The Application of Supra_Malleolar Orthosis (SMO) in Iraq: Design and Fabrication Approach

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Abstract. Due to the importance of the Supra-Malleolar Orthosis in providing treatment for the Iraqi patients, the design and fabrication of Supra-Malleolar Orthosis is presented. This includes studying the material properties and behaviour, and gait cycle for the patient. The experimental part incudes, ratification, molding with inner layer (soft). The material used is called (P-lite or EVA), molding with hard layer. It is polypropylene, reaching the final shape of SMO. Gait cycle for the patient was examined using force plate. Thus, it is found that the orthosis can be manufactured; and tests proved its successful application to satisfy the patient in a sense of comfort. SMOs improve the gait cycles. SMO manufacturing is successful and give good treatment results with low cost.

Keywords. Supra-Malleolar Orthosis (SMO), Gait cycle, Force plate.

1. Introduction
SMO is the abbreviation for Supra-Malleolar Orthosis. It, as with other orthoses, gets its name for the part of the body that it includes. Orthosis supports the leg just above the ankle or heel bone. SMO is considered the shortest ankle orthosis, or AFO. SMO is prescribed to patients who have soft, flexible and flat feet. SMO clothes are often worn by kids. The medical term for flat feet is flat feet and hyper-pronated feet. It is designed to keep the heel vertical or neutral while supporting the three arches of the foot. This can help improve the balance of standing and walking. Rizza et al. [1] suggested procedure utilizing computer aided design and the finite element method to develop a customized weight-bearing dynamic orthotic. Crenshaw et al. [2] studied and analyzed the effects of tone-reducing features in ankle-foot orthotics (AFOs) on the gait of eight children (age 4–11 years old). Kathy [3] explored the effects of a flexible supramalleolar orthosis (SMO), indicating pronation decrease associated with hypotonia, on postural stability in children with Down syndrome. Seven children were examined in the present study for tenweek period. Children with Down syndrome showed immediate and longer-term (after 7 weeks of use). Osama et al. [4] indicated that essential tools like foot orthoses, shoe modifications, and therapeutic footwear are useful for conservative management of different foot and ankle disorders. Danielle A. [5] developed a soft ankle support garment through user-centred research as an alternative to an AFO for the purpose of dressing up or participating in activities. There are many researches that deal with manufacturing and designing of SMO Orthesis. Many researchers worked in this field and studied the corresponding design developments of the Prostheses and Orthoses [6-20], some of them focused on the design procedures of the SMO. It was reported that the first development is Sure Step supramalleolar Orthosis, and the second Orthosis used as a Cascade DAFO #4. The results show that the Cascade DAFO #4 gives more response for treatment than the
Sure Step Orthosis. The training on using Prostheses and Orthesis are investigated by researchers such [21-35]. The products deal with Orthesis made by famous companies; they are costly and at the same times do not fit to the patient size. Therefore, it is important to develop the local manufacturing of orthosis in a scientific way. The research aims to manufacture the footstool within the available materials in Iraq and test its performance within the available practical tests.

2. Materials and methodology
This article deals with the material and apparatus used, case study which include the patient's information. Information involves causes of talipes calcaneo-valgus, the age of the patient, height of the patient and weight. Selection of materials from which SMO orthoses are made. Measurements procedure for how take SMO orthoses measurements. Manufacturing procedure of Supra malleolar Orthoses, hand casting involve making the negative mould, preparing for rectification which include making the plaster model and preparing the plaster model rectification, in rectification stage will be adding the plaster on the region which need add and sculpting to get the final plaster model, process for preparing plastic SMO which will be taking measurements of sheet of EVA and drape the EVA over the plaster model after heating EVA at the proper temperature, taking measurements for a sheet of polypropylene and drape the polypropylene after heating polypropylene at proper temperature and draw trim line to cut the orthosis, grind the trim line. In this case, it is not necessary to put on the straps because the orthoses will be inside the shoe.

2.1. Case study
The data was collected from a patient who suffers from talipes calcaneo-valgus by congenital cause for two feet. The age of the patient is about (7) years old with height (120 cm) and weights (22 kg). Patient wore insoles with arches to provide him a more normal and comfortable gait.

2.2. Manufacturing material
The materials that were used in manufacturing plastic SMO are as follow:

1- Polypropylene.
2- Ethyl Vinyl Acetate (EVA) is light synthetic rubber.
3- Materials for Jepson.

