], and so on.

AFOs are generally constructed out of thermoplastic or composite material, and act as a brace to support the ankle at a fixed angle. Built-in flexibility to the AFO provides some mobility, and some devices may be articulated to allow for a wider range of motion while still preventing hyperextension. Figure 1 illustrates solid and articulated AFOs. Articulated AFOs are more commonly prescribed at RCC than solid ones [7]. Demand at RCC for AFOs has been increasing steadily over the last few years, and current production levels are approximately 115 units per month [7].

a) Articulated (used with permission) [8] b) Solid (used with permission) [9]

Figure 1: Articulated AFO versus solid AFO

Recently AFO production has been commercialized and the role of the clinician has reduced [3]. However, due to the widely varying needs of children requiring AFOs, many cases still require the direct input of a certified orthotist, and RCC specializes in these cases [7]. Traditional manufacturing techniques are all rather similar, and involve taking a cast of the patient's leg, manipulating the 3D geometry in some way, and then vacuum forming the shell of the device. RCC currently uses a method that follows this general structure, which is reviewed in detail in Section 1.4.

Additive manufacturing has recently been applied to AFO production. Fused deposition modelling (FDM), selective laser sintering (SLS), and stereolithography (SLA) have all been applied to this field, with good clinical results and promising economics for moving towards production [10]. Additive manufacturing allows for a high degree of customization. However, these technologies are still being researched, and are not yet used for full-scale production. Instead of researching how these new technologies could improve production, this project focuses on how the existing process could be improved with minimal changes to the AFO design used by RCC.

The current AFO design requested by RCC to be taken as typical of RCC production for this project [7] has a unilateral articulating joint with a planarflexion (PF) stop, and the shell is made from 5/32" polypropylene (PP) [11]. Further details are listed below. The numbers refer to labels in Figure 2.

1) Free motion Tamarack joints to permit articulation
2) Otto Bock snap stop plantarflexion bumper to prevent hyperextension
3) Internal medial ankle control strap (Optek and Volera) with premade 1” strap
4) Internal molded pad for lateral malleolus (1/8” P-cell)
5) ¼” cork heel wedge to turn the toes downward
6) 1.5” premade tibial strap to secure the device to the leg
7) Transfer paper (pattern), which is chosen by the patient for aesthetics

Figure 2: Representative AFO design details [11]

Another reason this design is a good representative is that it incorporates most of the features provided in products RCC offers, meaning that improvements made to the process for producing this specific model will almost certainly be applicable to simpler models as well. All types are made with the same process and using the same equipment.

1.2. Problem Statement and Project Definition

Currently the process for producing AFOs at RCC takes up to six weeks to complete [7]. In addition to the patient having to wait for a long time before receiving their device, within RCC staff members report high variability in workload due to delays further upstream in the process [12]. The purpose of this project is to ameliorate these issues with the AFO production process.

The objectives of the project were determined based on communication with the client [7]. The team assigned a priority rank to each to provide focus for the project, with 3 being a high priority and 1 being a low priority. The objectives are listed in Table I.

TABLE I: PROJECT OBJECTIVES

ID	Objectives	Importance (1-3)
1	Decrease AFO lead time	3
2	Increase productivity of Orthotics Department	2
3	Stabilize workflow for clinicians and technicians	2
4	Improve use of human resources in the Orthotics Department	3
5	Increase production capacity of AFOs	1
6	Design for ease of implementation	2

The client's needs for the project were identified and categorized in Table II, and are closely tied to the objectives. Each need was given a rank, 3 for high priority, 2 for medium priority, and 1 for low priority. Though briefly explained below, these needs were thoroughly explained in the PDR, and the relevant passage is included in Appendix A. No changes were made to the client needs during the course of the project.

TABLE II: CLIENT NEEDS FOR THE AFO PRODUCTION PROCESS

ID	Need	Rank
	Procedural Needs	
1	The production process creates an AFO that is satisfactory to RCC standards	2
1a	The production process obtains a geometrical representation of the patient's anatomy	2
1b	The production process generates an AFO device based on that geometry	2
1c	The production process modifies the device until it passes clinician's assessment	2
	Suitability Needs	
2	The production process is easy to follow and implement	2
3	The production process accommodates walk-in and sudden clinic time	1
	Improvement Needs	
4	The production process facilitates a reduction to the lead time of an AFO	3
5	The production process facilitates improvement of the uses of RCC's human resources, specifically approaching an optimal clinician to technician ratio	3
6	The production process maximizes capacity	2
7	The production process reduces the work-in-progress inventory of AFOs	1

Procedural needs relate to the overall steps of AFO production, the goals of the production process itself. These are listed first, since they are minimum requirements. Suitability needs describe the need for the process to be straightforward and streamlined within RCC's existing setup. Improvement needs are the primary focus of the project, highlighted by the higher priority rankings. They should characterize the process after the suggested modifications as compared to the existing process. The most important needs are the reduction in lead time and the increase in efficiency of human resource utilization. This will

necessarily reduce work-in-progress (WIP) inventory, but that was not the most pressing concern for the client. Capacity is also a factor, as demand for RCC's customized services is steadily increasing [7].

The client's constraints are similarly reiterated in Table III. While these are briefly described here, a more detailed explanation of these constraints is included from the PDR in Appendix A.

TABLE III: CONSTRAINTS IMPOSED BY RCC

ID	Constraints
	Organizational
1	The number of clinicians or technicians cannot be reduced
2	The recommendation cannot reduce the number of AFOs produced
3	The clinician will maintain existing meeting slots with patient
4	The process will occur within RCC's facility
	Resources
5	The negative will continue to be manufactured using the fiberglass method
6	The modeling software and how it is used cannot be changed
7	The positive will continue to be manufactured with CNC carver
	Design
8	Thermoplastics are to remain the main material of an AFO
9	Major elements of AFO design are fixed
	Timeline
10	The project deadline is December 5, 2019

Organizational constraints are imposed by RCC policies and union regulations. There are few governmental regulations that apply to the suggested changes, so they were not included in this list [13]. Resource constraints refer to elements of the existing process that would require too much time, money, and/or research to change. The AFO design should not be changed, although small changes to the shape and size of various components are allowed if they do not impact the functionality of the device and are approved by the orthotists.

Likewise, the team identified several metrics used to evaluate success in the project. These are shown in Table IV. These metrics were combined with the needs in a House of Quality (HOQ) to generate priority rankings for each metric. A completed HOQ is included in Appendix B (see also Section 2.3).

TABLE IV: TARGET SPECIFICATIONS & METRICS FOR IMPROVEMENT SUGGESTIONS

ID	Metric	Current	Marginal	Optimal
1	Turnaround time (initial consultation – product delivery)	6 weeks	3-4 weeks	2 weeks
2	Average work-in-progress inventory	150 units	120 units	90 units
3	Capacity / month	115	120	130
4	Marginal clinician labour [minutes / AFO]	189	156	135
5	Marginal technician labour [minutes / AFO]	119	90	75
6	Rejections at first fitting appointment [%]	1%	1-0.5%	0.5-0.02%

1.3. Project Management Outline

The team developed a project management plan that was included in the PDR, which was adhered to throughout the generation of the CDR and FDR. The project management plan consists of scope, schedule, resource, stakeholder, communication, and risk management plans, as well as a work breakdown structure (WBS) and networked Gantt Chart. These plans can be viewed in detail in Appendix C. The management plan proved effective and tasks remained on schedule. As individual concepts were expanded, and scope was further realized the scope management plan guided in the inclusion of additional tasks that needed to be completed. These tasks were then able to be scheduled into the WBS and inserted into the networked Gantt Chart. Additions to the scope typically came in the form of broadening of existing tasks. For example, the process, “Generate Concepts” was created with the initial Gantt chart and was further broken down into research to find concepts derived from proven Lean methods and further broken into categories which could then be adapted to suit the desired area of application. The expansion of scope in this way relied heavily on the scope management plan and was crucial in order to determine the final concepts to be used in this report.

The networked Gantt Chart has been updated throughout the duration of the CDR and FDR. The original Gantt Chart has been added, shown in Figure 3; as well as the updated Gantt Chart, shown in Figure 4 with all tasks updated.

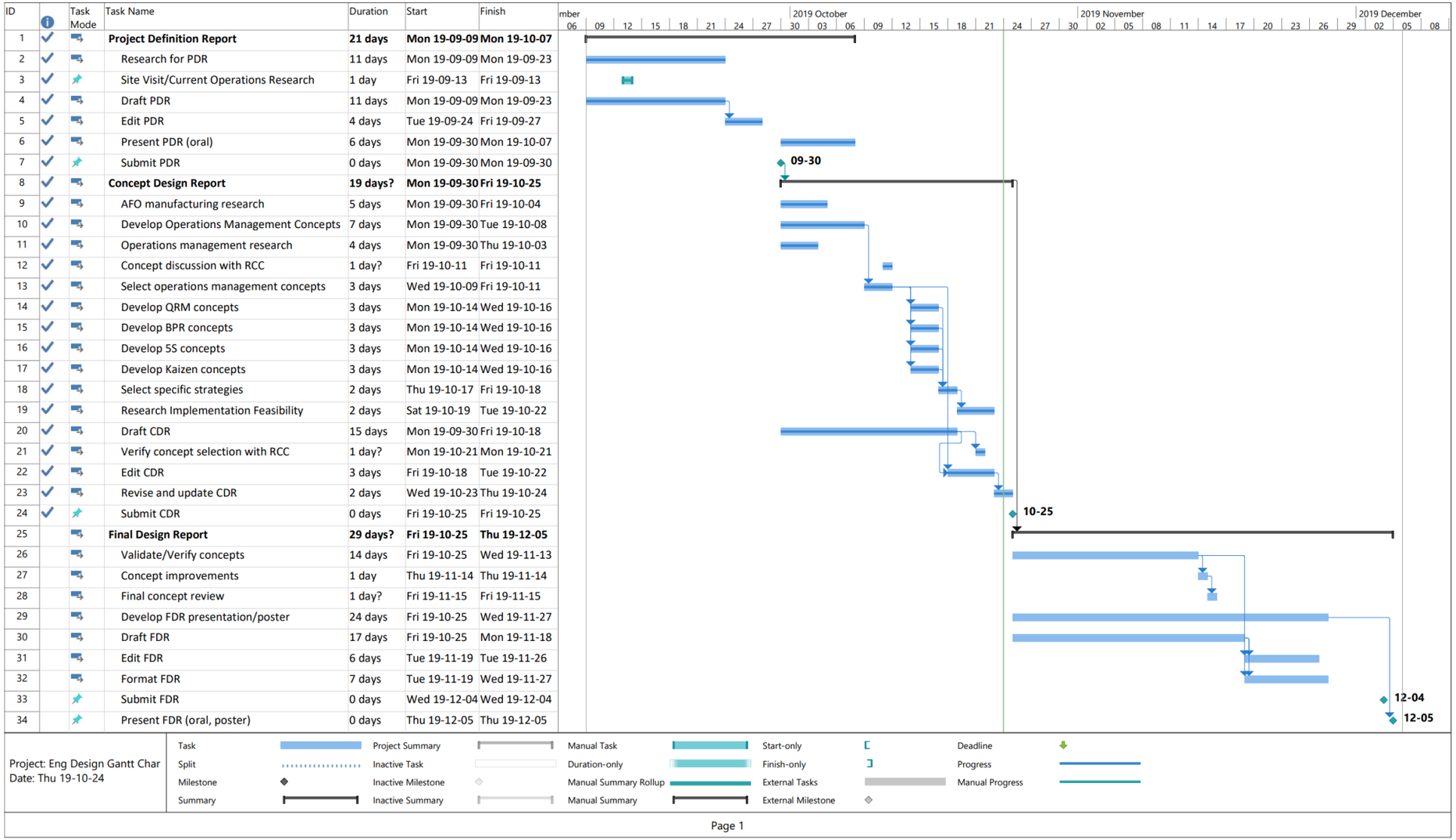


Figure 3: Gantt Chart as of October 24, 2019

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors
1		**Project Definition Report**	**21 days**	**Mon 19-09-09**	**Mon 19-10-07**	
2		Research for PDR	11 days	Mon 19-09-09	Mon 19-09-23	
3		Site Visit/Current Operations Research	1 day	Fri 19-09-13	Fri 19-09-13	
4		Draft PDR	11 days	Mon 19-09-09	Mon 19-09-23	
5		Edit PDR	4 days	Tue 19-09-24	Fri 19-09-27	4
6		Present PDR (oral)	6 days	Mon 19-09-30	Mon 19-10-07	
7		Submit PDR	0 days	Mon 19-09-30	Mon 19-09-30	
8		**Concept Design Report**	**19 days?**	**Mon 19-09-30**	**Thu 19-10-24**	**7**
9		AFO manufacturing research	5 days	Mon 19-09-30	Fri 19-10-04	
10		Develop Operations Management Concepts	7 days	Mon 19-09-30	Tue 19-10-08	
11		Operations management research	4 days	Mon 19-09-30	Thu 19-10-03	
12		Concept discussion with RCC	1 day?	Fri 19-10-11	Fri 19-10-11	
13		Select operations management concepts	3 days	Wed 19-10-09	Fri 19-10-11	10
14		Develop QRM concepts	3 days	Mon 19-10-14	Wed 19-10-16	13
15		Develop BPR concepts	3 days	Mon 19-10-14	Wed 19-10-16	13
16		Develop 5S concepts	3 days	Mon 19-10-14	Wed 19-10-16	13
17		Develop Kaizen concepts	3 days	Mon 19-10-14	Wed 19-10-16	13
18		Select specific strategies	2 days	Thu 19-10-17	Fri 19-10-18	14,15,16,17
19		Research Implementation Feasibility	2 days	Sat 19-10-19	Tue 19-10-22	18
20		Draft CDR	15 days	Mon 19-09-30	Fri 19-10-18	
21		Verify concept selection with RCC	1 day?	Mon 19-10-21	Mon 19-10-21	20
22		Edit CDR	3 days	Fri 19-10-18	Tue 19-10-22	20,13
23		Revise and update CDR	2 days	Wed 19-10-23	Thu 19-10-24	22
24		Submit CDR	0 days	Fri 19-10-25	Fri 19-10-25	
25		**Final Design Report**	**29 days**	**Fri 19-10-25**	**Thu 19-12-05**	**8**
26		Determine final concepts	1 day	Wed 19-10-30	Wed 19-10-30	24
27		Draft FDR	16 days	Thu 19-10-31	Thu 19-11-21	26
28		Validate/Verify concepts	14 days	Fri 19-10-25	Wed 19-11-13	
29		Concept improvements & Expansion	2 days	Thu 19-11-14	Fri 19-11-15	28
30		Draft concepts & Implementation plan	6 days	Thu 19-11-14	Thu 19-11-21	28
31		Final concept review	3 days	Mon 19-11-18	Wed 19-11-20	29
32		Draft poster layout	2 days	Fri 19-11-22	Mon 19-11-25	27
33		Develop FDR presentation/poster	7 days	Tue 19-11-26	Wed 19-12-04	32
34		Edit FDR	6 days	Fri 19-11-22	Fri 19-11-29	27,28
35		Format FDR	7 days	Fri 19-11-22	Mon 19-12-02	27,28
36		Submit FDR	0 days	Wed 19-12-04	Wed 19-12-04	
37		Present FDR (oral, poster)	0 days	Thu 19-12-05	Thu 19-12-05	33

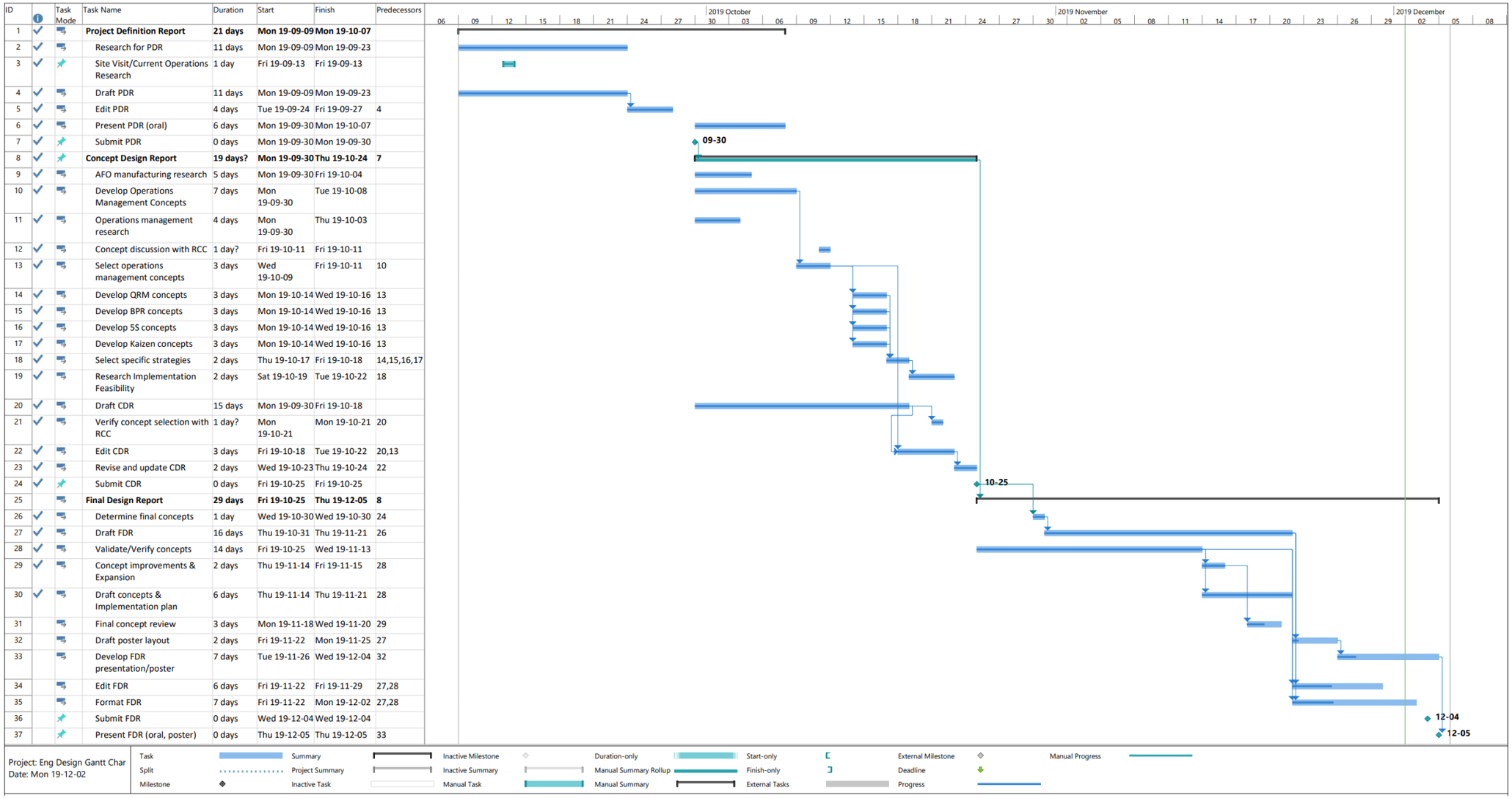


Figure 4: Updated Gantt Chart as of December 4, 2019

1.4. Existing AFO Production Process at RCC

Various aspects of the exiting AFO production process were researched. A broad overview of the process is presented, followed by a detailed breakdown and description of each step. RCC's facility layout is shown, with the flow of AFOs through the facility. Current statistics and scheduling are also shown. This information is used as the baseline for the generation and development of improvement concepts.

