The Impact of Novel 3D Printed Metamaterial Sole Charcot Restraint Orthotic Walker on Peak Vertical Ground Reaction Force in Patients with Charcot Neuroarthropathy

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Abstract
The purpose: Charcot neuroarthropathy is a chronic and progressive disease bone and joint degradation in limbs that have lost sensory function can be painful or painless. Synovitis, subluxation, instability and destruction are all figure of symptoms of affected joints. Trauma is believed to be a key initial element that symptoms exist, features of injury are foot deformities, bony prominence, and instability result from bonny fragmentation, fissures, and dislocation.Adapted Charcot restraint orthotic walker with rocker profiles design is one of the most useful shoes that has been cause the plantar pressure to be decreased. This type of orthosis facilitates “rocking” from heel contact to toe-off, helping the tibia to roll over the foot more smoothly and reducing both the range of motion of foot joint and pressure at plantar aspect, the current study is to asses a novel design sole of the CROW and replace the rocker bottom with a 3D printed metamaterial sole and the current study is to measure the impact of the Charcot neuroarthropathy subject during gait through peak vertical ground rection force using Nintendo wii force platform.
Subject:sixty participants with Charcot neuroarthropathic foot were randomized in a parallel group trial with concealed allocation, and assessor blinding. Participants were divided randomly in to two groups, Participants in the group A (n=30) were fitted with 3D printed metamaterial sole CROW. Participants in the group B (n=30) were fitted with generic rocker bottom CROW.
Procedure: the participants in both groups walk on the equipped walkway with the Nintendo Wii force platform to measure peak vertical ground reaction force in Newton. Data collected through four acceptable force platform strikes by the both study groups.**Results:** the 3D printed metamaterial sole CROW results showed a decrease in the vGRF in comparison to generic rocker bottom CROW , There was a significant decrease in the peak vertical ground reaction force in group A compared with group B treatment ($p = 0.00$) the statistical significance of (effect size) in the tests, $\eta 2$; a measure of effect size was high= $0.75 \geq 0.50$).
Conclusion: Results of the current study revealed decrease in peak vGRF for groups fitted with Charcot neuroarthropathic patients fitted with 3D printed metamaterial sole CROW in comparison to generic rocker bottom CROW group. That make a good potential for additive manufacturing in health care sector.
KeywordsCharcot neuroarthropathy joint, Peak vertical ground reaction force, 3D printed metamaterial Charcot restraint orthotic walker, Wii force platform.

1. Introduction

Off-loading the forefoot is an important clinical component in management of Charcot foot patients, repetitive microtrauma cause foot damage and ulcers in conjunction with infection as a reason of foot sensation loss. Charcot Neuropathic foot treatment protocol has many different methods of plantar pressure redistribution, both surgical and nonsurgical.**[1]** Less invasive modes of pressure offloading include, but are not limited to, casting techniques (total contact casts and cast shoes), specializedfootwear (removable walking walker), Adapted footwear with rocker profiles design is one of the most useful footwear that has been cause the plantar pressure to be decreased. This type of shoe facilitates “rocking” from heel contact to toe-off, helping the tibia to roll over the foot more smoothly and reducingboth the range of motion of foot joint and pressure at plantar aspect **[2]**, The CROW was initially developed for use in Stage I CN; however, more recently it is also proving effective in Stage III to preserve foot and ankle alignment. advocate the CROW for patients following surgical reconstruction, specifically after external fixation procedures. It is crucial to highlight that design and efficacy of the removable walker device relies greatly on patient adherence to wear it.Main aim of usage of CROW is to offload pressure from the foot and ankle and reduce plantar pressure in addition to providing immobilization and protection during the prolonged healing of difficult neuroarthropathic foot ulcers **[3].**

Generic rocker bottom CROW is a long-term custom-made device that essentially serves as a removable total contact cast (TCC) as an alternative with ease of application, durability and removable. The device is a custom molded, full-foot enclosure consisting of a polypropylene outer shell, plastizote padded inner lining as a soft bed and cushioned liner, a rocker bottom crepe sole is attached is attached to facilitate roll-off during walking **[4].**