2.3. Measurement procedure of SMO
The following steps wave are considered:

1- Measuring the circumference which is in the supra malleolar (18cm).
2- Measuring the distance between the medial malleolus and the end of the heel (9cm).
3- Measuring the length of the foot (18cm).
4- Measuring the distance between the edges of the heel (4cm).
5- Measuring the distance between the head of the 1st metatarsal and the head of the 5th metatarsal (7cm).

2.4. Manufacturing procedure of SMO
After previewing the patient by the orthotist and knowing the ability of the patient to rehabilitation, the description of the orthotist indicates the type of orthosis, SMO. The manufacturing process of SMO is explained in the following steps:

A. Hand casting
1- Allowing the patient wear a sock to easy remove the cast.
2- Marking the protrusions of the patient which include head of 1ST metatarsal, distal head of the 5th metatarsal, navicular and M & L malleolus prominences as shown in Figure 1.
3- Placing the plaster bandage (3 layers) after immersing it in water from the bottom of the patient's foot to the top so that the bottom layers make a fissure of the top and along the mold to facilitate donning of the cast.
4- After using the plaster bandage, the researchers performed a longitudinal medial arch massage to elevate this area, which would help apply the ground reaction force theory later. Then the lateral malleolus side of the palm was pressed parallel to the leg pressing the medial malleolus vertically. This process helps to apply the theory of three points pressure.

5- The cast was removed from the patient. Figure 2 shows the finishing cast which is called (negative mold).

![Figure 2. Finishing cast (negative mold).](image)

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B. Preparing for pectification

1- Coat the inside of the cast with little of liquid soap. this helps to remove the cast from the plaster.

2- Putting on the location of fissure slap of plaster bandage; this prevents the plaster into force from the fissure location.

3- Put inside of the cast pipe of metal.

4- Fill the cast with plaster. It is important to install the cast in good position.

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C. Rectification

1- Prepare the tools that will be used for rectification which include knife, surform blades and buckle.

2- Remove the plaster model from the negative mold, the mold that appears after removing the negative mold is called (positive mold) as shown in Figure 3.

3- Install the plaster model on the installation device.

4- Putting the marks to be applied to the mould, which means the areas to be taken from, which need to be added to achieve 3PP system as shown in Figure 4.

![Figure 3. Positive mould.](image)  ![Figure 4. Clarification the marks in the positive mold.](image)

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5- After preparing the mould, the rectification will be necessary for the final positive mould to prepare for polypropylene SMO that as shown in Figure 5.

6- Add a light powder of plaster to fill small cavities and use buckle to get an outside surface smooth.
D. Process for preparing the plastic AFO

1- Adding EVA to improve comfort, and prevent skin breakage in patients with sensation loss and for orthoses used at night.

2- Cut the sheet of EVA according to the measurement of the positive mold. The thickness of the soft is (4mm), the length of the sheet is (37cm), the total length of the positive mold is (27cm) and add (10cm).

3- Glue the edges of the EVA, leaving one edge without glue; this edge will be positioned at the suction cone.

4- Heat the EVA at (187°C) for (3 to 5 minutes), depending on the thickness of the EVA and the performance of the oven available in Babylon Center for Prosthetics and Orthotics.

5- Drape the EVA manually over the plaster model and hold it in place until it has cooled completely, as shown in Figure 6.

6- Cut a sheet of polypropylene with length (37cm) and width (45), the thickness of polypropylene (4mm), the thickness depends on the patient’s weight.

7- The polypropylene sheet is heated at (187°C) for (25 to 30 minutes) depending on the thickness of the polypropylene.

8- Now the polypropylene can be draped over the plaster model, laying the polypropylene over the plaster model without stretching it with sticking it together along the anterior side, as shown in the Figure 7.

9- The polypropylene is tightened around the suction cone with a rope or something similar. Then, by opening the vacuum valve, the most of remaining air between the negative pattern and PP sheet will be removed. Leaving the plaster model to cold by air, the polypropylene model can be carved by special tool (vibrational cutter) as required.

10- Draw trim line on the polypropylene, draw trim line just over the malleolus.

11- Cut the orthosis with an oscillating saw, following the outline.

12- Remove the plastic shell from the plaster model.

13- Grind the orthosis trim line and smooth it.

14- In this design the straps for fixed the orthosis are not required, so the final design for the SMO orthosis is shown in Figure 8.
3. Results and discussion

There are two models of power plate used: the first is called Tekscan’s Walkway Pressure Assessment Systems and the second is AMTI Force Plate Form. Each one has functions and privileges that help to show acceptable results in this research.