1.4.1. Overview of AFO Production

The AFO production process was divided into ten high-level steps, which are shown in Figure 5. Green blocks are performed by the clinician, and purple blocks are performed by the technician. The time required for each step is indicated, as well as the waiting period between each step if there is usually a waiting period.

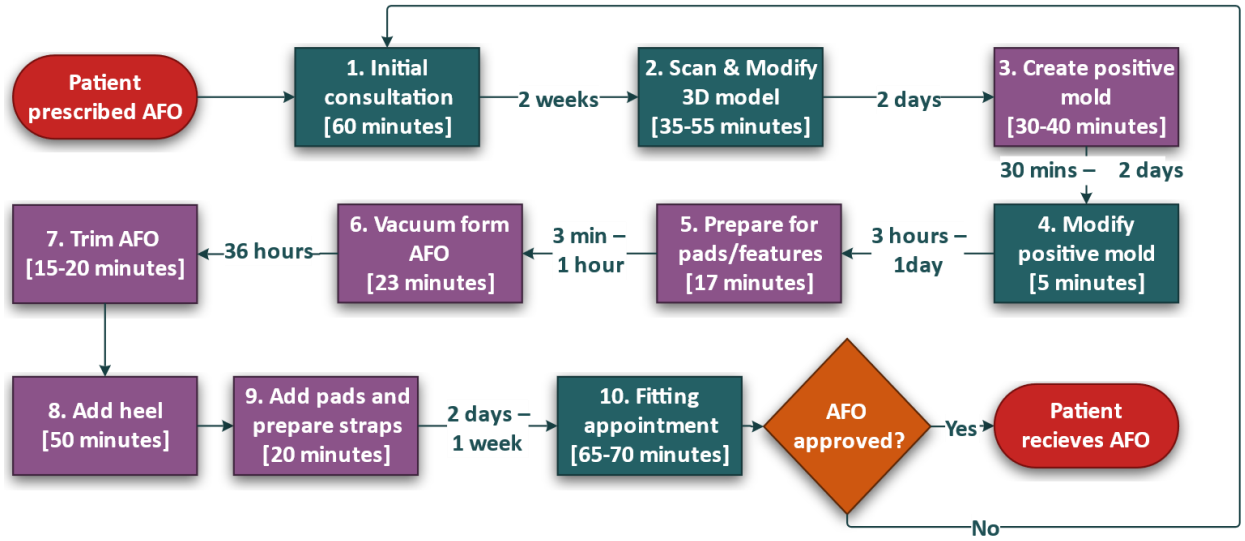


Figure 5: Flowchart of existing AFO production process, with data from [14]

More detailed steps are described in Table V, with the step number corresponding to each block in Figure 5 and green and purple again referring to clinician work and technician work respectively. Grey areas indicate steps in the process where the device must wait while plastic cools or while a machine is running, highlighting waiting periods seen in Figure 5 that cannot be eliminated without impacting the final product. For example, the device must cool and set after Step 6, or the plastic will not retain its shape when it is removed from the mold [7]. This is referred to as "zero resource time." Each major step is then described with explanations and figures.

TABLE V: DETAILED STEPS OF AFO PRODUCTION PROCESS [14]

Step	Task	Minutes		Step	Task	Minutes
1	Assess patient	30			Plastic under vacuum cool down	24 hours
	Cast patient leg	15			Plastic out of vacuum rest	Overnight
	Charting, work order, billing	15		7	Cut plastic	5
2	Prep cast for scanning	2			Grind trimlines	10-15
	Scan cast	10		8	Cut and prepare cork for heel wedge	3
	Import scan to CANFIT	2			Glue drying	20
	Modify positive model in CANFIT	20-40			Heat cork	5
3	Digitally set up scan on block (in CANFIT)	5			Mold cork and wrap with tensor	1
	Set up carver	5			Cool cork	15
	Carver carves positive model from block	20-30			Grind heel wedge	5
4	Clean up carved cast (smooth, draw trimlines and pads)	5		9	Cut and finish internal control pad	5
5	Cut out material for pads	5			Glue lateral malleolus pad	10
	Mold internal control pad	3			Select and trim straps/pads	3
	Make dummy pads for control strap and lateral malleolus pad, attach to cast	6			Clean device	2
	Align and attach dummy joints	2		10	Initial trial of device on patient (mark trimlines and strap placement)	10
	Align and attach PF stop dummy	1			Grind final trimlines	15-20
6	Measure and cut plastic	5			Rivet straps	5
	Measure and cut transfer paper	2			Second trial on patient	5
	Set up cast in vacuum station	5			Static alignment check	5
	Heat plastic in oven	8			Dynamic alignment check	10
	Apply transfer paper to heated plastic	1			Adjustments if needed	10
	Additional heating of plastic	1			Patient education	5
	Mold plastic to cast	1				

1.4.2. Description of Each Step

The process starts with an initial consultation with RCC, in which the clinician interacts directly with the patient. A fiberglass cast of the patient's leg is taken, as shown in Figure 6. The fiberglass cast is then scanned into a 3D model. The model is modified to remove the thickness of the fiberglass, correct the angle of the ankle joint, and to add reliefs for pads. This is all done using the CANFIT software package. The CANFIT user interface is shown in Figure 7.

Figure 6: Fiberglass casting during initial consultation

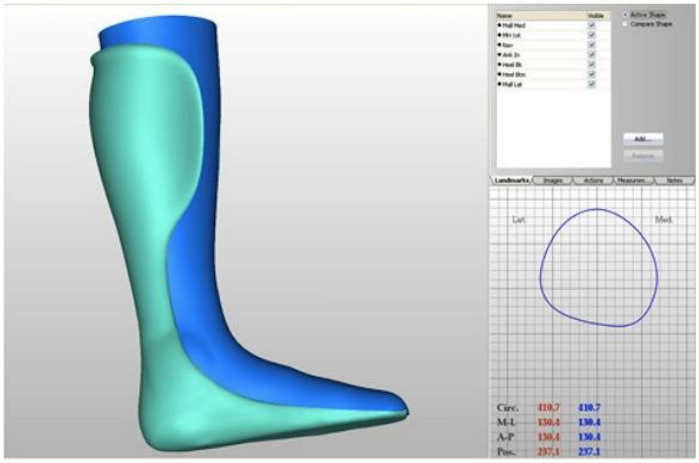


Figure 7: 3D model in CANFIT (used with permission) [15]

The technician then sets up the CNC carver to create a mold out of foam. This mold must be finished by hand, which can be done either by the clinician or the technician, and then marked on by the clinician to indicate the position of pads and trimlines. Foam molds before and after these steps are illustrated in Figure 8.

Figure 8: Foam models before (L) and after (R) the clinician has trimmed and marked them.

Once the mold is back with the technician, he/she prepares dummy pads for the device. A dummy planarflexion bumper and dummy joints are also attached to the foam model, to ensure that the shell has sufficient clearance for all these components. The technician then heats a sheet of 5/32" polypropylene. The transfer paper is laid over the heated plastic to transfer the decorative pattern on the sheet. After a short reheat, the plastic sheet is pulled over the mold using a vacuum. This creates the main shell of the AFO. The vacuum forming setup is shown in Figure 9. The part must be left under suction for several hours, after which the suction may be switched off, but the parts must stay on the setup for another 24 hours before they are stable enough to remove. They must then be left to cool further overnight. Insufficient cooling or cooling at an improper rate can result in the device springing too far open when it is removed from the mold, making it not fit snugly on the patient.

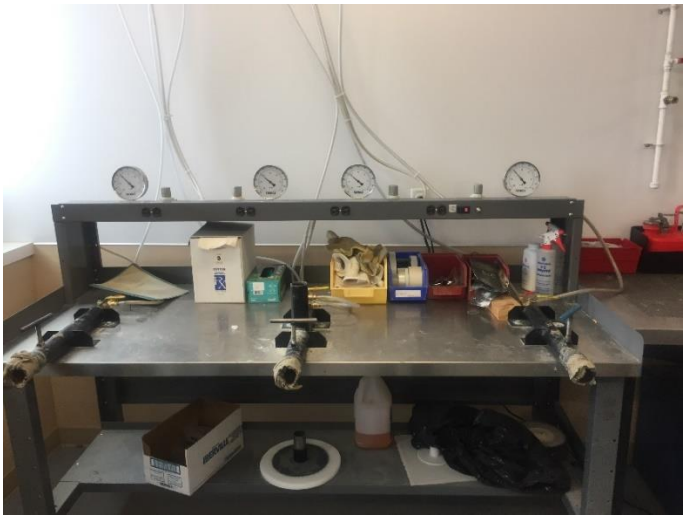


Figure 9: Vacuum forming station

Once excess material from the front of the AFO has been trimmed along the trimlines demarcated earlier by the clinician, a cork heel is added, as shown in Figure 10. This is done by gluing a cork block to the bottom of the device, heating it, molding it, wrapping it with a tensor, and allowing it to cool. The cork must then be trimmed and ground to give a smooth, even finish. The final pads from the proper material are cut, molded, and fastened to the device. The straps are prepared by the technician but are added by the clinician during the fitting appointment, typically after a trial run on the patient to determine where they should be placed.

Figure 10: AFO ready for fitting appointment

The final step in the AFO production process is the fitting appointment, during which the patient returns to RCC and meets again with the clinician. These appointments are currently scheduled six weeks after the initial consultation. The fitting appointment starts with an initial trial, during which the clinician observes where final trimlines and straps should be placed. The clinician takes the device to the workshop to make these changes, and the patient must wait while the clinician completes these final steps. The second trial includes a more detailed alignment check, and the patient's leg is inspected after walking in the device for several minutes to see if there is any abrasion or impingement on the patient's skin. If the device passes this inspection, the device is dispensed, and the process is complete.

1.4.3. Orthotics Production Facility Layout

The layout of the part of RCC's facility dedicated to AFOs is shown in Figure 11. Along with it are colored arrows that indicate the flow of the device, from the patient coming in for the initial appointment until the device leaves the facility. The places indicated by the heads of each colored arrow are listed in Table VI.

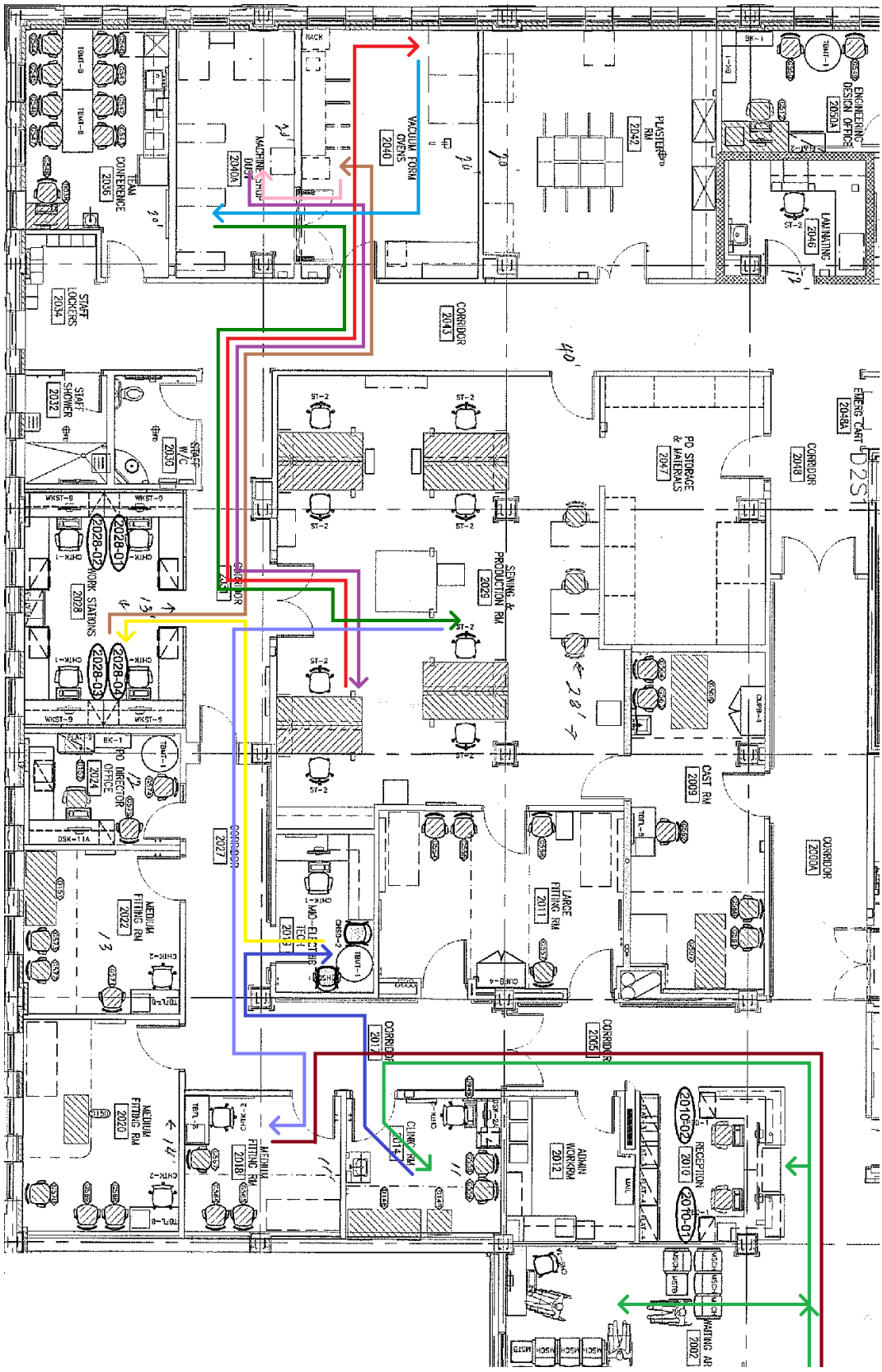
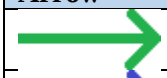
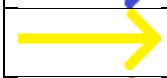
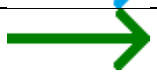
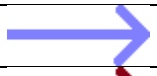
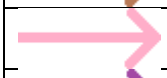


Figure 11: RCC facility layout with flow of product shown (used with permission) [16]

TABLE VI: ARROW COLOR LEGEND FOR FIGURE 11

Arrow	Task		Arrow	Task
	Initial Consultation			Vacuum forming
	Scanning 3D model			Trimming AFO shell
	Modifying model (clinician's computer)			Addition of heel, pads
	Carving			Fitting appointment
	Cleaning up foam model			Device dispensed
	Preparing foam model for vacuum forming			

1.4.4. Current Statistics

The process requires 189 minutes of clinician time and 119 minutes of technician time per AFO (see Table V). Although AFOs are not the only product made by the Orthotics division, technicians can be assumed to spend all their time working on AFOs [12]. Clinicians maintain a weekly schedule, which includes two half-days of on-call clinic work, as shown in Table VII.