3D printed metamaterial sole CROW; 3D printing is a type of additive manufacturing, i.e. creating objects by sequential layering, for pre-production or production. After creating a 3D model with a Computer Aided Designing (CAD) program, a printable file is used to create a layer design which is printed afterwards, while 3D printing is often more expensive than traditional techniques such as injection molding, it allows for greater flexibility and the creation of parts that would be impossible to produce using traditional methods. Computer-aided design (CAD), rapid prototyping (RP), and computer-aided manufacture (CAM) of physical models or even final items directly from 3D computer data can revolutionize the traditional manual design and manufacturing of tailored therapeutic solutions, metamaterial designed structure sole, consisting of several buckled rods, that has the ability to increase this Cushioning Parameter (CP) during gait motion **[5].** Because of its structure, a metamaterial exhibits a wide range of mechanical behaviors,the Metamaterial concept is said to have a higher Cushioning Parameter value, compared to the existing condition, the impact pressure has been spread out and the loading rate has been reduced. The metamaterial architecture can certainly enhance the pressure distribution and reduce the loading rate **[6].**

Wii balance board (WBB) force platform by Nintendo Co. Ltd. was used in this study as a portable low-cost force platform as it was evaluated in many studies for its feasibility as an instrument for the assessment of balance and mobility proficiency, as WBB measures were used for estimating posturography and biomechanical parameters related to the vertical ground reaction force tasks as an objective assessment **[7].**

2. Materials and Methods

2.1. Participants:

Sixty patients suffer from Charcot neuropathic foot divided in to two equal groups:

- Group A: thirty patients fitted with 3D printed metamaterial sole CROW.
- Group B: thirty patients fitted with generic rocker bottom CROW.

Patients was recruited from vascular surgery Departments of General Hospitals and privet clinics.

- **Inclusion criteria:**

Patient's ages ranged from 45 to 65 years, both sexes included in the study.

- **Exclusion criteria:**

The potential participants have been excluded if they meet one of the following criteria:
- Preceding surgical procedure on affected foot.
- Patients on hemodialysis.
- Patients who had any pathological conditions (active malignancy, osteomyelitis and pes planus)

2.2. Equipment:

2.2.1. Measurement equipment:

Force platform to measure peak vertical ground reaction force (Nintendo Wii balance board)

2.2.2. Therapeutic equipment:

- 3D printed metamaterial sole CROW.
- Generic rocker bottom CROW.

2.3. Procedures of the study:

2.3.1 Measurement procedures:

Measurement procedure of peak vertical ground reaction force (Wii balance board force platform): Plantar vertical ground reaction force (vGRF) obtained at a rate of 100 Hz measured by Nintendo Wii Balance Board WBB through a four strain gauge sensors (uniaxial vertical force transducers) located at the corners of the board with a usable size of 45 x 26.5 cm were used for data collection **Figure 1;** wirelessly via Bluetooth by using third party software illustrates the peak vertical GRF force parameter **[8]**. The force platform is mounted longitudinally inside the gait analysis walkway 1-2 mm away from the line of propagation to measure a single leg stance during walking across the walkway 7 m long **Figure 2[9]**.Each group wear the CROW specified for each group and the protocol of gait analysis testing starts with a reacclimation period during which the subject walked usual freely walking across the path for a duration of four minutes and then the testing session data collection done by four acceptable force platform strikes for the feet fitted with the CROW. All results are averages of four such peak values from successive trials **[10]. Figure 3**

2.3.2. Therapeutic procedures:

- **3D printed metamaterial sole CROW:** The Charcot Restraint Orthotic Walker (CROW) consists of anterior and posterior shells creating a total contact environment based on a rocker sole. the sole is manufactured by 3D printed metamaterial,Manufacture of the 3D printed sole of the CROW paths through two stages; Computer aided designing (CAD) and computer aided manufacturing (CAM), The resulting 3D printed Metamaterial Sole is then attached to the CROW from underneath The patient is then fitted with the orthosis and initiat the gait procedure on the walkway as described previously and the data of the vGRF is collected through out the session by the Wii force platform. **[11].Figure 4**