3.1. Gait cycle with ground reaction force test

The gait cycle analysis was performed in the laboratories of the P & O Department at Al-Nahrain University on a strength panel (Texcan Passage Pressure Rating Systems). The Walkway system provides static and dynamic gait data, bare feet pressure and force measurements across multiple steps using a low-altitude ground walkway. It is ideal for capturing multiple foot strikes during natural or perturbed gait. The Walkway system is an essential tool for plantar pressures and gait studies for adult and paediatric patients, as well as the animal research as shown in Figure 9.

The ground reaction force was measured through walking by means of piezoelectric sensors distributed around the area of force plate. The data given from sensors were analysed through microcomputer and received to the desktop computer to output the results in the form of time tables, curves and contours. The main advantage of using force plate is its ability to measure the force distribution through small time steps and through foot area. It gives a brief view about pressure carried by feet through walking. Designing it in two areas allows to measure the pressure distribution with time for two feet, and then make a comparison between them, knowing the effect of one on the other.

Following the online measuring of pressure distribution, the centre of pressure can be monitored through walking, which give the decision to how can help the patient and improve the orthosis to makes the walking more comfort. Figure 10 shows patients walking on the strength board with the SMO. The results are discussed in detail for each case as follows:

3.1.1. Testing the patient without SMOs (barefoot).

The results of gait as shown in Table 1. The gait cycle parameter for patient with barefoot was shown in Table 2. It indicates that there is a variation for the parameters between the right foot and left foot. This is because of difference in the degree of deformity between them, as well as the human fact of depends on of his legs. Note* The difference is smaller between the left and right foot, and the greater the degree of deformity in both feet. The force variation through the gait cycle time is shown in Figure 11. Figures 12 and 13 show respectively Area mean load distributed on the area of the orthosis versus time and the pressure variation with time respectively.
### Table 1. Gait Table (Patient is barefoot).

|                   | Patient is barefoot |
|-------------------|---------------------|
| Number of Strikes | 8                   |
| Cadence (steps/min) | 83.7               |
| Gait Time (sec)   | 3.58                |
| Gait Distance (m) | 2.242               |
| Gait Velocity (m/sec) | 0.626             |

### Table 2. Gait Cycle table (sec) (Patient is barefoot).

| Gait Cycle Table (sec)                          | Patient is barefoot |
|-----------------------------------------------|---------------------|
| Left                                         | Right               | Difference        |
| Gait Cycle Time                               | 1.42                | 1.55              | 0.13              |
| Stance Time                                   | 1.07                | 0.93              | 0.13              |
| Swing Time                                    | 0.82                | 0.63              | 0.19              |
| Single Support Time                           | 0.61                | 0.57              | 0.04              |
| Initial Double Support Time                   | 0.06                | 0.01              | 0.05              |
| Terminal Double Support Time                  | 0.16                | 0.13              | 0.03              |
| Total Double Support Time                     | 0.31                | 0.31              | 0.00              |
| Heel Contact Time                             | 0.46                | 0.22              | 0.24              |
| Foot Flat Time                                | 0.19                | 0.46              | 0.27              |
| Mid stance Time                               | 0.53                | 0.22              | 0.31              |
| Propulsion Time                               | 0.52                | 0.38              | 0.14              |
| Active Propulsion Time                        | 0.43                | 0.23              | 0.20              |
| Passive Propulsion Time                       | 0.09                | 0.15              | 0.06              |

**Figure 11.** Force vs. time (Patient is barefoot).

**Figure 12.** Area vs. time (Patient is barefoot). Note Area mean load distributed on the area of the orthosis.

**Figure 13.** Pressure vs. time (Patient is barefoot).

3.1.2. *Testing the patient with SMOs.* The results of gait is shown in table 3.

The gait cycle parameters are recorded in Table 4. It shows that the variation between the feet decreases after using the presented SMOs. The force distribution developed under sole due to patient gait for two feet as shown in Figures 14 and 15.
3.2. Testing the patient with SMOs inside shoe
The results of gait are shown in Table 5.

Table 5. Gait table (patient with SMOs inside shoe).

| Gait Table                    | Patient with SMOs inside shoe |
|-------------------------------|-------------------------------|
| Number of Strikes            | 12                            |
| Cadence (steps/min)          | 76                            |
| Gait Time (sec)              | 6.32                          |
| Gait Distance (m)            | 3.786                         |
| Gait Velocity (m/sec)        | 0.599                         |
The main parameters are shown in Table 6, describing the gait cycle behaviour of a patient wearing SMO separately as the data mean for a complete gait cycle from heel to heel. It is noticeable that there is clear symmetry between the right foot and the left foot. The force distribution developed under sole due to patient gait for two feet is shown in Figures 16, 17 and 18.