TABLE VII: CURRENT CLINICIAN WEEKLY SCHEDULE [14]

Monday	Tuesday	Wednesday	Thursday	Friday
8am-12pm Seeing patients (2-4)	8am-12pm Seeing patients (2-4)	8am-12pm On-Call Clinic	8am-12pm Modifying Time	8am-12pm Seeing patients (2-4)
12:30-4:30pm Modifying time	12:30-4:30pm On-Call Clinic	12:30-4:30pm Seeing patients (2-4)	12:30-4:30pm Seeing patients (2-4)	12:30-4:30pm Seeing patients (2-4)

On-call clinics involve clinicians visiting two to six patients [17]. These may or may not be related to AFO cases, and potentially result in other types of work for technicians as well. Consequently, work unrelated to AFOs is assumed to be equally shared between clinicians and technicians. As a result, a week of production at RCC is assumed to be 4.5 days.

Based on this assumption, and the time requirements indicated above, the current optimal clinician-to-technician ratio is approximately 3:2 and maximum capacity approximately 130 AFOs/month. Given a current production rate of about 115 AFOs/month [7], RCC is currently operating at 89% capacity.

The standard lead time for AFOs at RCC is currently six weeks. This is determined by the fact that fitting appointments are booked six weeks after the initial consultation. However, the sum of the times in Figure 5 is only at most 23 business days. This indicates that extra time is built in for security, as well as

for unforeseen delays. Additionally, WIP waiting time data presented above was based on estimates, not rigorous statistical process control. For example, upon discussion with the technician regarding the waiting time between creating the mold and the modifying step by the clinician, it was discovered that at times this was much longer than two days [12]. Since the task is very short, the clinician usually waits until a large number are ready, meaning the time block in of 30 mins – 2 days could be an average, not a full range. This and other small variabilities throughout the process require RCC to allow themselves a six-week lead time to make the devices.

2.0 Concept Generation

Concept generation occurred in two phases. First, the team investigated high-level operations management strategies. Once several of the strategies were selected as most applicable to RCC's needs, the team developed concrete ways to implement these in RCC's operations. Discussed at length in the CDR, both levels of selected concepts are summarized here. Then an underlying principle, known as the Response Time Spiral, is explained, which underlines the importance of some of these concepts. Understanding of the Response Time Spiral informed all stages of concept generation.

2.1. Methodology

The first stage of concept generation involved looking into various Lean strategies to determine which would be the most useful to RCC. The second stage was to develop solutions specific to improving the process at RCC using the strategies found in the first stage. Throughout both stages of concept generation, the team used both individual and group brainstorming, as well as other techniques such as 5 Why's, Root Cause Analysis, and Decomposition. The criteria used to evaluate the first set of concepts were ease of implementation, effectiveness, relevance, implementation timeframe, complexity, and required resources. The top four strategies were chosen to use as a starting point for developing concepts specific to RCC.

A Criteria Weighting Matrix (CWM) was used to determine the relative importance of the selection criteria. The team completed the CWM as a group, comparing each criterion and weighting more heavily in favor of the option that the majority voted for. A weighted decision matrix (WDM) was used to compare the first set of concepts, and a house of quality (HOQ) for the second set, since they corresponded more with the customer needs and metrics defined in Section 1.2. For the WDM and the HOQ, each team member filled out the rankings individually, reducing estimation errors. The four values were averaged in the final matrix to calculate the final rankings. Since none of the concepts were mutually exclusive, the top five were selected again to go into further detail and recommend as part of the final design.

2.2. Operations Management Strategy Concepts

The strategies evaluated in the first stage of concept generation are shown and ranked in Table VIII. The concepts considered were Just-In-Time (JIT), Kaizen, 5S, Total Quality Management (TQM), Business Process Reengineering (BPR), Quick Response Manufacturing (QRM), Agile Manufacturing, 3P/Kaikaku, and Supply Chain Management (SCM). These terms have widely recognized definitions in the field, and are excluded from this report, although a brief description of each was included in the CDR.

TABLE VIII: WDM FOR FIRST LEVEL CONCEPT GENERATION

	Selection Criteria	Ease of Implementation	Effectiveness	Relevance	Implementation Timeframe	Complexity	Required Resources		
%	**Weight**	0.24	0.14	0.29	0.05	0.10	0.19	**SCORE**	**RANK**
Concept	**JIT**	3.8	3.5	3.5	3.0	3.0	3.3	3.44	**5**
	Kaizen	4.8	2.3	3.0	3.8	3.8	4.3	3.65	**4**
	5S	4.5	2.8	3.3	4.8	3.5	4.5	3.81	**3**
	TQM	3.0	2.3	2.3	3.0	2.5	2.8	2.58	**9**
	SCM	2.3	3.0	2.8	3.3	3.0	3.8	2.90	**7**
	BPR	3.5	4.0	4.8	3.5	3.0	4.0	3.98	**2**
	QRM	4.3	5.0	5.0	3.8	3.3	3.8	4.36	**1**
	Agile	2.5	3.5	4.0	3.0	2.5	3.8	3.33	**6**
	3P	2.0	4.5	3.0	1.8	2.0	2.3	2.68	**8**

Using the selection methods outlined in Section 2.1, each strategy's applicability to the project was ranked and the top four strategies were chosen to move forward with: QRM, BPR, 5S, and Kaizen. QRM was the strategy with the highest ranking, due to its focus on improving responsiveness and reducing lead time. BPR followed, as it is the application of QRM principles in office operations as opposed to shop floor operations. 5S and Kaizen are both continuous improvement strategies that apply lean to the smaller details of operations and reduce small elements of waste throughout the production process. These four strategies could be used individually or implemented together to produce further improvements.

2.3. Project-Specific Improvement

Each of the chosen strategies was delegated to a specific team member for brainstorming. However, before the individual brainstorming the team first did some group brainstorming to generate strategies for each of the top four strategies to ensure all members had an opportunity to suggest ideas for all strategies, not only the one they were assigned. The concepts discussed in the CDR were organized under each of the four chosen general strategies. Under Kaizen, the concepts are a standard of cleanliness and employee education. The second strategy 5S covers the concepts of workplace organization, process

standardization, and an organizational culture. Business Process Reengineering includes 4 concepts, including a live tracking system, immediate scanning/ modifying, a new walk-in appointment policy, and restructuring of the clinicians' schedule. The last strategy of Quick Response Manufacturing yielded the two concepts: physical pads during casting, and a revision of the foam mold cleanup process

In order to rank these concepts a table was developed as part of the HOQ and is shown below which allowed us to estimate metrics for each concept and compare which ones will be able to most improve the process. Similar to the first stage each team member filled out the table individually and an average was taken to make the final decision.

TABLE IX: ESTIMATED METRICS FOR SELECTED CONCEPTS

Design Metrics	Turnaround time [weeks]	Average WIP inventory [total units]	Capacity [total units / month]	Marginal clinician labour [minutes / AFO]	Marginal technician labour [minutes / AFO]	Rejections at first fitting appointment [%]
Current	6	150	110	0	0	1
4.1.1 Standard of Cleanliness	5.5	147.5	110	-2	-3	0.25
4.1.2 Employee Education	5	130	112.5	-5	-3.25	0.125
4.2.1 Workplace Organization	5.5	145	112.5	-4	-2	0.125
4.2.2 Process Standardization	5.25	133.8	118.8	-3	-7.25	1.125
4.2.3 Organizational Culture	5.5	146.3	110	-1.25	-1.25	0.25
4.3.1 Live Tracking System	4.625	123.8	120	0	-0.25	0.75
4.3.2 Immediate Scanning/Modifying	4	118.8	128.8	-8.75	-3.75	0.875
4.3.3 Walk-In Appointment Policy	5	130	110	-5	0	1
4.3.4 Restructure Clinician's Schedule	5.125	138.8	117.5	-0.5	0	0.625
4.4.1 Physical Pads During Casting	4.625	121.3	118.8	-9.5	-2.75	2
4.4.2 Foam Mold Cleanup Revision	4.5	123	125	-13.3	-2.25	2.625

The concepts were then ranked using the HOQ (see Appendix B) and matrix above, and two clear tiers emerged. The following concepts were generated during this stage, ordered by descending score:

Tier 1:

- Immediate scanning/modifying
- Foam mold cleanup revision
- Physical pads during casting

- Process standardization
- Employee education

Tier 2:

- Workplace organization
- Integrated tracking/scheduling
- Standard of cleanliness
- Walk-in appointment policy
- Restructure clinician's schedule
- Organizational culture

Tier 2 concepts are recommended for RCC to research themselves once Tier 1 concepts have been successfully implemented. For this project, only Tier 1 concepts were considered further, although elements from Tier 2 were retained with them. The Tier 1 concepts are extensively described in the remainder of this report. It was decided to rename "Employee Education" to "Continuous Improvement," which includes but is not limited to employee education, and covers all aspects of ongoing initiatives to sustain the changes made to improve the operations.

2.4. Response Time Spiral Process Improvement Theory

The Response Time Spiral is an operations management phenomenon that the longer a process takes to complete, the further the planning horizon extends [18]. The further ahead predictions are made, the less reliable they are, and the higher the chances that some unanticipated delay will arise. Companies will react by extending their lead time, pushing the horizon out even further, and soon the extended lead time will not be long enough and the cycle repeats. This is a negative Response Time Spiral. Conversely, the less time a process takes to complete, the less time there is for error, poor forecasting, or interruption; and therefore, the faster the process will go. This is a positive Response Time Spiral.

In RCC's case, implementing any one of the strategies suggested should cause a positive Response Time Spiral to occur, leading to further decreases in lead time in the future. An example of this in the current process at RCC is how clinicians often must deal with walk in appointments and other unexpected tasks that come up during their modifying time. This takes the clinician away from the job they were scheduled to be working on, causing it to be delayed. Currently there is six weeks' worth of time where these interruptions can occur; however, if the lead time is reduced to 4 weeks, there would be less time for mistakes and delays to occur, leading to further reliability in delivering within the specified lead time.

3.0 Concept 1: Immediate Scanning & Modifying

Based on the process statistics presented in Section 1.4, most of the lead time of the AFO manufacturing process occupied with periods where the device is waiting and not being worked on. These represent the biggest area for improvement in lead time. The largest waiting time in the current process is between when the clinician takes the cast and when they scan and modify it. The first recommended change is requiring the clinicians to perform the modifications right away so that the device can go directly to the technician to be carved. This change in the process will eliminate ten business days from the processing time, which translates to two weeks for the patient [14]. This section outlines the existing scanning and modifying process, and then describes steps RCC should take to make immediate scanning and modifying more feasible.

3.1. Existing Scanning & Modifying Process

The first step of the production process is the initial appointment between the clinician and the patient. Each appointment is scheduled for one hour [14]. During this consultation the clinician first assesses the patient to determine their needs and what type of device they will require. This part of the appointment takes about 30 minutes. Next the clinician takes a cast of the patient's leg using fiberglass, shown in Figure 12. This process takes about 15 minutes.

Figure 12: Clinician applying and removing the fiberglass cast [19]

The last portion of the appointment is spent filling out the required charting and billing information and creating a work order for the AFO. Once the appointment is complete the clinician will typically see another patient right away, as they can see anywhere from two to four patients in a given morning or afternoon. It will take the clinician approximately two weeks (ten working days) to get to the scanning and 3D model modifying. The clinician will bring multiple casts to the scanning room to do all the casts consecutively while the software is running to reduce the amount of set up time on the computer and scanning program. Then the clinician will use a block of modifying time to modify the 3D model, during which he/she can complete 6-12 jobs. They have two of these modification blocks laid out throughout the week, so each clinician can finish a minimum of 12 jobs per week. The current clinicians' schedule detailing how these blocks are laid out was shown in Section 1.4.4.

During this step, which is illustrated in Figure 13, the clinician adjusts the 3D model to:

- provide proper clearance between the patient's ankle and the device
- ensure clearance is left for pads
- correct the angle of the foot, reduce the thickness of the scan by the thickness of the fiberglass
- make other modifications that were deemed necessary during the initial consultation

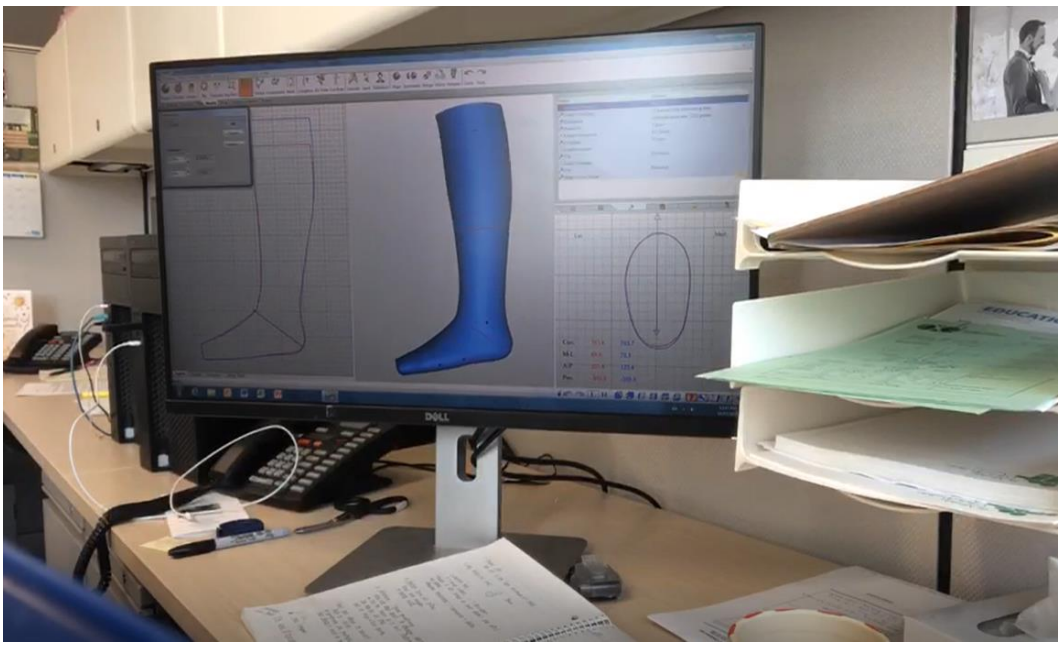


Figure 13: Modifying the 3D model in CANFIT [19]

3.2. Recommended Scanning & Modifying Process Changes

In order to accommodate the immediate scanning and modifying of each job, the main change that will have to occur is to the appointment scheduling. Instead of booking 1 hour for each appointment, it would

be recommended to allow for 1.5 hours. The patient will still only have one hour with the clinician, but the extra time will give the clinician the opportunity to scan the cast as soon as the patient leaves, and to complete the modifications before the next patient arrives. Based on the range of 20-40 minutes for modifying one job, 30 minutes is a reasonable average, and the clinician can use time left over from simpler jobs to complete more complicated ones. The modification times in the clinicians' schedule can be removed, and the extra time used for additional appointment times in order to accommodate seeing the same number of patients. In fact, this should allow for more patient appointments. Walk-in appointments and emergency appointments can be fitted into empty appointment slots throughout the week, meaning they will not disrupt the flow of work.

Another recommendation that would assist in making this change would be to leave the scanning software running all the time. Currently the software is turned on and set up when the clinician (or technician) comes in to scan a batch of casts. However, since the clinician will be required to now scan them one at a time, it would be beneficial to remove the setup time and set up the computer so that the clinician only has to log in and then can begin a new scan.

3.3. Implementation Plan

Because the clinicians already have two weeks' worth of jobs waiting to be modified it may be difficult to transition to the implementation of this new schedule. To begin RCC should increase appointment times to 1.5 hours, which will temporarily decrease the number of patients they can see. This will allow clinicians to start modifying the jobs as they come in, but still have time set aside to work on the jobs which have been waiting. This could be done for two weeks, in which time clinicians could finish at minimum 24 of the 50 jobs they each have in WIP. This period would also allow RCC to note if 1.5 hours is a reasonable time to complete the assessment and scanning and modification. During this period there will be fewer appointments and patients while clinicians' transition to this new schedule.

After this, there are several alternatives from which RCC can choose how quickly they want to complete the transition. This decision would be based on the availability of the clinicians and technicians, the urgency of in progress jobs, and the number of patients that need to be seen. The three options are described below.

1. The transition could occur by immediately switching the two modifying blocks to appointment times. This would require any remaining in progress devices to be completed by having the clinicians work overtime. This option would allow RCC to see the most patients and have the fastest lead time across all patients. However, it would have a high cost financially for the company and timewise for the clinicians due to the overtime hours required.

2. Both modifying blocks could be left until all the previous WIP devices have been completed. Using this method, it will take about four weeks to phase out the modifying blocks. This would result in having possibly 24-36 patients not getting their device finished in the six weeks, as well as having to turn away up to approximately 45 patients. This is because jobs in WIP waiting to be modified would normally be modified about two weeks after the initial appointment; however, once the schedule changes the clinicians will be working on newer jobs first and this will cause some older jobs to have to wait even longer. Additionally, since appointment times are being made 50% longer, RCC will not be able to take on as many patients until all the modifying block are converted to additional appointment time. This option would help with the workflow for the technicians, and if there are some less urgent cases where the patient could be notified well in advance that their follow up appointment will have to be delayed, this could be feasible.