- **Generic rocker bottom CROW:**
  It consists of (two piece) design that provides complete contact around the leg over the shin, calf and foot as the patient leg measurements was taken by plaster cast. The CROW reduces all motion in the ankle joint and foot to reduce potentialfor further injury. It is fully padded on the inside, and the bottom is rocker designed. It is not worn with a shoe **[12]**. **Figure 5**

2.4. Statistical Procedures:

1. T-test for comparison of peak vertical ground reaction force.
2. The level of significance for all statistical tests was set at $p < 0.05$ **[13]**.
3. All statistical measures were carried out using the statistics software for social studies(SPSS) version 24 for windows

3. Results

Data obtained from both groups regarding peak vertical ground reaction force were statistically analyzed and compared and presented as follow:

3.1. Mean values of peak vertical ground reaction force of both groups (group A and group B):

The mean ± SD peak vertical ground reaction force of group A was 944.03 ± 197.18 N and that of group B was 952.00 ± 186.27 N. The mean difference between both groups was 7.98 . There was a non significant in the peak vertical ground reaction force the group A compared with group B although there is a clinical significance ($p = 0.87$). **(Table 1, Figure 6).**

3.2. Treatment mean differences values of peak vertical ground reaction force of both groups (group A and group B):

The mean ± SD peak vertical ground reaction force mean differences of group A was 34.34 ± 12.71 N and that of group B was 0.39 ± 7.01 N. The mean difference between both groups was 34.73 . There was asignificant decrease in the peak vertical ground reaction force in group A compared with group B treatment ($p = 0.00$) the statistical significance of (effect size) in the tests, η^2; a measure of effect size was high= $0.75 \geq 0.50$)**(Table 2, Figure 7).**

4. Conclusion

Within the limitation of the study, the notable conclusions is that both 3D printed metamaterial sole CROW and Generic rocker bottom CROW were of a significant benefit in managing patients with Charcot foot, a decrease in the peak vertical ground reaction force occurred through using the 3D printed metamaterial sole CROW, that was successfully measured by a low budget force platform (Nintendo Wii balance board).

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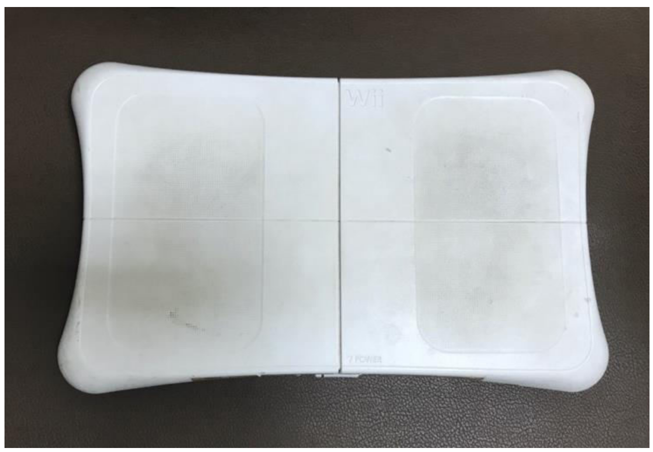