### Table 6. Gait cycle table (sec) (patient with SMOs inside shoe).

| Gait Cycle Table (sec)                  | Patient with SMOs inside shoe |
|----------------------------------------|-------------------------------|
|                                        | Left | Right | Difference |
| Gait Cycle Time                        | 1.55 | 1.59  | 0.04       |
| Stance Time                            | 0.88 | 0.89  | 0.01       |
| Swing Time                             | 0.49 | 0.66  | 0.17       |
| Single Support Time                    | 0.66 | 0.72  | 0.06       |
| Initial Double Support Time            | 0.16 | 0.18  | 0.02       |
| Terminal Double Support Time           | 0.18 | 0.16  | 0.02       |
| Total Double Support Time              | 0.34 | 0.34  | 0.00       |
| Heel Contact Time                      | 0.46 | 0.41  | 0.05       |
| Foot Flat Time                         | 0.05 | 0.04  | 0.01       |
| Mid stance Time                        | 0.41 | 0.26  | 0.15       |
| Propulsion Time                        | 0.33 | 0.43  | 0.10       |
| Active Propulsion Time                 | 0.26 | 0.23  | 0.03       |
| Passive Propulsion Time                | 0.15 | 0.16  | 0.01       |

#### Figure 16. Force vs. time (patient with SMOs inside shoe).

#### Figure 17. Area vs. time (patient with SMOs inside shoe).

#### Figure 18. Pressure vs. time (patient with SMOs inside shoe).

### 3.3. Gait cycle with three point pressure control test

Gait cycle analysis was done in the laboratories of the Medical Engineering Department of Al-Nahrain University on force plate (AMTI Force Plate Form). AMTI currently has the units of gait, balance and power unit. This system determines the distribution areas of the pressure on the soles of the foot and determines the direction of forces on three axes (sagittal, coronal and transverse). It has the ability to analyze gait cycle and distinguish the phases of the step and identify the abnormal phenomena of that step, as shown in Figures 19.
3.4. The gait cycle test
The purpose of this test is to show the gait cycle curve for each of the three cases and compare them with the normal gait cycle curve and determine which of these cases is closer to the normal position. Figure 20 (a) is for left leg, while figure 20 (b) is for right leg. 1 is for gait cycle test for patient barefoot, 2 is for gait cycle test for patient wearing SMOs, 3 is for gait cycle test for patient wearing SMOs inside shoe, 4 is for 3PP (three point pressure) test. 5 is for patient wearing SMOs, and finally 6 is for patient wearing SMOs inside shoe. The objective of 3PP Control System on the ankle joint of the patient in the case of wearing the SMOs only and in the case of wearing SMOs inside the shoe and show the curves of this test and compare the result with the natural state. it was shown that the SMOs was improving the gait cycles.

![AMTI force plate](image)

**Figure 19.** AMTI force plate.
4. Conclusion and final remarks

- In the GRF test, the stability of the foot and the distribution of force on the Gait cycle phases are weak when the patient is bare, but the stability of the force also increases the distribution of force on the soles of the foot is increased regularly after the patient has reached the SMO only. The stability is very strong when the patient is wearing the SMO inside shoe and the Gait cycle phases are remarkably regular.

- In the 3PP test, there is no correction rate for Talipes Calcaneo Valgus deformity in the foot when the patient is with bare foot. We note that the distribution of the load from the body to the foot on the inner side (medial) is more than the outside (lateral) of the foot. However, the correction is noticeable when the patient wears the SMO only because the internal wall of the SMO being a corrective force (F1) pushing the ankle joint from the medial to lateral, but this force is not sufficient to completely correct the deformation due to the absence of straps. The correction is clear and strong as the patient wears the SMO inside the shoe, here the shoe work as straps and strengthen the corrective force (F1) on the ankle joint.

- After applying the GRF and 3PP systems, SMO wear inside the shoe proved to be the best result in terms of Talipes Calcaneo Valgus deformation modification and the return of the Achilles tendon to the vertical position and also gives more stability.

- After removing the long arm of the brace and the sticker straps (this is what distinguishes the SMOs from the AFOs), the ankle joint has a certain amount of freedom for two Dorsiflexion/Planter flexion movements (These two movements are limited in AFOs), which gives the patient good movement and greater psychological comfort.

- The SMOs provides a high degree of cosmetic property, which is due to removing the long arm and the sticker straps.

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