3. One modifying block could be converted to appointment time, and the remaining modifying time could be used to finish any unfinished jobs. Each clinician has approximately 50 devices waiting to be modified at any time. Using a conservative estimate of 40 minutes to modify each job, a clinician can complete 12 jobs a week. To finish all devices remaining in WIP, the clinicians could complete a minimum of 24 in the first two weeks, and then with half the amount of modifying time it will take approximately an additional month to complete all the previous jobs.

TABLE X: COMPARISON OF IMPLEMENTATION OPTIONS

Option	Implementation Time	Number of Patients Missed	Overtime Required
1	4 weeks	30	48 hours
2	5 weeks	45	24 hours
3	6 weeks	60	0 hours

The three options are compared in Table X above. Option 1 has the most overtime hours, but will have the least affect on the number of patients seen. Option 3 requires no overtime but RCC will have to turn away or delay approximately 60 patients. Another factor to consider is the number of jobs that will be late; however, this is dependent on when overtime hours can be worked so it was not used as a metric for this comparison. This decision of which to use is left open to RCC to make based on their requirements.

The final schedule can be seen below in Table XI which shows that there is no longer any designated modifying time, and these blocks have been converted to more appointment times. As well, the number of patients can be found from adding the number of patients seen in each block, which gives the range of 16-24 patients per clinician per week.

TABLE XI: CLINICIANS NEW SCHEDULE

Monday	Tuesday	Wednesday	Thursday	Friday
8am-12pm Seeing patients (2-3)	8am-12pm Seeing patients (2-3)	8am-12pm On-Call Clinic	8am-12pm Seeing patients (2-3)	8am-12pm Seeing patients (2-3)
12:30-4:30pm Seeing patients (2-3)	12:30-4:30pm On-Call Clinic	12:30-4:30pm Seeing patients (2-3)	12:30-4:30pm Seeing patients (2-3)	12:30-4:30pm Seeing patients (2-3)

These changes should not require any additional physical resources, as there will not be any additional inventory created. The work-in-progress inventory is the modified files which do not take up any physical space. The only additional resources that may be required would be clinicians temporarily putting in some overtime to complete certain jobs that are subject to a strict timeline. The cost to RCC will be the lost opportunity costs due to the reduced number of patients during the transition.

The risk with this change is that for some complicated jobs the clinician may not be able to finish the modifications before the next patient comes in. If this is the case, they could delay an appointment to allow the clinician to finish. Alternatively, the order in which jobs are completed may be affected. Some new patients may get finished ahead of ones who had their initial appointment first. To make sure that jobs never fall behind there could be a built-in buffer time to modify at the end of each day to account for any jobs that may have not been completed. Empty appointment slots could also be used for this purpose.

3.4. Expected Savings

This recommendation is projected to save at least two weeks from the lead time on AFOs. The elimination of the waiting period allows the modified scan to go straight to the technician to carve whenever they are ready. This also provides a more manageable schedule for both the clinicians and technicians because it will even out the workflow and reduce the number of in-progress devices. Since the clinicians will not be scanning in batches anymore, jobs should flow more steadily to the technicians.

It is also expected that the modifying time will be reduced by doing it immediately after the appointment. The clinician will have the patient fresh in their mind and be able to make the adjustments more easily than if they had to refer back to their notes and charts that they made two weeks prior. If this is the case, the appointment time could potentially be reduced below 90 minutes to allow for more patients to be seen.

A third benefit is that RCC will be able to take on more patients. By changing all the modifying time to appointment time, after subtracting the on-call clinics, the clinician’s week becomes the equivalent of

four days of appointment times. This is equivalent to 30 hours of time the clinicians have with patients. A minimum of 16 patients could be seen, based on the layout of the new appointment times and how easily the modifying can be done in the appointment time. This is an improvement compared to the current minimum of 12 patients they are currently each seeing. If the new schedule allows clinicians to see an average of 18 patients a week, this could increase the monthly output to 170 devices, or 150% of the original. The ideal clinician-to-technician ratio for this recommendation is to remain at 3:2.

4.0 Concept 2: Foam Mold Cleanup Revision

This second part of the process improvement plan describes how the clinician could draw the pad lines and trimlines on the fiberglass cast instead of the foam mold, as well as how the technician could clean up the carved mold. This would eliminate the need for the technician to pass the foam mold to the clinician after carving, wait for the clinician to make the marks, and then have the clinician pass it back to them. The existing process behind this step is explored in detail, as well as how this can be accomplished in a more efficient way. A detailed plan is presented on how to implement this change.

4.1. Reasons for Foam Mold Cleanup

Currently, once the foam mold has been machined on the CNC carver it has several areas where it was mounted on the carver that have not taken the desired shape, which are pointed out in Figure 14. Once the technician has finished carving, he/she puts it in a WIP inventory, writing the patient's name onto the foam (redacted in the figure).

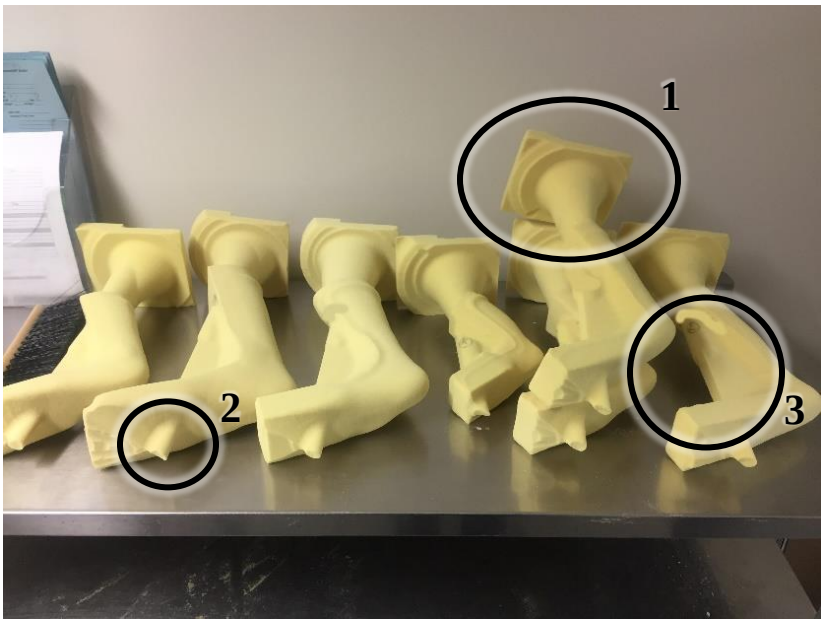


Figure 14: Foam models before clinician's modification [11]

The top flange (1) is indicated, which is where the foam was connected to the chuck. This must be fully removed. Near the ball of the foot is another protrusion used for the center in the tailstock to support the foam while carving (2). These could not be completely removed by the carver without repositioning the foam part, and so they must be removed by hand. There is also an angled gusset between the top of the foot and the front of the calf (3). This is left for added strength to the foam part, to prevent the mold from breaking. This does not require removal, as the final AFO has material at the front trimmed away and does not need to match the shape of the patient's leg in that region.

The clinician is currently responsible for making these changes to the foam mold, which are done by cutting, trimming, and grinding the foam. The foam mold after this step is seen in Figure 15. After this stage, the foam mold is the exact shape it needs to be for vacuum forming the AFO shell.

Figure 15: Foam models after clinician's modification

At this time the clinician also draws on the foam mold to indicate to the technician where the plastic should be trimmed after the vacuum formed AFO shell has cooled. These marks can be seen in Figure 15. Also demarcated at this time is the size and position of the pads. This enables the technician to prepare the pads to the right size and shape for the AFO. Pads are typically applied around the lateral malleolus and under the internal medial control strap. The entire modifying and marking process takes the clinician approximately five minutes; however, it can wait up to two days and possibly more between carving and the clinician working on it, and then another day before the technician comes back to it [14]. This is a large source of wasted time.

4.2. Recommendation Revisions to Foam Cleanup

The removal of the excess foam after carving could easily be done by the technician, saving the clinician time. Since the clinician's time spent on the production of an AFO is more per unit than the technician's, their time is more valuable. This change on its own would improve performance, as it would shorten the time required for the clinician to demarcate the pad lines and trim lines. This would also mean it would sit waiting for the clinician to attend to it for a shorter period. However, these improvements are minor compared to the complete removal of the hand-off altogether.

Instead of drawing the pad lines and trim lines on the foam mold, the clinician could draw them on the fiberglass cast. This process would occur during the initial consultation, ideally while the cast is still on the patient. Besides time savings, during the consultation it will be obvious to the clinician where pads and trim lines are required. The patient's leg will be right in front of them, and the patient's needs in the forefront of their minds. It is hoped that this will also improve quality, as the process relies less on the clinician's recollection of the patient's needs. Trimlines should more often be placed correctly.

4.3. Anticipated Quality Concerns and Countermeasures

The first technical issue with this plan is that the fiberglass cast is slightly larger than the patient's leg; therefore, the pad size might be exaggerated. A slight adjustment to the new process must be made either by the clinician during drawing, or by the technician during cutting. The clinician is responsible for approving the final shape of the pads, so he/she should make this adjustment. The effect on the lateral malleolus pad is not expected to be large. More challenging is the internal control pad, which currently is molded to the foam mold as well as cut to size based on the trimlines. Geometric distortion will have a larger effect on the size of the pad (the pad itself is larger, and it also has significant curvature across the bridge of the foot). Pad lines should not extend as far down on the fiberglass as they will in the final product. One minute has been added to the expected casting time in the clinician's schedule. The difference only needs to be approximately the thickness of the fiberglass. However, size control issues would be removed if the pads were standardized as per the recommendations in Section 6.0. These issues would also be absorbed if the recommendations in Section 0 are followed.

The pad must still be molded on the foam mold, since molding it to the fiberglass would result in the wrong radius of curvature. Since the position of the pad relative to other features on the foot is approximately standard, the technician may not need to transcribe the pad lines to the foam mold in order to correctly position the pad for molding, but doing so would also be possible. This is also another way to mitigate sizing issues just mentioned.

Another technical challenge is that the fiberglass must be associated with the patient's case for longer. However, the fiberglass cast is already related to the patient's case. Casts waiting to be scanned are stored in a small container in the general workshop. A second bin could used to store casts that have already been scanned but are still needed for transcribing trimlines. If the recommendations suggested in Section 3.0 are followed, then the first bin mentioned to store unscanned casts would be obsolete, and so inventory requirements would see no net change.

The last issue to overcome is how trimlines on the fiberglass cast will guide the technician in trimming. Currently, the technician follows the lines visible through the translucent plastic wrap. In cases where the plastic is too thick or opaque to see through, the technician trims away from where the lines are typically located, the foam model is extracted, and the markings are transcribed onto the plastic shell itself. In some cases, the trimlines are integrated with the 3D model, and a slight flare is added during carving, with a ridge on the other side of it [13]. This could routinely be used for all devices. However, in many cases this is not desired, meaning the trimlines would have to be transcribed either to the plastic part or to the foam. Trimlines should ideally be transferred to the foam mold, as marking the plastic directly risks marking the final product; however, the marks can be removed using paint thinner [13].

The success of this improvement suggestion depends on the ability of the technician to transcribe these marks by sight and by hand, as there is no clear method to automate or digitize the transfer of this information. Two minutes have been added to the cleanup step in light of this. No compensation is required to be made for the thickness of the fiberglass here. Due to the curved surfaces, there can be no direct measurement, and the human eye is better at perceiving proportions rather than actual distances. Furthermore, the exact dimensions are not critical for the articulated AFOs. Solid AFOs are not as common and not the direct focus of the project. In these cases, the process already has built-in modifications to accommodate improperly placed trim lines, and the trim the technician does is rarely final. If all steps in the process err on the side of leaving material on, this issue is not expected to outweigh the benefits of making this change, which are listed below.

4.4. Expected Savings

If the changes above are implemented, the clinician's portion of the work will be reduced from three blocks to two: from the initial consultation until the 3D model is ready for carving, and the duration of the fitting appointment. Furthermore, the technician's work will be all in one continuous block, requiring no waiting on the clinician. During this time, the technician can manage his/her own schedule, and only needs to work around the mandatory cooling period. One minute needs to be added to the clinician's schedule and two minutes to the technician's schedule, as described in Section 4.3. However, these changes allow for a new optimal schedule for the technician, which is given below.

The 36 hours are best suited to being left overnight twice. Technicians would spend about 90 minutes before and 90 minutes after the 36 hour wait on a given AFO. However, this includes some zero-resource time, specifically occurring while the glue is drying on the cork heel and while the carver is running. To maximize efficiency, the technician should adopt the schedule shown in Table XII. The rightmost column shows the minimum estimated time. Additional time has been added on the left to account for the changes mentioned in Section 4.3, as well as some built-in flex time.

TABLE XII: MODIFIED TECHNICIAN DAILY SCHEDULE

Schedule	Task	Time [min]
0:00	Trim and prepare cork heel on AFO #1	23
0:25	Set up carver to carve AFO #4	10
0:45	Heat cork, finish heel, add pads, add straps, clean. [AFO #1 complete]	46
1:40	Trim and prepare cork heel on AFO #2	23
2:05	Set up carver to carve AFO #5	10
2:25	Heat cork, finish heel, add pads, add straps, clean. [AFO #2 complete]	46
3:15	Trim and prepare cork heel on AFO #3	23
3:40	Set up carver to carve AFO #6	10
4:00	Break	30
4:30	Heat cork, finish heel, add pads, add straps, clean. [AFO #3 complete]	46
5:20	Cut and prepare pads for AFO #4, wrap AFO #4	40
6:10	Cut and prepare pads for AFO #5, wrap AFO #5	40
7:00	Cut and prepare pads for AFO #6, wrap AFO #6	40
7:50	Clean up	10

With this schedule, which staggers zero resource time, the technician can maintain a consistent volume of 3 AFOs per day. AFO #4 of one day becomes AFO #1 two days later, making the technician's throughput time one day + 5 hours 10 minutes. With the current process, after modifying, the AFO sits in inventory for seven days, and is worked on during four of those days before the technician releases it for the final fitting. This shorter time period also minimizes the effect of the response time spiral, mentioned in Section 2.4.

At this rate, ignoring recommendations from other sections, the technician can process 60 AFOs per month, and the clinician can process 50 AFOs per month, if both operate at maximum capacity. The optimal clinician-to-technician ratio in this scenario is 6:5.

5.0 Concept 3: Addition of Mock Pads During Casting

This process change simplifies the addition of pad relief areas. This is currently done by modifying the 3D model to account for relief in areas where pressure points must be avoided, or pads will need to be included. The suggested change incorporates space for pads or relief areas into the initial casting in order to reduce modification time in the CANFIT software and produce a casting closer to the desired final

geometry. This eliminates the waste of over-processing and excessive motion between the clinician and technician. This modification prioritizes streamlining the cast modification process as this is a current bottleneck due to the high cycle time of up to 40 minutes. Reducing this cycle time could enable more consistent throughput at this stage, enabling an increased stability in the technician workload.

5.1. Purpose of Pad Molding Process

Currently the pads are molded to the AFO during the vacuum foming process and then the excess trimmed for the final product. The location where modification is necessary to accommodate the addition of pads is shown below in Figure 16.

Figure 16: Current pad alignment [11]

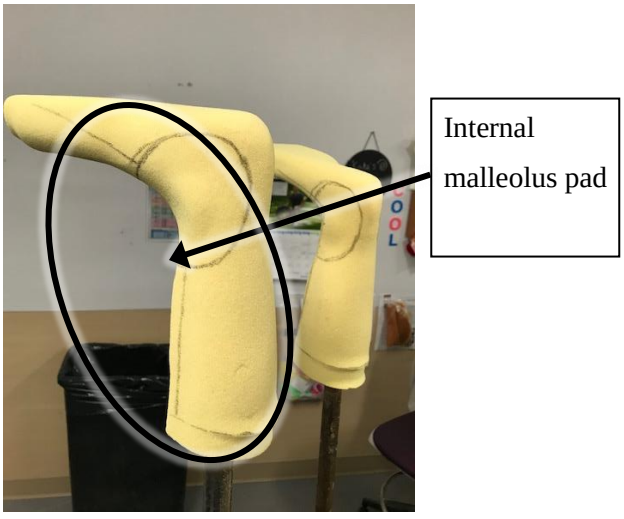


Figure 17: Pad location as indicated on the foam model

The lateral malleolus pad is made of P-cell foam, a closed-cell ethylene-vinyl acetate (EVA) foam which is resistant to moisture, pack-down, and abrasion, and provides good shock-absorbent and frictional properties [20]. Figure 16 shows approximately 5 mm of clearance must be provided to accommodate pad thickness as the lateral malleolus pad will not pack down. The clinician currently modifies the model to accommodate this clearance using CANFIT software.

5.2. Recommended Changes to Pad Molding

Using mock pads during the initial patient casting will have the same effect as modifying the 3D model of the cast. The mock pads should be large enough to incorporate the desired clearance in the scanned model and would also benefit from being a standardized item that can be added to the cast with minimal change to casting time (Section 6.0 covers this idea in great detail).