Figure 1. Nintendo Wii balance board force platform

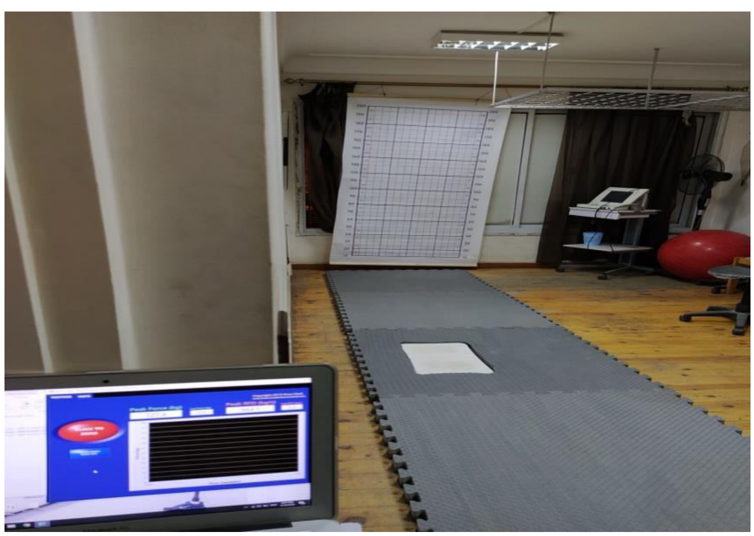

Figure (2): Gait analysis walkway

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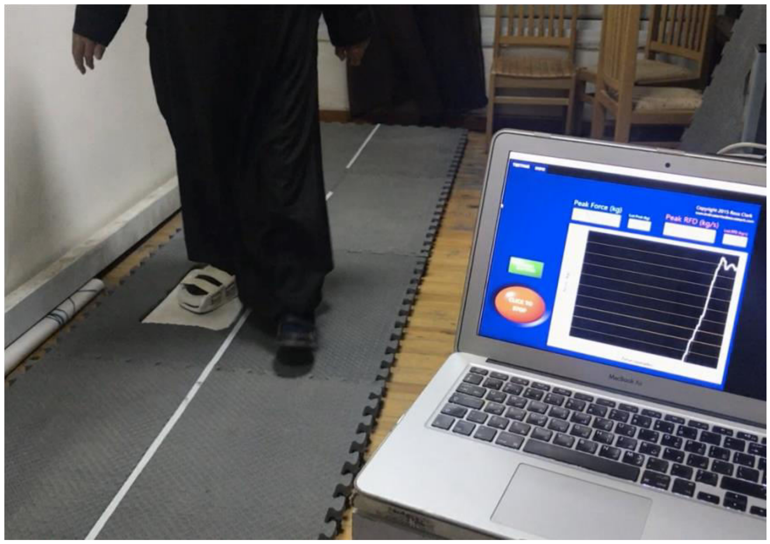

Figure 3. Patient trial on Walkway

Figure 4. 3D printed metamaterial sole CROW

Figure 5. Generic rocker bottom CROW

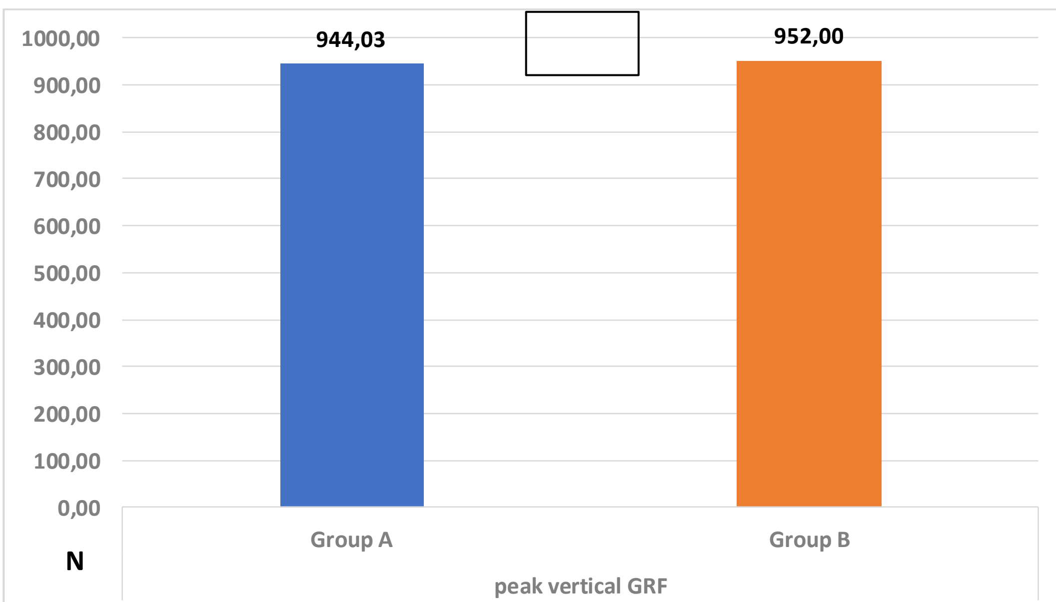

Figure 6. mean values of peak vertical ground reaction force of group A and group B

