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Open-source 3-D Printable Infant Clubfoot Brace

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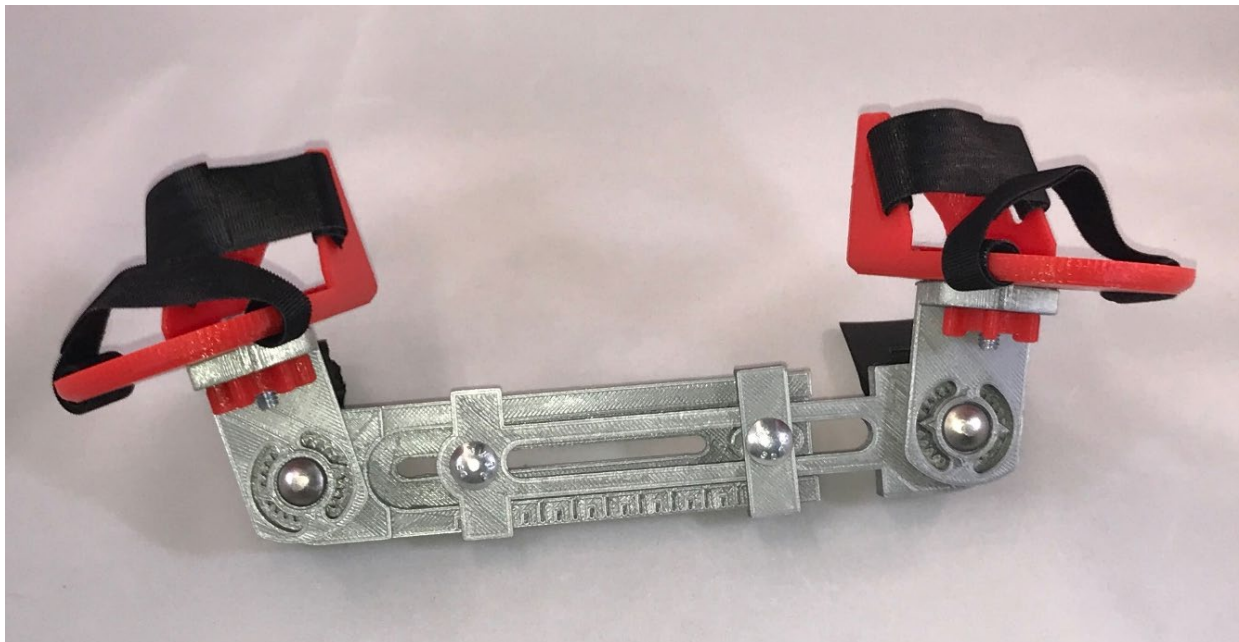
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Background

Open-source, self-replicating rapid prototypers (RepRaps) have radically reduced the costs of 3-D printing while expanding its access. 3-D printing's model of distributed manufacturing can produce medical technologies at significantly reduced costs. We investigate this potential by evaluating the viability of an open-source 3-D printable infant clubfoot brace.

Methods

Starting with a list of key features present in currently available clubfoot braces, a 3-D printed clubfoot brace was developed in free and open-source CAD software (FreeCAD) to enable future customization. Poly-lactic acid (PLA), a biodegradable and recyclable bioplastic was selected among the various commercial 3-D printable materials based on strength and cost.

Results

The results show that the open-source clubfoot brace matches or surpasses the physical features and mechanical degrees of freedom of all commercial- and non-profit-developed brace designs while substantially reducing the costs of the braces to hospitals and families.

Conclusions

The 3-D printed brace has the features of commercially available braces while significantly reducing the cost, making this clubfoot brace particularly appropriate for use in developing countries. In addition, the results indicated that this model of distributed manufacturing of medical technology is technically and economically appropriate through much of the Global South.

34 **Level of Evidence: II**

35 **Keywords:** clubfoot, clubfoot brace, foot abduction orthosis, 3-D printing, distributed
36 manufacturing.

37

38 **1. Background**

39 Congenital talipes equinovarus (clubfoot) is one of the most common congenital
40 physical deformities, with an incidence of at least one case per 1000 births¹⁻³. The condition is
41 characterized by infants being born with a foot in a position of cavus, forefoot adduction and
42 calcaneal equinovarus¹⁻³. The condition may be idiopathic or associated with other medical
43 conditions¹⁻³. In developed countries, clubfoot is identified before or at the time of birth and is
44 treated in early infancy⁴⁻⁸. Idiopathic clubfeet are effectively treated using the Ponseti method
45 of weekly manipulation and casting, followed by Achilles tenotomy and a bracing protocol
46 that includes a foot abduction orthosis (FAO or “boots and bar” brace shown in Figure 1) to
47 prevent deformity recurrence⁴⁻⁸. The child initially wears the brace full-time except for
48 bathing (> 95% of a typical day) for the first three months, followed by weaning it to nap and
49 nighttime wear until the age of four years⁴⁻⁸. In developing countries, where treatment options
50 may be far less available, however, clubfoot can lead to life-long disability⁹. In East Africa, in
51 particular, clubfoot may be at least twice as prevalent² with up to 8 cases per 1000 births¹⁰.
52 Even in situations where treatment is possible, the costs of the FAOs are expensive. If the
53 patients’ families do not comply with the FAO bracing after correction of the deformities,
54 relapse is common¹¹. While still more expensive to American and European families (> \$300
55 in the U.S. and Europe¹²), the cost of braces (bar and AFO) to families across the developing
56 world (\$150 in China¹³, \$90 - \$200 in Latin America¹⁴, and an average of \$60 in Africa¹⁵) can
57 still be prohibitively expensive.