Pads could be added before the fiberglass wrap, and held in place by the "sock" that separates the cast from the patient's skin. The sock currently used is shown in Figure 18.

Figure 18: Sock used in casting to protect patient's skin [19]

In Figure 18, the clinician is inserting a tube, which extends through the length of the sock along the anterior of the patient's leg, which further protects the skin when the fiberglass cast is removed. This shows the clinician can easily reach into the sock and insert objects. The team performed a brief experiment to demonstrate the steps added to preparing the patient for casting by implementing this concept. This is shown in Figure 19.

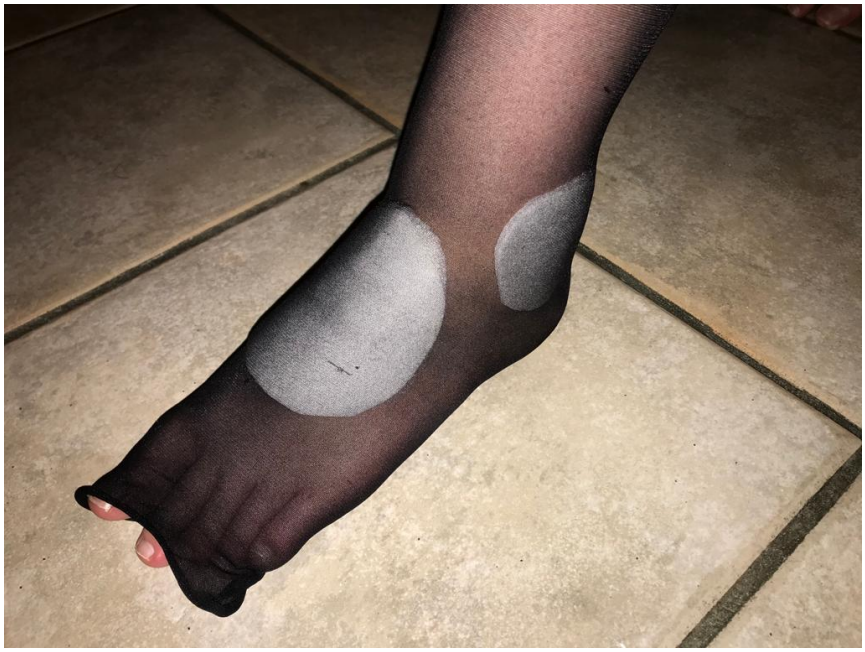


Figure 19: Illustration of how mock pads could be inserted into the protective sock

This illustrates the internal control pad and the lateral malleolus pad relief geometry already incorporated at the casting stage. The process change should reduce time spent modifying the 3D model, contributing to load balancing, with the goal being an increased rate of throughput at this stage. Furthermore, the change should simplify pad placement during vacuum forming, since the pad location would be made more distinct due to the use of mock pads.

5.3. Implementation Plan and Risk Assessment

In order to implement the change, the process may be slowed initially. One risk is the potential for the mock pads to not accurately produce a large enough relief around pressure points. This could be due to the smoothing that occurs when layers of fiberglass are covering the mock pad requiring an exaggeration in size with the mock pads that correlates to the necessary volume of relief in the digital model. In order to address this variability, this change would benefit from standardized mock pad sizes as well as standardized final pad sizes. An example of three sizes of pads for a variety of leg and foot sizes is shown in Figure 20.

Figure 20: “Mock” pad sizes ranging from 75-140 mm diameter shown for reference with 130-275 mm foot lengths (Mondopoint 13-27.5) [1]

The mock pad should include a method for adhering to the patient’s ankle in order to maintain a similar initial casting time. Also, the pad should be sufficiently supple in order to conform to natural contours of the ankle. These criteria should provide guidelines during the initial testing of this concept for determining pad material and thickness. The thickness may be greater than the thickness of the final pad used in the device, to provide some clearance between the patient’s skin and the pad, as this is also often incorporated into the 3D model during modifying [7]. The current pad alignment and geometry from

Figure 16 closely resembles the suggested mock pad alignment and geometry in Figure 20; thus, a circular mock pad should not introduce a major risk to patient comfort.

5.4. Expected Savings

Implementing this change is expected to save five minutes of clinician process time as well as two minutes of technician process time. However, these savings do not accurately represent the true gains resulting from making this change. The primary advantage would be potentially enabling a clinician modification step to be removed after the positive model of the cast is carved. Another advantage is that this process makes the changes suggested in Section 4.0 much easier, helping eliminate the trade-off between the clinician and technician and further streamlining the process. In order to enable an immediate

[1] Models created using existing scans of legs publicly available on GRABCAD community. These 3D model files were used for an accurate representation of lower leg geometry [55]

handoff from carving to the technician, further standardization of pad sizes and other individual steps is encouraged and outlined in more detail in Section 6.0 regarding process standardization.

Also, it is expected the use of mock pads could be further utilized, resulting in further time savings. Using dummy pads during molding of the AFO as well as the insertion of final pads would result in increased consistency in pad sizing with only two variables: position and depth. Additionally, savings are expected are due to shortening the cycle time for modification in CANFIT by up to 10 minutes. This reduces the need to find a large enough time block to complete modifications. This in turn complements the switch to immediate scanning and modifying as mentioned in Section 3.0.

It also contributes to balancing the clinician to technician ratio. The estimated clinician to technician ratio after implementing only this suggested process change is 6:5. This is mainly due to the time savings in the modification in CANFIT as well as savings at the physical modification step of the carved foam mold. Casting was estimated to take up to five minutes longer, which provides time for the clinician to locate and place the mock pad on the patient before beginning to do the fiberglass wrap.

6.0 Concept 4: Process Standardization

Process standardization eliminates variability in the fabrication of AFOs, by eliminating the need for custom cut and shaped pads and cork heels for RCC's AFOs. The suggested change utilizes pre-cut standardized sized pads to be pulled off the shelf during the fabrication of the AFOs to reduce the production time for the technician, as well as cork heel blanks prepared ahead of time. Process standardization removes the need for excessive motion of the technician and the need to produce dummy pads. It also aids in streamlining the workflow of the staff. The control strap and lateral malleolus pads, cork heel wedges, and control straps are all ideal candidates for process standardization, as the shape of these production items maintain standard shapes and contours on a majority of AFO devices. Control straps are already standardized in the production process [13]. This section provides a detailed recommendation for standardization of the pad sizes and the cork heels, along with a plan on how to implement the changes.

6.1. Current Pad, Heel, and Strap Fabrication Process

Currently the first step the technician performs in the fabrication process is cutting out internal control and dummy pads to be used further along in the process. The technician then molds the internal control pads by heating up the material in the oven and shaping them using the foam mold. The technician then creates dummy pads for the medial ankle control strap and lateral malleolus pads. The dummy pads are used during vacuum forming to create the recess needed for the final pad. Once the dummy pads are

fabricated, they are then attached to the foam mold, and the mold is ready for wrapping. The internal medial ankle control strap pad is fabricated out of the Volara and Optek foams, whereas the lateral malleolus pad is made from 1/8” P-Cell material.

The cork wedges are fabricated using a similar concept of cutting the material to fit a desired size and contours then fastened to the device. The cork heel wedges are glued to the sole of the AFO. After this, they are heated and molded into the correct shape. They must be then left to cool.

The straps are already standardized [13]. The technician simply selects the correct strap and cuts it to the required length. During the fitting appointment, the clinician rivets the straps to the device. This must be done after an initial check on the patient to determine the best location for the straps. The locations of the pads, straps and cork heel wedge are identified in Figure 21 for clarity below.

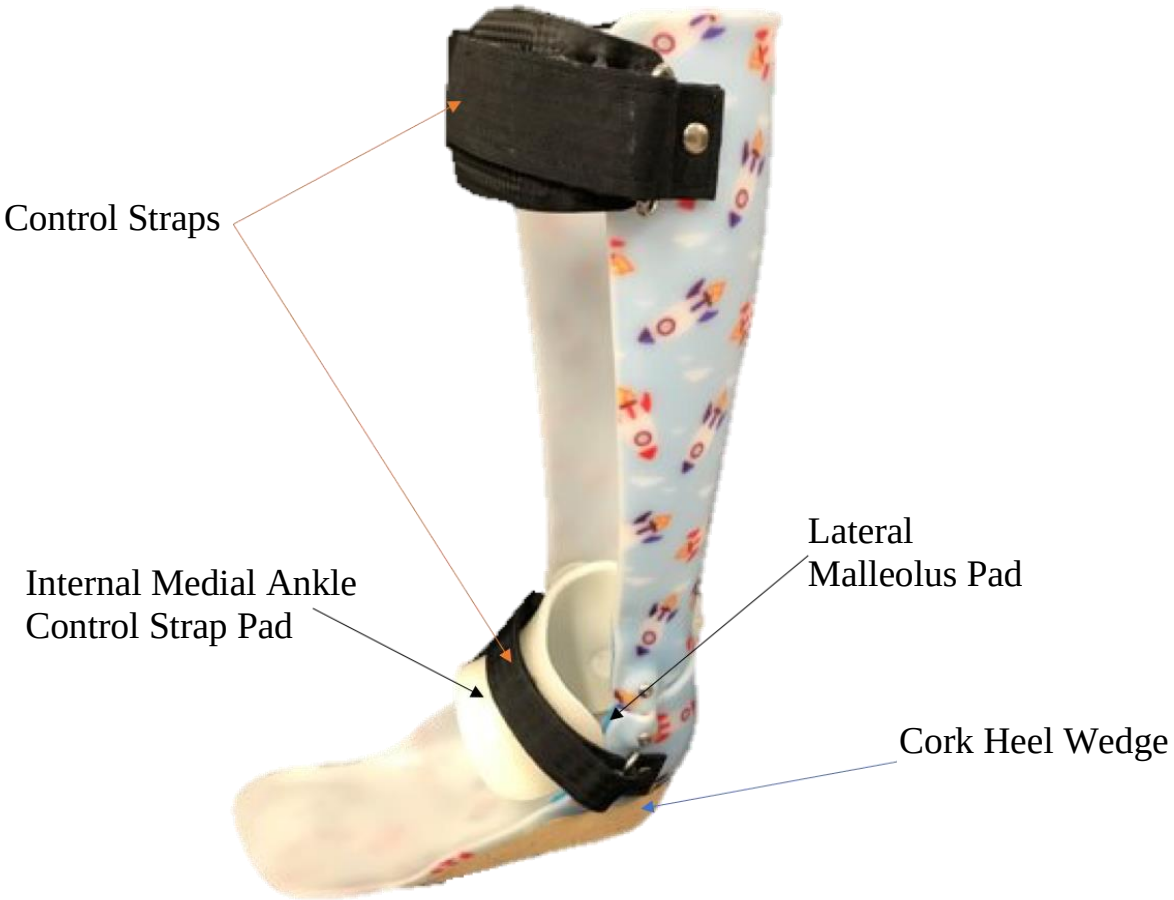


Figure 21: AFO diagram showing location of pads, straps and cork wedge [11]

6.2. Pad Size & Cork Heel Standardization Recommendation

The recommended process change is to have a stock inventory of standard-sized control strap and lateral malleolus pads as well as cork heel blanks readily available for technicians during the AFO production process. A suggested breakdown of each of these areas of standardization is outlined here.

There is little variability between the shapes of lateral malleolus pads or the internal control pads [13]. A simple circle could be used in both cases. Since the devices are prepared in a range of sizes, incremental sizes could be determined, labelled simply as small / medium / large, or instead by the size measurement itself, such as 1” / 1.5” / 2”. Pads could be made ahead during a free session of the technician’s time. The internal control pads would still require molding to the foam mold, as this part requires more precise control over the geometry. RCC can also incorporate premade dummy pads to be pulled off the shelf during production to eliminate the need of making custom dummy pads that are currently discarded at the end of the process.

Stock cork heels could be made ahead of time, to a rough shape known as a blank that could be later adapted to a specific device. The cork heel requires more customization with the current AFO design. The angle the patient’s foot makes with the ground is controlled by this cork heel. However, the general shape varies little from one device to the next. During production, the technician would only have to mold the top of the heel so that it fit tight against the heel of the AFO, and the bottom so that it made the desired angle with the plane of the patient’s foot.

6.3. Implementation and Resource Requirements

Implementing the process standardization plan may require some resources for RCC to see the results and benefits of the plan. The main resource required for implementation would be RCC’s time. To set this system up, a trial period will be required, during which the optimal pad sizes and heel sizes are determined. Introducing more increments may result in higher quality of devices, but it will require keeping stock of more variants. At some point, increasing the resolution will no longer meaningfully affect quality. Clinicians and technicians will need to work together during this trial period to determine what standardized items should be stocked.

Once in place, this plan will initially require several hours weekly for technicians to cut out the standard pads and cork heel wedges in the various sizes weekly. A schedule could be created to determine who is responsible for cutting the parts weekly, to ensure a there is always a readily available stock of these items. As the need for the standard parts required increases, the technicians will have to increase the volume of standard-sized items they fabricate. Another resource that will be required will be a location to store the standard parts in inventory, in an area easily accessible for all technicians.

A risk associated with standardizing the cork heel is that the heel no longer provides the required adaptability for different patient needs. If this risk may only be addressed by maintaining a fully custom process, it is recommended that RCC only standardize the pad size. Standardization should not compromise the output quality.

6.4. Expected Benefits

Although the process standardization recommendation provides a minimal amount of time saving to the AFO production process, the process change will provide RCC with a variety of other benefits. It will eliminate a form of variability in the process and streamlining the fabrication process for the staff. The inclusion of standard parts to the process removes the needs for custom items, which tend to all be approximately the same size and shape for most devices produced.

The standardized parts would work well in conjunction with the other process improvement concepts. For example, “mock” pads used in the previous process improvement strategy of Section 5.0 could be made to a standard size that would correspond to the standard sizes the technician would prepare. Having the pad size standardized would make it easier to compensate for geometric distortion arising from the use of mock pads. The use of standard size pads and cork heels will ultimately simplify Steps 5, 8, and 9 of the existing AFO fabrication process described in Table V. The technician will experience a small reduction in required time per AFO and a more efficient AFO production process. The main benefit of process standardization is its ability to streamline the fabrication process and stabilize the workflow for RCC. This stability mitigates the effect of the Response Time Spiral. This process improvement strategy does not change the optimal clinician-to-technician ratio from the existing ratio of 3:2.

7.0 Concept 5: Continuous Improvement

This section describes general continuous improvement strategies that RCC should employ to sustain the changes described in Section 3.0-6.0, and to help them develop their own changes once these ones are successfully implemented.

7.1. Organizational Involvement

Continuous improvement is highly dependent on creating a companywide culture where waste is noticed, and employees feel individual responsibility and freedom to suggest changes that work to remove these wastes. This is where difficulty arises, as change is difficult to begin. However, continuous improvement can be done in small incremental steps as well as larger more radical changes, and therefore small changes such as cleaning emails, organizing computers, or adding a small challenge at the weekly meeting can “normalize” the overall movement towards less waste [21].

The use of 5S boards is an effective method for smoothly implementing a Lean program into the workplace. The boards aid in workplace organization by using visual representations and management of various 5S concepts. The information on the board explains how to keep a workstation clean by using standard methods, 5S and Kaizen concepts, continuous improvement news and ideas. A 5S Board provides a location for stand-up weekly meetings, for frequently accessed information, and for new resources. Stand-up meetings are good opportunities for management to discuss new developments in the organization with staff. An example of a potential resource for a 5S board are displayed in Figure 22 and other examples can be found in Appendix D. The main goal of a 5S board is the increase in workplace efficiency through standardization, clear and simple strategies.

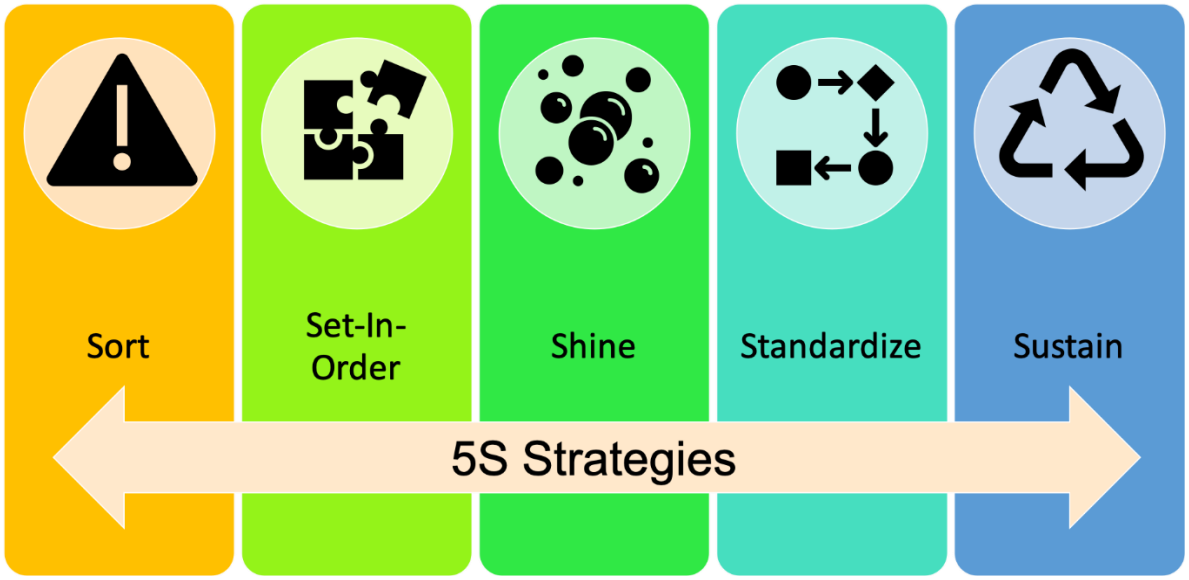


Figure 22: 5S poster concept for a 5S Board

Organizing inter-departmental competitions is an important 5S strategy to implement and sustain Lean and continuous improvement initiatives. The main objective of the competitions is aimed at improving the organization's overall productivity. Anyone in the organization can participate in the competitions at any level of 5S. Inter-departmental competitions last a period of six months; therefore, there are two competitions per year. The main rule of the competitions is to establish evaluation and incentive plans. Establishing the metric for the competition is the most important way to ensure the competition does indeed contribute towards continuous improvement. A 5S/continuous improvement team could determine the concepts and strategies the workplace will want to implement with a competition. Successful competitions would be determined through regular audits and inspections from appointed auditors. Successful strategies would be awarded with predetermined incentives.