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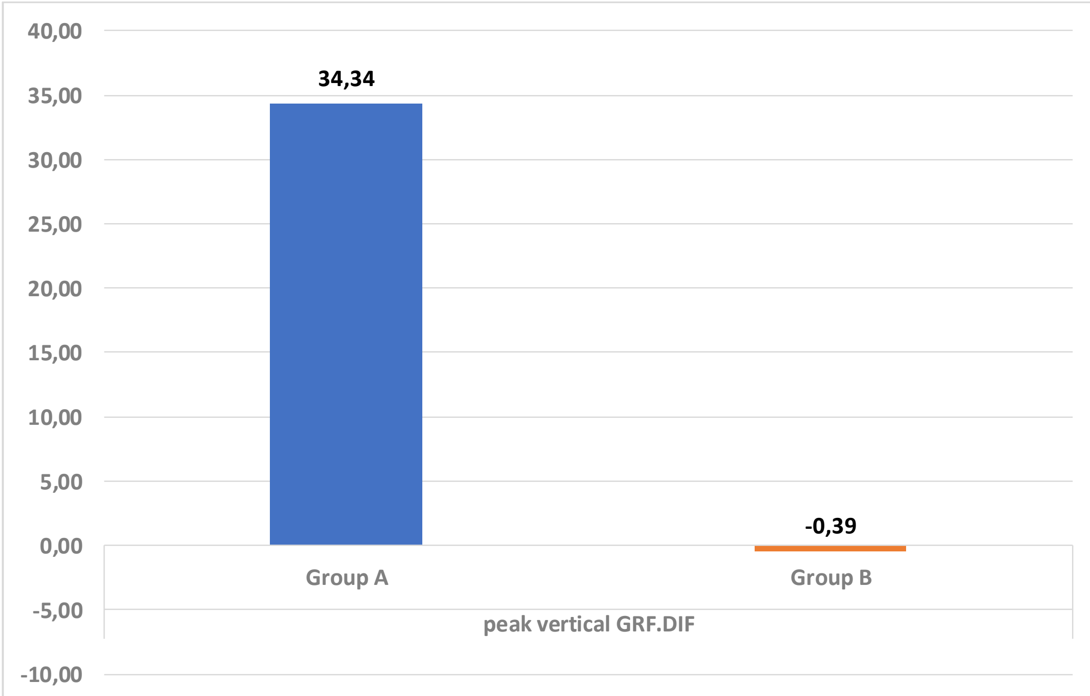

Figure 7. Treatment mean difference values of peak vertical ground reaction force of group A and group B.

Table 1. Comparison between post treatment mean values of peak vertical ground reaction force of group A and group B.

	Peak vertical ground reaction force(N) $\bar{X}$ ±SD	**MD**	**t- value**	**p-value**	**Sig**
Group A	944.03 ± 197.18	7.98	0.16	0.87	**NS**
Group B	952.00 ± 186.27				

$\bar{X}$: Mean MD : Mean difference p value : Probability value

SD : Standard deviation t value : Unpaired t value NS : Non Significant

Table 2. Comparison between treatment mean differences values of peak vertical ground reaction force of group A and group B.

	Wound surface area (N) $\bar{X}$ ±SD	**MD**	**t- value**	**p-value**	**Sig**	**η2**

Group A	34.34 ± 12.71	34.73	13.11	0.000	**S**	**0.75**
Group B	0.39 ± 7.01					

$\overline{X}$: Mean MD : Mean difference p value : Probability value

SD : Standard deviation t value : Unpaired t value S : Significant