CROW Design using OWLS™ Technology

shark-o™

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While the Charcot Restraining Orthotic Walker "CROW" has been in use for over thirty years, little in its design and materials has changed. The CROW orthosis has been the industry "gold standard" orthosis of choice for Charcot deformity by many, if not most healthcare providers.

Throughout the years, many materials have evolved to make the CROW somewhat lighter and stronger and a little more stable at the Charcot site. Some professionals have highlighted the need to reduce weight bearing at the Charcot deformity in the attempt to control further collapse of the fracture. To that end, some doctors prescribe patellar tendon bearing designs to further unweight the affected area. One major issue of these designs becomes apparent during periods of fluctuating edema.

For all of the CROW accolades in treating the Charcot foot, there can be just as many negatives. These issues tend to manifest in fitting and follow-up visits and can be real time consuming and challenging in an environment that is already "time taxed". When edema fluctuates in the leg, it changes the proper fit of the orthosis and can have a negative effect on the goal of reducing weight bearing and stabilizing the fracture site. Often a patient will return to the Orthotist in need of as much as 1" of padding in the tibia section (fig. 1). This adjustment to tighten up the calf circumference may often be removed days or weeks later due to fluctuating edema.

In 2014, during clinical trials for the OWLS/WHO™ product line, we saw that the basic Midfoot WHO design had better results unweighting the plantar surface of a patient's foot than that of his existing CROW orthosis. This finding led our team to begin testing a concept for a new CROW design using circumferential pressure in the calf region with the anterior portion of the orthosis underlapping the posterior portion, while maintaining the classic CROW design in the foot area (fig. 2). Such a design alleviates the need to continually add and subtract padding to accommodate for edema fluctuations allowing the patient to maintain total contact in the calf section. Further, we included the OWLS posterior window design that allows for easy heat adjustments should it be required and reduces the weight of the orthosis (fig. 3).

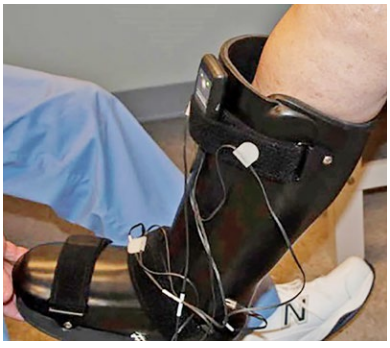

Figure 1

Figure 2

Figure 3

During clinical testing, we supplied each patient with one traditional style CROW orthosis and one OWLS shark-o. Each patient was casted using fiberglass casting tape. The cast was filled and the positive model modified to the patient requirements. The modified model was splash molded to create a duplicate positive mold so that each orthosis would be fabricated using the same modified mold.

Pressure Guardian™ pressure sensors were used to measure plantar foot pressure. Plantar foot pressure was recorded during patient ambulation at the heel, first and fifth metataral heads, and finally at the midfoot under the apex of the Charcot site.

While clinical testing is still ongoing, we have currently recorded fourteen patient Pressure Guardian tests resulting in as much as a 72% reduction of average midfoot pressure using a shark-o orthosis versus a traditional CROW. Testing showed a slight increase of average pressure at the heel in shark-o versus traditional CROW and improvement at the first and fifth metatarsal heads (fig. 4).

LOCATION	Max PSI CROW - AVG	Max PSI shark-o - AVG	% Improve
S1 = Heel	9.95	9.01	9%
S2 = Midfoot	6.01	1.47	76%
S3 = 1st Met Head	3.51	2.84	19%
S4 = 5th Met Head	4.67	3.58	23%
RANGE	6.44	7.55	

LOCATION	Avg. PSI CROW - AVG	Avg. PSI shark-o - AVG	% Improve
S1 = Heel	2.12	2.26	-7%
S2 = Midfoot	1.36	0.38	72%
S3 = 1st Met Head	0.66	0.31	53%
S4 = 5th Met Head	0.76	0.63	18%
RANGE	1.46	1.96	

Figure 4

Conclusion: Based on preliminary test results, the shark-o style CROW orthosis is a viable design that makes fitting and follow-up of the Charcot foot easier and more effective than the traditional CROW orthosis. The shark-o design features reduce both the weight of the orthosis and pressure to the plantar foot surface as compared to the traditional CROW orthosis.