Inter-departmental competitions at RCC could occur amongst the technicians and clinicians or even among the individual staff members. For example, a competition could occur amongst the technicians and clinicians on who could successfully utilize the 5S methodologies and implement 5S shadow boards at their work benches in the modifying room. As another example, clinicians could compete to see who could maintain the shortest average appointment time, or the most on-time appointments. The staff member with the best metric wins the competition and the incentive. The predetermined incentive could be a gift card, bragging rights in the office, or even the ability to leave work early on a Friday.

7.2. Cross-Training

To make the workflow more balanced, RCC is recommended to have administrative personnel do the billing and generation of a work order, rather than having the clinician doing this during the scheduled appointment time with the patient. Training the administrative employee to do this would help the clinicians by giving them more time to work on modifying and seeing more patients. Since the administrative team likely already has experience with similar tasks, it would make sense to delegate this job to them and keep similar tasks together. This would reduce 10 minutes of clinician time from the initial consultation appointment. Sustaining this change would require regular communication between clinicians and administrative staff to ensure that no problems arise.

7.3. Dealing with Organizational Inertia

One challenge with Lean is that while all members of an organization want to see increased productivity and quality, different interpretations of the expectations can lead to friction within an organization. This may arise due to any of the suggestions made above but is especially anticipated of the suggestion made in Section 3.0 to immediately scan and modify the 3D model. To some, this may be interpreted as “Work faster and harder,” when already they feel overwhelmed with a backlog of orders. One effective way to deal with this is to educate all staff members on the Response Time Spiral. In other words, the fact that staff feel overwhelmed and are bombarded by unexpected delays is an effect of the six-week lead time, as well as a cause.

Rajan Suri, a prominent QRM consultant, put together a 10-question quiz which is designed to challenge traditional approaches to manufacturing and highlight the mindset shift required to move to QRM [18]. This counterintuitive quiz is included in Appendix E, along with the team’s own comments on certain points that might be applicable to RCC. This might help staff be willing to question what is typically regarded as unquestionable in manufacturing. This tool might be a helpful first step in presenting the changes recommended in this report to RCC’s staff.

8.0 Final Recommendations

This section summarizes the major process changes recommended to RCC described in Section 3.0-7.0. It then combines all stages into an optimal schedule with an optimal clinician-to-technician ratio for several cases. The results are compared against the project objectives to evaluate the success of the project.

8.1. Process Flow

First, the suggested process is reviewed in a similar format to how the existing process was reviewed in Section 1.4. The top-level flow chart is shown in Figure 23.

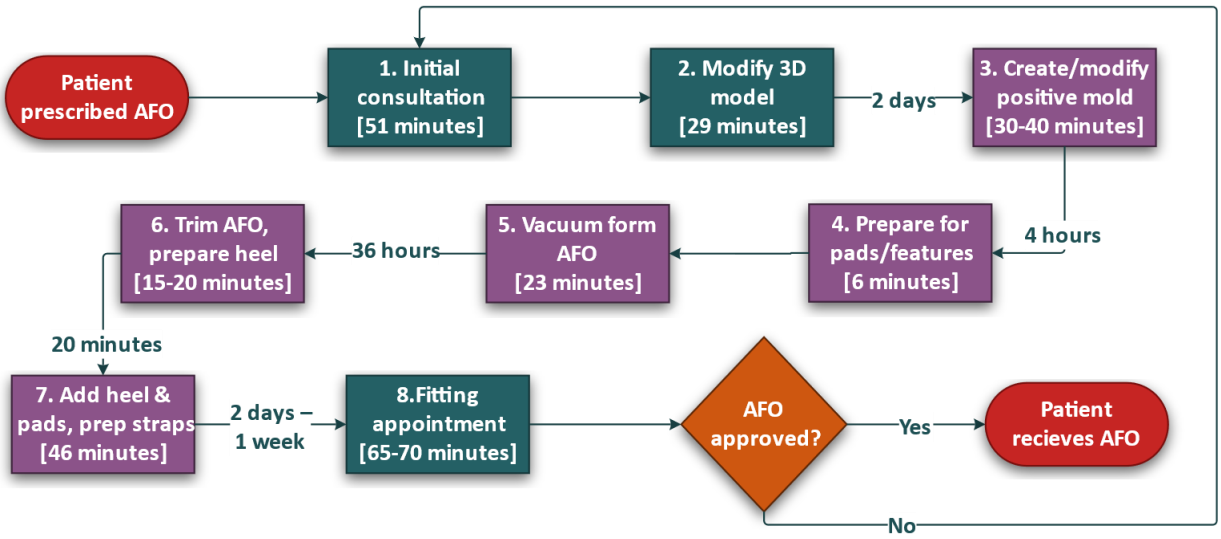


Figure 23: Recommended AFO process, incorporating all changes

This flow chart represents what a reasonable expectation given the changes suggested in this report. The main difference from the original process flow diagram in Figure 5 is that several steps have been combined. This shows that the process has been simplified and streamlined, mainly due to the elimination of the clinician's role in modifying the foam model. Another difference is the removal of the two week delay between steps 1 and 2. Additionally, the time expected for step 2 (which includes scanning, importing, and modifying the 3D model, see Table XIII below) has decreased significantly. This is due to the combination of many factors that contribute to the 3D model modification taking some time. The physical pads have been incorporated into the appointment, and the patient is fresh on the mind of the clinician. The trimlines on the fiberglass model may also accelerate in modifying the 3D model.

Lead time could be further reduced by finding a way to eliminate the non-value-add two day wait between steps 2 and 3, as well as the two day to one week wait between steps 7 and 8. Ultimately the time

between the initial consultation and the fitting appointment is fixed by how the appointments are scheduled, which is done based on the normally-expected lead time. Given the time-period shown above, RCC should experiment reducing the lead time to two weeks. It is likely that doing so will eliminate many of the effects of the response time spiral, described in Section 2.4. This will require less padding between the completion of the AFO in step 7 and the final fitting appointment, meaning the lead time could be reduced even further, to less than one week. The team has not presented a concrete analysis of whether this is the case, as the Response Time Spiral works on the principle of random, unanticipated events occurring during production. Idealized calculations conducted in Sections 8.2 and 8.3 ignore this padding time.

Detailed step-by-step process, as in Table V, is shown below in Table XIII.

TABLE XIII: IMPROVED PROCESS – DETAILED STEPS

Step	Task	Minutes		Step	Task	Minutes
1	Assess patient	30				
	Cast patient leg	16			Plastic out of vacuum rest	Overnight
	Charting, work order, billing	5		6	Cut plastic	5
2	Prep cast for scanning	2			Grind trimlines	10-15
	Scan cast	10			Cut and prepare cork for heel wedge	3
	Import scan to CANFIT	2			Glue drying	20
	Modify positive model in CANFIT	15		7	Heat cork	5
3	Digitally set up scan on block in CANFIT)	5			Mold cork and wrap with tensor	1
	Set up carver	5			Cool cork	15
	Carver carves positive model from block	20-30			Grind heel wedge	5
	Clean up carved cast (smooth, draw trimlines and pads)	7			Cut and finish internal control pad	2
4	Mold internal control pad	3			Glue lateral malleolus pad	10
	Align and attach tamarack dummy joints	2			Select and trim straps/pads	2
	Align and attach PF stop dummy	1			Clean device	2
	Measure and cut plastic	5		8	Initial trial of device on patient (mark trimlines and strap placement)	10
	Measure and cut transfer paper	2			Grind final trimlines	15-20
5	Set up cast in vacuum station	5			Rivet straps	5
	Heat plastic in oven	8			Second trial on patient	5
	Apply transfer paper to heated plastic	1			Static alignment check	5
	Additional heating of plastic	1			Dynamic alignment check	10
	Mold plastic to cast	1			Adjustments if needed	10
	Plastic under vacuum cool down	24 hours			Patient education	5

8.2. Optimal Schedules and Clinician-to-Technician Ratios

The maximum expected time for the clinician per AFO is 150 minutes. The maximum expected time for the technician (excluding zero-resource time it is convenient to take advantage of) is 111 minutes. This yields an optimal ratio of 1.35, approximately four clinicians to three technicians.

However, the technician's day is broken into many more steps, incorporating more variability. On the other hand, the clinicians have their tasks entirely within appointments, apart from the post-appointment scanning and modifying of the 3D model. With the schedule indicated in Table XII (reviewed below), the

technicians could perform all required steps for 3 AFOs in one day (8 hours, 450 minutes of working time), requiring 150 minutes per AFO as a buffer. Assuming the clinicians were able to exactly meet the targets anticipated by the team, this suggests an optimal clinician-to-technician ratio of 1:1. This would align exactly with RCC's current staff. Table XIV contains the schedule the team recommends as optimal.

TABLE XIV: OPTIMAL SCHEDULE FOR 1:1 CLINICIAN-TO-TECHNICIAN RATIO

Time	Clinician Tasks	Technician Tasks	Time
0:00	Initial Consultation (AFO #5)	Trim and prepare cork heel on AFO #1	0:00
		Set up carver to carve AFO #4	0:25
		Heat cork, finish heel, add pads, add straps, clean. AFO #1 complete	0:45
1:20	Initial Consultation (AFO #6)		
		Trim and prepare cork heel on AFO #2	1:40
		Set up carver to carve AFO #5	2:05
		Heat cork, finish heel, add pads, add straps, clean. AFO #2 complete	2:25
2:40	Initial Consultation (AFO #4)		
		Trim and prepare cork heel on AFO #3	3:15
		Set up carver to carve AFO #6	3:40
4:00	Break	Break	4:00
4:30	Fitting Appointment (AFO #1)	Heat cork, finish heel, add pads, add straps, clean. AFO #3 complete	4:30
		Cut and prepare pads for AFO #4, wrap AFO #4	5:20
5:40	Fitting Appointment (AFO #2)		
		Cut and prepare pads for AFO #5, wrap AFO #5	6:10
6:50	Fitting Appointment (AFO #3)		
		Cut and prepare pads for AFO #6, wrap AFO #6	7:00
		Clean up	7:50

The minimum lead time is two days for 2/3 of patients and three days for 1/3 of patients. AFO #4, the first AFO to be carved, must be carved too early in the morning and therefore should come from the last initial consultation on the previous day. Since on-call clinics may also disrupt this schedule, the lead time can be assumed to be three days. On one day with on-call clinics, two initial consultations and one fitting appointment should be held, and on the other day two fitting appointments and one initial consultation. These calculations also ignore any arbitrary padding time for scheduling fitting appointments, which can be progressively eliminated by RCC if production can be shown to follow this schedule.

This schedule and calculated lead time assume ideal conditions, allowing for no unforeseen delays. However, with this schedule, three AFOs are produced per day for each clinician/technician team. This results in a total capacity of 162 AFOs/month (again assuming only half of on-call clinic time contributes to AFO production). This is 40% more than current demand, meaning only 3/5 of appointments specified need to occur. This means the clinicians are not anticipated to have such a tight schedule every day, and time can be spent focused on measuring the changes recommended in this report as well as those developed as a result of RCC's own continuous improvement activities. Then in the event of loss of a staff member, or that demand reaches 162 devices/month, RCC would be fully ready to transition to the 100% capacity schedule. Table XV compares all possible realization cases, including the existing process. C-to-T ratio in Table XV refers to the clinician-to-technician ratio.

TABLE XV: COMPARISON OF FINAL ALTERNATIVES

Process Changes	Capacity	Units/Month	C-to-T Ratio
Recommended Process, ideal conditions	100%	162	1:1
	70%	115	1:1
Current process	89%	115	3:2

8.3. Assessment of Project Objectives

To investigate whether the project was successful, the target specifications and metrics determined during the Project Definition phase, shown in Table XVI (see also Table IV). The final evaluation will be based on the final schedule presented in Table XIV, for both the 70% capacity case and the full capacity case.

TABLE XVI: EVALUATION OF PERFORMANCE AGAINST TARGET METRICS

ID	Metric	Current	Marginal	Optimal	70% Capacity	Full Capacity
1	Turnaround time (initial consultation – product delivery)	6 weeks	3-4 weeks	2 weeks	2 days	2.33 days
2	Average work-in-progress inventory	150 units	120 units	90 units	12 units	18 units
3	Capacity / month	115	120	130	115	162
4	Marginal clinician labour [minutes / AFO]	189	156	135	150-160	150
5	Marginal technician labour [minutes / AFO]	119	90	75	111	111
6	Rejections at first fitting appointment [%]	1%	1-0.5%	0.5-0.02%	1%*	1%*

*requires testing

On the first two metrics, turnaround time (lead time) and WIP inventory, expectations were surpassed. The two cases are distinguished by capacity. Current demand can be met by utilizing only 70% capacity, and full capacity could far exceed this if the appointments were shrunk slightly. It was found that reducing clinician labour and technician labour helped but was not required as much as initially thought to obtain the first objectives. No comment can be made on the accuracy or quality of the process – this would require implementation and testing.

More generally, results are compared to the project objectives in Table XVII. These were also defined in the project definition report and reiterated in Table I.

TABLE XVII: EVALUATION OF PROJECT SUCCESS AGAINST OBJECTIVES

ID	Objectives	Importance (1-3)
1	Decrease AFO lead time	3
2	Increase productivity of Orthotics Department	2
3	Stabilize workflow for clinicians and technicians	2
4	Improve use of human resources in the Orthotics Department	3
5	Increase production capacity of AFOs	1
6	Design for ease of implementation	2

Items highlighted in dark green are deemed by the team as addressed well by the proposed solutions. Items highlighted in light green are deemed by the team as addressed satisfactorily by the proposed solutions. All items were addressed. All items of high importance (ranked 3), specifically decreasing AFO lead time and improving the use of human resources in the Orthotics department (determining a suitable clinician-to-technician ratio), received additional focus during the project and are the main objectives to receive significant improvement as a result of the project.

9.0 Conclusion

The objective of this project was to design a process improvement plan for RCC's AFO production that will decrease lead time, increase productivity and production capacity, and stabilize workflow. The process improvement plan successfully meets the objectives and therefore meets the client's needs.

The project was completed using two stages. The first stage involved investigating Lean strategies and selecting ones applicable to the project. The second stage involved creating solutions specific to improving the processes at RCC based on the strategies chosen in the first stage. The best concepts were then developed and merged to produce the final recommendation. The main differences between RCC's original production process and the engineered recommendation process is the removal and combination of several steps. This streamlines the process and removes non-value-added wait time. The new process eliminates the clinician's responsibility of cleaning up the foam model, and shortens many other activities

the clinician is involved in, lowering the optimal clinician-to-technician ratio. This increases capacity, increasing potential utilization of technician hours.

The process improvement plan includes five major methods that achieve the projects objectives. The first method will reduce lead time for RCC by scanning and modifying the mold immediately after the initial consultation. The second recommendation is to modify the fiberglass cast rather than the foam mold as well as to have the technician clean up the foam mold. This will eliminate the transfer of the positive mold between the clinicians and technicians. The third recommendation is to use mock pads during the initial casting to create reliefs in the fibreglass cast. This saves time during modification of the 3D model in CANFIT. The fourth method to reduce lead time is process standardization, which removes variability by using standard-sized pre-made control strap and lateral malleolus pads and cork heels to be used in AFO fabrication. Lastly, continuous improvement strategies were developed to be used by RCC to sustain the changes and benefits from the other four process improvement methods.

Under ideal conditions, implementing the changes suggested in this report, it was predicted that RCC's lead time could reach a minimum of 3 days. If wait periods that were not the subject of the report were left untouched, the lead time of the AFO would be two weeks, compared to the current six-week lead time. The optimal clinician-to-technician ratio would be 1:1, matching exactly with RCC's existing staff ratio. Capacity can be increased to a maximum of 162 units per month, but it is suggested that RCC continue to plan for the existing average of 115 units per month, working out to about two AFOs per day per clinician/technician team. The additional time can be used to test and adapt the recommendations presented here until they perform as intended.

10.0 References

[1] Rehabilitation Center for Children, "Rehabilitation Engineering," 2019. [Online]. Available: http://rccinc.ca. [Accessed 14 September 2019].

[2] R. Bancroft, T. McDonough, J. Shakespeare and K. Lynas, "Orthotics," *European Geriatric Medicine,* vol. 2, pp. 122-125, 2011.

[3] K. A. Ball and M. J. Afhelt, "Evolution of Foot Orthotics - Part 2: Research Reshapes Long-Standing Theory," *Journal of Manipulative and Physiological Therapeutics,* vol. 25, pp. 125-134, 2002.

[4] C. M. Bono and W. S. Berberian, "Orthotic Devices - Degenerative Disorders of the Foot and Ankle," *Foot and Ankle Clinics,* vol. 6, no. 2, pp. 329-340, 2001.

[5] M. A. de Souza, M. M. L. Figueiredo, C. R. de Baptista, R. D. Aldaves and A. C. Mattiello-Sverzut, "Beneficial effects of ankle-foot orthosis daytime use on the gait of Duchenne muscular dystrophy patients," *Clinical Biomechanics,* vol. 35, pp. 102-110, 2016.

[6] K. Kane, K. Musselman and J. Lanovaz, "Individualizing the ankle angle in ankle-foot orthosis: Effects at the knee for children with cerbral palsy and equinus," *Gait & Posture,* vol. 65, pp. 128-129, 2018.

[7] C. Korstrom and M. Gale, Interviewees, *Rehabilitation Center for Children.* [Interview]. 13 September 2019.

[8] Cascade Orthotics Ltd., "Ankle-Foot Orthosis (AFO)," 2019. [Online]. Available: http://www.cascadeorthotics.com. [Accessed 14 September 2019].

[9] Tillges Technologies, "Custom Bracing," 2019. [Online]. Available: http:///www.tillgestechnologies.com. [Accessed 14 September 2019].

[10] Y.-a. Jin, J. Plott, R. Chen, J. Wensman and A. Shih, "Additive manufacturing of custom orthoses and prostheses - a review," in *CIRP 25th Designn Conference Innovation Production Creation,* 2015.

[11] C. Korstrom, *AFO Design Pictures for IDEA Project,* Winnipeg: [private communication], 2019.

[12] A. Hill, Interviewee, *RCC Fabrication Process.* [Interview]. 12 October 2019.

[13] C. Korstrom and A. Hill, Interviewees, *Review of Concept Definition Report.* [Interview]. 8 November 2019.

[14] C. Korstrom, *AFO Process Timeline,* Winnipeg, 2019.

[15] Vorum, "Canfit 3D CAD Prosthetic and Orthotic Design Software," 2019. [Online]. [Accessed 21 November 2019].

[16] Stantec Consluting Ltd., *Workstation Numbering for T.I. Data Partial Second Floor Plan - Part A,* Winnipeg, 2015.

[17] C. Korstrom, Interviewee, *Re: Final Questions.* [Interview]. 2 December 2019.

[18] R. Suri, Quick Response Manufacturing, Portland, OR: Productivity Press, 1998.

[19] C. Korstrom, "RCC Manufacturing Process Videos," Rehabilitation Center for Children, Winnipeg, 2019.

[20] Acor Orthopaedic, "Acor P-Cell EVA Foam," 2019. [Online]. Available: https://store.acor.com/acor-p-cell-eva-foam/. [Accessed 6 November 2019].

[21] ASQ, "CONTINUOUS IMPROVEMENT," ASQ, [Online]. Available: https://asq.org/quality-resources/continuous-improvement. [Accessed 21 November 2019].

[22] S. Gerasin, "SCANNED HUMAN FOOT AND LEG," 20 November 2019. [Online]. Available: https://grabcad.com/library/scanned-human-foot-and-leg-1.

Appendix A: Needs, Constraints, and Limitations

List of Tables

The following information is adapted from the Project Definition Report, and provides a detailed explanation of the needs, constraint, and limitations. Section numbers refer to section numbers of the Project Definition Report.

The client's needs are itemized here, in order to better understand the purpose of the project. Associated with each need is an importance ranking. These needs and rankings will be reviewed with the client and are summarized in Table A-I. For the importance rankings, 3 indicates "high", 2 indicates "medium," and 1 indicates "low." Low importance needs may not necessarily be low in importance generally but have an anticipated low importance to or low impact on the project.

TABLE A-I: CLIENT NEEDS FOR THE AFO PRODUCTION PROCESS

ID	Need	Rank
	Procedural Needs	
1	The production process creates an AFO that is satisfactory to RCC standards	2
1a	The production process obtains a geometrical representation of the patient's anatomy	2
1b	The production process generates an AFO device based on that geometry	2
1c	The production process modifies the device until it passes clinician's assessment	2
	Suitability Needs	
2	The production process is easy to follow and implement	2
3	The production process accommodates walk-in and sudden clinic time	1
	Improvement Needs	
4	The production process facilitates a reduction to the lead time of an AFO	3
5	The production process facilitates improvement of the uses of RCC's human resources, specifically approaching an optimal clinician to technician ratio	3
6	The production process maximizes capacity	2
7	The production process reduces the work-in-progress inventory of AFOs	1

Needs have been arranged into several categories. It may be generally said that the procedure must generate a satisfactory AFO (need 1); however, in order to make this somewhat more useful to the design process, it has been broken down into three main stages, which must all be accomplished. These could have been further broken down, but at risk of implying a solution in the need statements.

Suitability needs describe how well the process works in the real world. Need 2 indicates that the process must be "easy," taking as a benchmark the current process. Process changes suggested in the final report that would be significantly more challenging (requiring more cooperation from the patient, dexterity from the technician, etc) would likely never be implemented, and therefore would be not worth suggesting. As well, understanding must be built in for unforeseen circumstances encountered in day-to-day reality. Again, the current process is the benchmark for this.

Procedural needs and suitability needs are needs that the current process already meets. Any suggestions that are made may improve on the suitability needs, but certainly cannot cease to meet any of these needs. On the other hand, improvement needs describe things the process currently lacks, and are the true inspiration for the project. This is where the higher-ranking needs can be found, as they will receive more attention throughout the project.

The client has imposed several constraints, indicating elements of the process that cannot change. These are summarized in Table A-II.

TABLE A-II: CONSTRAINTS IMPOSED BY RCC

ID	Constraints
	Organizational
1	The number of clinicians or technicians cannot be reduced
2	The recommendation cannot reduce the number of AFOs produced
3	The clinician will maintain existing meeting slots with patient
4	The process will occur within RCC's facility
	Resources
5	The negative will continue to be manufactured using the fiberglass method
6	The modeling software and how it is used cannot be changed
7	The positive will continue to be manufactured with CNC carver
	Design
8	Thermoplastics are to remain the main material of an AFO
9	Major elements of AFO design are fixed
	Timeline
10	The project deadline is December 5, 2019

Organizational constraints refer to legal and logistical constraints that are imposed at a level completely beyond the control of anyone actively involved in the project. These are enforced by labour laws, the current AFO market, and RCC organizational policies.

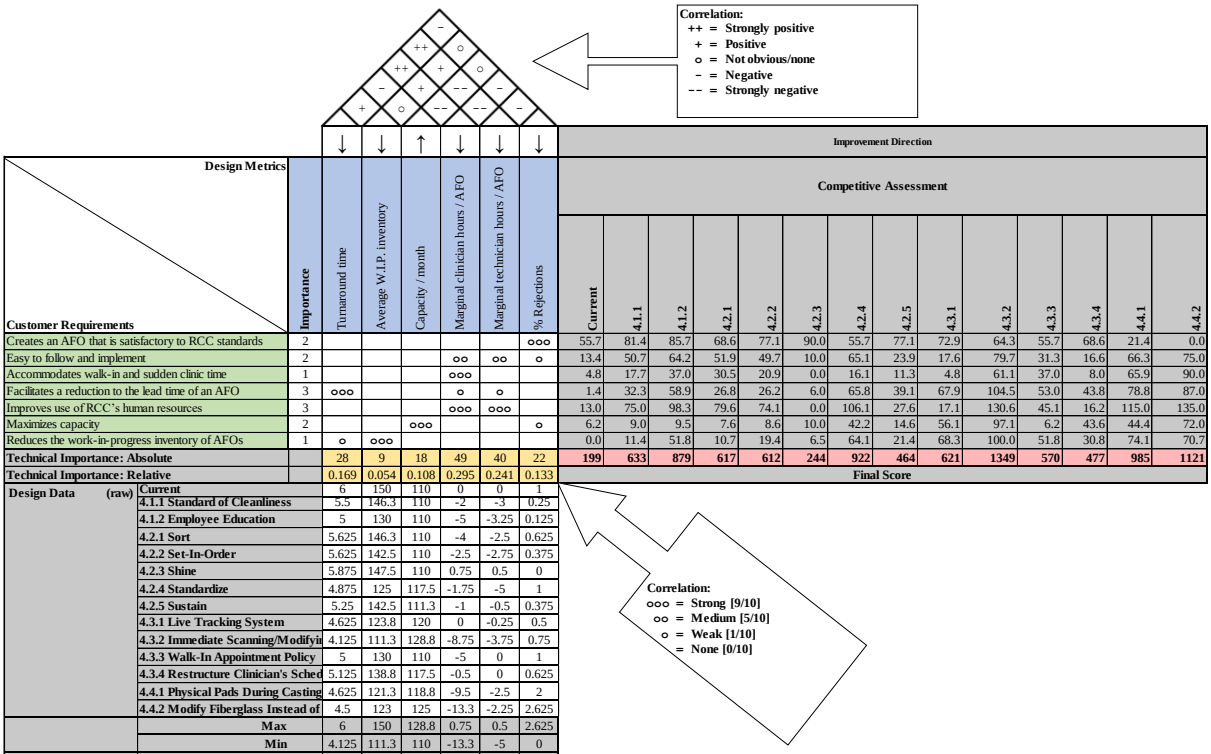
Constraints #5-7 are imposed because of the capital already invested in equipment that the organization is not willing to change. A solution suggestion that does not require a positive mold at all, however, may still be suggested (although this is quite unlikely). The constraint is saying that *if* a positive mold is to be manufactured, it must be done using the CNC carver – and likewise for #5 and #6.

As indicated by constraints #8-9, the design of the AFO is essentially fixed. Section 2.3 outlines what all the design entails. Certain non-critical elements of the design may be open to change. For a design change to be considered, it must not require medical expertise, and must not affect the functionality of the end product. If a design change is fundamental to a major part of the final process improvement plan suggested, consideration of the design change must be approved by certified orthotic clinicians at RCC prior to any further development of the plan based on that design change.

Since RCC produces AFOs custom to each individual, dimensions and tolerances for the final product are not available. However, guidelines indicating quality and acceptability of the design and the technical requirements of the process were discussed in Section 2.4. This could also be considered an expansion upon Needs 1a-c (see Table A-I), although were considered too solution-specific to be directly included in the needs statement.

Appendix B: House of Quality

The House of Quality is included as per the advisor's request. See a digital copy if unreadable in print.



Design Metrics / Customer Requirements	Importance	Turnaround time	Average W.I.P. inventory	Capacity / month	Marginal clinician hours / AFO	Marginal technician hours / AFO	% Rejections	Current	4.1.1	4.1.2	4.2.1	4.2.2	4.2.3	4.2.4	4.2.5	4.3.1	4.3.2	4.3.3	4.3.4	4.4.1	4.4.2
		↓	↓	↑	↓	↓	↓	Improvement Direction													
								Competitive Assessment													
Creates an AFO that is satisfactory to RCC standards	2						ooo	55.7	81.4	85.7	68.6	77.1	90.0	55.7	77.1	72.9	64.3	55.7	68.6	21.4	0.0
Easy to follow and implement	2				oo	oo	o	13.4	50.7	64.2	51.9	49.7	10.0	65.1	23.9	17.6	79.7	31.3	16.6	66.3	75.0
Accommodates walk-in and sudden clinic time	1				ooo			4.8	17.7	37.0	30.5	20.9	0.0	16.1	11.3	4.8	61.1	37.0	8.0	65.9	90.0
Facilitates a reduction to the lead time of an AFO	3	ooo			o	o		1.4	32.3	58.9	26.8	26.2	6.0	65.8	39.1	67.9	104.5	53.0	43.8	78.8	87.0
Improves use of RCC's human resources	3				ooo	ooo		13.0	75.0	98.3	79.6	74.1	0.0	106.1	27.6	17.1	130.6	45.1	16.2	115.0	135.0
Maximizes capacity	2			ooo			o	6.2	9.0	9.5	7.6	8.6	10.0	42.2	14.6	56.1	97.1	6.2	43.6	44.4	72.0
Reduces the work-in-progress inventory of AFOs	1	o	ooo					0.0	11.4	51.8	10.7	19.4	6.5	64.1	21.4	68.3	100.0	51.8	30.8	74.1	70.7
Technical Importance: Absolute		28	9	18	49	40	22	**199**	**633**	**879**	**617**	**612**	**244**	**922**	**464**	**621**	**1349**	**570**	**477**	**985**	**1121**
Technical Importance: Relative		0.169	0.054	0.108	0.295	0.241	0.133	**Final Score**													

Design Data (raw)						
	Current	6	150	110	0	0	1
	4.1.1 Standard of Cleanliness	5.5	146.3	110	-2	-3	0.25
	4.1.2 Employee Education	5	130	110	-5	-3.25	0.125
	4.2.1 Sort	5.625	146.3	110	-4	-2.5	0.625
	4.2.2 Set-In-Order	5.625	142.5	110	-2.5	-2.75	0.375
	4.2.3 Shine	5.875	147.5	110	0.75	0.5	0
	4.2.4 Standardize	4.875	125	117.5	-1.75	-5	1
	4.2.5 Sustain	5.25	142.5	111.3	-1	-0.5	0.375
	4.3.1 Live Tracking System	4.625	123.8	120	0	-0.25	0.5
	4.3.2 Immediate Scanning/Modifyi	4.125	111.3	128.8	-8.75	-3.75	0.75
	4.3.3 Walk-In Appointment Policy	5	130	110	-5	0	1
	4.3.4 Restructure Clinician's Sched	5.125	138.8	117.5	-0.5	0	0.625
	4.4.1 Physical Pads During Casting	4.625	121.3	118.8	-9.5	-2.5	2
	4.4.2 Modify Fiberglass Instead of	4.5	123	125	-13.3	-2.25	2.625
	Max	6	150	128.8	0.75	0.5	2.625
	Min	4.125	111.3	110	-13.3	-5	0
Normalized Data (score out of 10)	Current	0	0	0	0.536	0.909	6.19
	4.1.1 Standard of Cleanliness	2.667	0.968	0	1.964	6.364	9.048
	4.1.2 Employee Education	5.333	5.161	0	4.107	6.818	9.524
	4.2.1 Sort	2	0.968	0	3.393	5.455	7.619
	4.2.2 Set-In-Order	2	1.935	0	2.321	5.909	8.571
	4.2.3 Shine	0.667	0.645	0	0	0	10
	4.2.4 Standardize	6	6.452	4	1.786	10	6.19
	4.2.5 Sustain	4	1.935	0.667	1.25	1.818	8.571
	4.3.1 Live Tracking System	7.333	6.774	5.333	0.536	1.364	8.095
	4.3.2 Immediate Scanning/Modifyi	10	10	10	6.786	7.727	7.143
	4.3.3 Walk-In Appointment Policy	5.333	5.161	0	4.107	0.909	6.19
	4.3.4 Restructure Clinician's Sched	4.667	2.903	4	0.893	0.909	7.619
	4.4.1 Physical Pads During Casting	7.333	7.419	4.667	7.321	5.455	2.381
	4.4.2 Modify Fiberglass Instead of	8	6.968	8	10	5	0

Appendix C: Project Management Plan

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C.1 Scope Management Plan

The project scope is defined by the entire team, including Team Manager, Secretary, Coordinator, and Logistician to monitor both depth and clarity. Metrics for management include individual tasks, project milestones, team and client meetings, and Gantt Charts. These metrics will be used to monitor the scope throughout the entirety of the project. Changes to scope may only be made with an approved change request. A change request may be presented at a team meeting and is subject to the review of each team member and the team advisor. Only upon approval may a change to the scope be implemented. If the change is deemed more than a communication error a majority vote will be required in order to approve an amendment.

C.1.1 Work Breakdown Structure & Project Schedule

A Work Breakdown Structure (WBS), and Project Schedule were created as a further reference. The WBS is a useful tool which can be used to avoid scope creep, and it provides a clear visual of the major tasks to complete the project. The WBS is found below in Figure C:

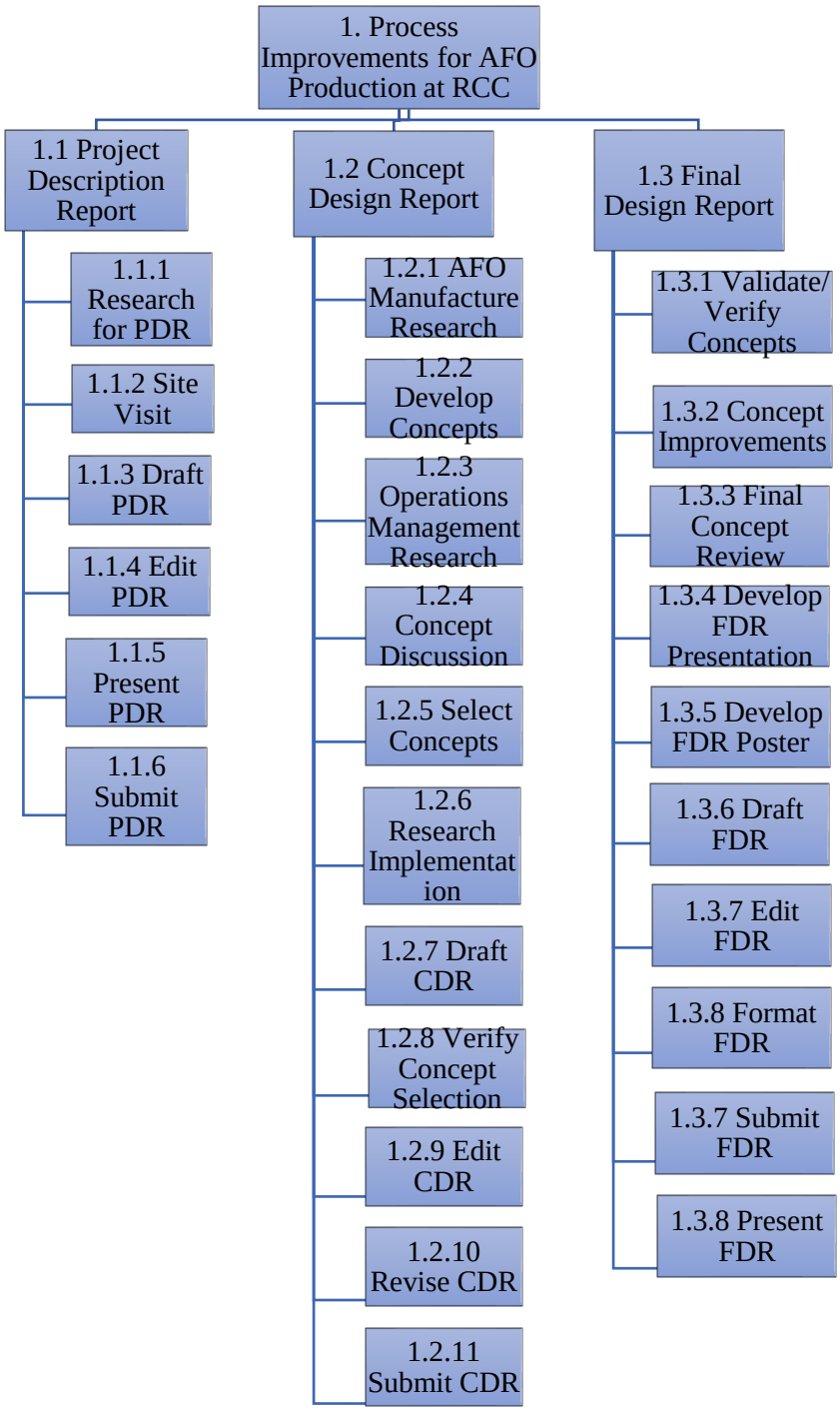

Figure C-1: Project's work breakdown structure

The Project Schedule lists major milestones and can also be used as a metric to measure progress throughout the project. A schedule management plan was created to further define team expectations regarding major tasks. The major tasks are listed in Table C-I with completion dates up until the final submission due December 4, 2019:

TABLE C-I: PROJECT TASK SCHEDULE

Task Name	Date Complete
Project Definition Report	**Oct. 7**
Research for PDR	Sep. 23
Site Visit/Current Operations Research	Sep. 13
Draft PDR	Sep. 23
Edit PDR	Sep. 27
Present PDR (oral)	Oct. 7
Submit PDR	Sep. 30
Concept Design Report	**Oct. 25**
AFO manufacturing research	Oct. 2
Develop concepts	Oct. 11
Operations management research	Oct. 03
Concept discussion with RCC	Oct. 11 (Tentative)
Select concepts	Oct. 16
Research Implementation Feasibility	Oct. 15
Draft CDR	Oct. 17
Verify concept selection with RCC	Oct. 18
Edit CDR	Oct. 22
Revise and update CDR	Oct. 24
Submit CDR	Oct. 25
Final Design Report	**Dec. 5**
Validate/Verify concepts	Nov. 13
Concept improvements	Nov. 14
Final concept review	Nov. 15
Develop FDR presentation/poster	Nov. 27
Draft FDR	Nov. 18
Edit FDR	Nov. 26
Format FDR	Nov. 27
Submit FDR	Dec. 4
Present FDR (oral, poster)	Dec. 5

C.2 Schedule Management Plan

The project schedule will be managed using a networked Gantt chart as it will provide a benchmark for the team to determine early and late start dates for individual tasks, milestones and important dates. The team also agreed to set review dates for all major documents a minimum of one week prior to

submission. This includes tentative final drafts for each of these documents, in order to provide what was deemed ample time for final revisions and alleviate stresses associated with late or hurried completion.

The process is split into three sections, one for each report that is to be handed in. Each phase cannot begin until the previous one has been handed in, which is noted in the Gantt chart by having those tasks as predecessors. Client meetings will be determined by discussing with RCC when the time is appropriate, but we will tentatively plan to have one meeting at RCC before each report is due and two before the final report draft is due to ensure that the project is staying on schedule and moving in the correct direction.

C.3 Resource Management Plan

The resource management plan will account for available resources and specify the responsibilities for each individual resource. Resources can be broken down into Human, Software, Monetary, Facility, and Material resources.

Human resources include Team Manager, Secretary, Logistician and Coordinator as internally. External human resources include The Technical Communication advisory, Professor, Advisor, and the client; RCC. Human resources will be used primarily for either consult or task completion. Tasks will be shared equally by the four team members. Task assignment and breakdown are listed in the WBS.

Additionally, any electronic software used for the completion of the project is considered a resource including the Microsoft Office Suite, OneDrive, University of Manitoba Library Services, and any other software that will be used for research and content generation. The software to be used is primarily provided by the University of Manitoba and therefore is readily available. To manage this resource each team member ensured they had all the necessary software for the project available to them prior to the second weekly meeting. This will limit the possibility of negative impacts due to Software resource management.

Monetary Resources include the funding available for project completion which will be used to cover report and poster printing costs, parking costs and any other costs associated with travel. Any other costs will be reviewed by the team and if approved by majority vote sent for approval by the course professor.

Facility and Material resources include all spaces which are used for presentations, demonstrations, meetings or project related testing. These resources do not have an associated cost however they must be managed by booking spaces that must be well in advance to ensure a shortage of this resource does not occur. This may mean that spaces for major tasks are booked further in advance than for others to mitigate the risk of not having a space available.

C.4 Stakeholder Management Plan

This section covers the major stakeholders that stand to benefit or lose from the outcome of this project. The following Table C-II outlines the major stakeholders as well as their roles, expectations, influence and further details relating to this project. The data tabulated below will aid the effective management of the stakeholders and their expectations as the project continues. The table lists only major stakeholders for the sake of brevity however minor stakeholders are present and will be monitored with a lesser priority throughout the project in team meetings with and without the team advisor.

TABLE C-II: STAKEHOLDER MANAGEMENT PLAN

Name of Stakeholder	Designation	Role	Type	Type of Communication	Expectations	Impact
Samantha Rosenberg	Student	Team Manager	Internal	Weekly meetings, emails and group chat	Project Scheduling, team meetings, distributing work, ordering parts.	High
David Pries	Student	Team Coordinator	Internal	Weekly meetings, emails and group chat	Point of contact between client and team.	High
Ben Gibson	Student	Team Secretary	Internal	Weekly meetings, emails and group chat	Recording and compiling major information from meetings.	High
Heather Pankratz	Student	Team Logistician	Internal	Weekly meetings, emails and group chat	Organization of team regarding meeting location and document completion.	High
Sean O'Brien	Professor	Advisor	External	Emails, Weekly Meetings	Promoting and helping the group to generate high quality solution.	Medium
Paul Labossiere	Customer	Professor	Internal	Emails, Report Criteria/ Feedback	Provide feedback & guidance throughout the project	Medium
Rehabilitation Center for Children	Customer	Client	External	Emails, Meetings	Supply all requested facility information	Medium
Clinicians	Customer	Client	External	Emails, Meetings	Provide data for the project, explain existing AFO process, limitations, project constraints	High
Technicians	Customer	Client	External	Site visits	Identify bottlenecks in their daily work, communicate needs	High
AFO Patients	Community	End user	External	[-]	[-]	Low
Health Authorities	Government	Regulatory body	External	[-]	[-]	Low

C.5 Communication Management Plan

Communication will occur both internally between team members as well as externally between team members and stakeholders. The team will utilize predefined channels and scheduling to insure consistency in communication methods and frequency of communication. The team will also use a designated Coordinator to ensure clarity and continuity when communicating with the client.

The channels used for internal communication include face-to-face communication, electronic communication and written communication. Face-to-face communication will occur in the form of weekly meetings. Additional meetings will take place with electronic notice provided. Electronic communication will be used for distributing information and general discussion. WhatsApp will be used as the primary method for notices and general conversation regarding the project. Additionally, a shared OneDrive folder will be used as the primary storage of digital information pertinent to the project. Finally, written communication will occur in the form of the Project Definition Report, Concept Design Report, and Final Design Report.

External communication with the client will utilize the same three channels of communication as internal communication, however meetings will be held less frequently with a minimum of one meeting per report stage. Electronic communication will remain primarily within email and between the Primary Contact and Team Coordinator. Written communication will include the three reports though only preliminary drafts will be required for the Project Definition Report and Concept Design Report. A final draft of the Final Design Report will be delivered to the client.

Changes to the determined communication channels, methods or the designated Coordinator may be made by an approved change request at any internal meeting with a minimum 1-day notice. Change requests must be approved by majority vote by team members.

C.6 Risk Management Plan

A risk management plan is important to ensure that any issues that arise throughout the course of the semester can be resolved without compromising the project. A risk register will help to plan for the events that may cause the project to be delayed or unsuccessful. By determining the severity (S), occurrence (O), and detectability (D) of each risk the team can focus on mitigating and avoiding the most critical risks. Risks can be from a variety of categories, such as schedule, budget, or design. One of the important mitigation techniques our team will use is to have slack time allocated in the schedule. By ensuring that we are consistently ahead of schedule and finishing reports with the desired 1-week slack time we can mitigate multiple risks at once, such as is shown in the risk register below.

The risk priority number (RPN) is calculated by multiplying the severity by the occurrence and the detectability. The higher the RPN the more necessary it is to avoid the risk if possible, because they are of a higher importance. Lower priority risks should still be mitigated or avoided but are less important. The criticality is similar; however, it does not consider the detectability.

TABLE C-III: RISK REGISTER

Risk	**Impact**	**S**	**Potential Cause/Trigger**	**O**	**D**	**RPN**	**Criticality**	**Advised Action(s)**
Report Drafts not completed on time	Group loses marks	7	Poor communication/ time management	3	3	63	21	Regular meetings, internal deadlines, slack time
Not being able to get in touch with client	Missing info for reports, scope creep	4	Poor communication or differing busy schedules	5	3	105	20	Planning meetings in advance
New process is too complicated to implement/ perform	Design is not helpful, process is not used	7	Team not aware of clinicians/technicians needs	5	5	175	35	Discussing possibilities with RCC in advance
New process budget is not accepted by WHRA	Design is not implemented	7	Sufficient justification not given	4	5	140	28	Reasonable budget is discussed with RCC
New process requires unavailable resources	Design is not implemented	7	No new clinicians are applying for jobs in Manitoba	7	4	196	49	Optimize ratio with what we have
Quality of AFO is not preserved in new process	AFO is not comfortable or helpful for patient	7	New process changes properties of material	4	7	196	28	Manufacturing process changes need extensive research

Appendix D: 5S Posters

Lean strategy posters have been created as per the client's request, to provide ideas and resources for a possible 5S Board.

AVOID

Defects

Overproduction

Waiting

Not utilizing talent

Transportation

Inventory excess

Motion waste

Excess processing

RCC'S 5S STANDARDS

RCC'S SIX SIGMA STRATEGY

GET TO THE ROOT CAUSE!

WITH THE 5 WHYS

Appendix E: QRM Quiz

The following is a quiz developed by Rajan Suri [1], who is a prominent Quick Response Manufacturing (QRM) writer and consultant. He has administered this quiz to hundreds of North American companies, and seen an average score of between 3 and 4 out of 10, highlighting how it challenges stereotypes, assumptions, and preconceived ideas within the world of manufacturing. The quiz is used with his permission[2]. Each question is a True/False question, and the answer is always False.

1. "Everyone will have to work faster, harder, and longer hours to get jobs done in less time."

Find new ways of doing the job; do not keep doing it the same way only with more stress. Be mindful of the Response Time Spiral. This is especially applicable to instant scanning and modifying by the clinician. It has already been acknowledged by one clinician at RCC that this would in fact be less work, so hopefully this is universally recognized [2].

2. "To get jobs out fast [sic] we must keep our machines and people busy all the time."

Traditional operations management states that the bottleneck of a process should be running at 100% capacity. In reality, this should only be the case if the bottleneck has 100% reliability. In the case of the clinician's schedule, planning for 100% capacity will result in a back-log due to unforeseen circumstances such as walk-in appointments and paperwork. Planning for only 2 appointments of each type a day, though it seems inefficient as the clinician's schedule is not fully booked, will prevent a back-log from building up.

3. "To reduce our lead times, we have to improve our efficiencies."

It is true in some sense, but QRM prefers to reverse the causality – reducing lead time will improve efficiency. However, traditional measures of improving efficiency tend to work counter to lead time reduction, because the calculation of efficiency tends to ignore aspects of waste of which the cost impact is unknown, such as wasted time transporting a product or storing it in inventory.

4. "We must place great importance on 'on-time' delivery performance by each of our departments and suppliers."

While it sounds good at first, if everything must always be on time, as soon as one or two products are not delivered on time, the company is tempted to increase the specified lead time. This is likely why

[2] Dr. Suri personally expressed interest in the project, and encouraged researching his more recent publications, on subjects such as POLCA and MCT [3].

RCC's lead time is currently 6 weeks. It may have been less at one time in the past, and after a particularly busy period where several appointments were missed, management decided to increase lead time to 6 weeks to enable everything to always be complete on time. At first, this works well. Over time, this leads to the Response Time Spiral, and soon 6 weeks is as hard to maintain as 4 weeks. Instead, RCC should relax expectations on always delivering on time, and instead focus on delivering in as short a time as possible.

5. "Installing a Material Requirements Planning (MRP) system will help in reducing lead times."

The common perception is that a centralized MRP system will ensure that no workstation ever runs out of material. However, if there is a failure in the MRP system, workers who are used to relying on it are taken by surprise. Instead, workers should manage their own workstation materials, with a simpler, more manageable system that is less prone to errors and when it does fail has less serious consequences. Material procurement was never discussed in any of the client meetings, likely because this already seems to be how RCC performs material procurement.

6. "Since long lead time items need to be ordered in large quantities, we should negotiate quantity discounts with suppliers."

Again, this is not a challenged faced by RCC. Lead time on the foam is 1-2 days, for example, as with most other components [4]. The principle here is to negotiate shorter lead times, not price discounts on larger quantities (which will inflate lead times even more).

7. "We should encourage customers to buy our products in large quantities by offering price breaks and quantity discounts."

This is even less relevant to RCC, and emphasizes the same principles as Question 6.

8. "We can implement QRM by forming teams in each department."

QRM cuts across departmental boundaries. Although the word "department" is not used to distinguish between clinicians and technicians at RCC, this is how this principle can be applied. The team should be a single clinician and a single technician. This is already done quite well, but some of the opportunities for improvement continue this idea, especially allowing the technician to modify the foam model after carving, based on trimlines on the fiberglass model.

9. "The reason for implementing QRM is so we can charge our customers more for rush jobs."

This question is not as relevant to RCC, since it is tied to the health service. The principle here is that QRM cuts cost without having to increase sell-price simply by reducing waste. This is part of lean.

10. “Implementing QRM will require large investments in technology.”

Likely RCC employees when they hear of a project to reduce lead time will anticipate hearing of a faster carver, a faster cooling process, or even a simpler AFO design or using additive manufacturing. However, this project has shown that significant reductions to the lead time can be made by implementing extremely simple organizational changes. Once these have been made, if further reduction in lead time is required, these may be implemented. However, to be truly impactful, they must simplify the entire process, rather than just accelerate a single step.

References

[1] R. Suri, Quick Response Manufacturing, Portland, OR: Productivity Press, 1998.

[2] C. Korstrom and A. Hill, Interviewees, *Review of Concept Definition Report.* [Interview]. 8 November 2019

[3] R. Suri, “RE: Permission to use my QRM Quiz.” [E-mail]. 30 November 2019

[4] C. Korstrom and M. Gale, Interviewees, *Rehabilitation Center for Children.* [Interview]. 13 September 2019.