58 3-D printing has been shown to be a positive method of democratizing manufacturing
59 for sustainable development, while radically reducing costs for products in marginalized
60 communities¹⁶⁻²⁰. This has been made possible by the technological evolution of the self-
61 replicating rapid prototyper (RepRap), an open-source 3-D printer that costs as little as a few
62 hundred dollars and can fabricate more than half of its own parts²¹⁻²³. The application of 3-D
63 printers in the developing world has enabled the manufacturing of necessities in the field
64 following humanitarian crises by groups such as Field Ready^{24,25}. In addition, these low-cost
65 open-source 3-D printers have been shown to be useful for fabricating both scientific and
66 medical equipment²⁶⁻³². It is thus possible that this method of distributed manufacturing could
67 be useful for producing low cost FAO for clubfoot patients.

68 To investigate the potential of distributed manufacturing of an FAO for clubfoot patients
69 in the developing world, this study makes a careful investigation of the use of RepRap 3-D
70 printers to fabricate an open-source clubfoot brace.

71

72 **2. Methods**

73 The methodology includes first selecting among the various commercial 3-D printing
74 materials based on material properties and cost, developing an open-source design using only
75 open-source tools, and describing the open-source 3-D printer used and the settings to fabricate
76 the clubfoot brace. Then, the brace’s features were examined to ensure that it met the required
77 features for foot abduction orthoses designed for treating clubfoot. Finally, this brace was then
78 examined by doing a cost and functionality comparison with existing designs.

79 **2.1 Material Selection**

80 In the RepRap community, poly-lactic acid (PLA), a biodegradable and recyclable
81 bioplastic, is the most popular 3-D printing material, being available from the vast majority of
82 3-D printing supplies vendors. PLA has a relatively low melting point, 150°-160°C, thus
83 requiring less energy to print - a distinct advantage for off-grid applications in the developing

84 world^{33,34}. The mechanical properties of RepRap 3-D printing materials are well established^{35,36}
85 and PLA has the highest strength to cost ratio for commercial 3-D printing filaments³⁷, and was
86 thus chosen for the brace in this study.

87 **2.2 Open-Source Design**

88 The open-source clubfoot brace was entirely designed with FreeCAD, an open-source
89 CAD software³⁸, which will enable customization or changes by anyone in the world with no
90 software costs. The design was made for ease of printing (e.g., minimizing overhangs and
91 material usage, while achieving strength and dimensional accuracy). It was created with the
92 intent of being able to meet criteria collected from the literature and shown in Table 1.

93 The features determined to be of importance in the design of the FAO are as follows:
94 (1) the ability to maintain foot positioning in order to prevent relapses, (2) the ability to adjust
95 the angle of abduction, (3) the ability to dorsiflex the feet is an optimal feature for proper
96 bracing^{12,39-41}. An adjustable width between the feet allows for a more cost effective product,
97 as the brace needs to be replaced far less frequently as the child grows. The ability of the foot
98 pads to move independently and attach and detach from the abduction bar increases comfort
99 and encourages proper usage⁴².

100 **2.3 3-D Printer Settings**

101 Although any RepRap class FFF 3-D printer capable of printing PLA, with or without
102 a heated bed could fabricate this open source design⁴³, the 3-D printer used to fabricate the
103 brace components was a MOST delta RepRap⁴⁴. Cura version 15.04.6⁴⁵ was the software used
104 to slice the CAD models into printing layers using the following settings: layer height of 0.2mm,
105 shell thickness of 1mm, fill density of 80%, print speed of 40mm/s, and a print temperature of
106 185°C.

107

108 **2.4. Cost Calculations**

109 A multivariable cost analysis was run on the three primary driving variables in the cost
110 of locally manufacturing the clubfoot brace - 1) labor cost, 2) filament cost, and 3) electricity
111 cost. Because economic specifics can vary greatly throughout the developing world, the cost
112 sensitivity analysis was performed using data collected on labor, electricity, and filament costs
113 in the context of manufacturing them in a single economy: Kenya. Clubfoot is especially
114 prevalent in Kenya, with clubfoot being the most common congenital malformation occurring
115 throughout the country with approximately 3 instances per 1000 children⁴⁶. Even when
116 subsidized, the cost of procuring braces in Kenya can be difficult for many Kenyan families⁴⁷.

117 Kenyan labor costs were varied from \$0 (volunteers or zero marginal cost for existing
118 employees that could periodically monitor the 3-D printer and do the simple assembly
119 procedure while doing other tasks) to \$1.30/hr (the government dictated wage for a Kenyan
120 machinist in an urban area⁴⁸) in \$0.10 increments. Three commercial filament sources were
121 found to be available in Kenya (prices, including shipping and VAT shown in Table 2). It should
122 be noted that these are real consumer costs in Kenya and not the costs per kg at the manufacturer.
123 These values were then compared to less than \$0.10/kg for filament generated by a recyclebot
124 (post-consumer waste plastic extruder capable of making 3-D printer filament from
125 thermopolymers)^{49,50}.

126 The electricity was varied between the cost to run a solar powered printer (\$0/kWh), to
127 21.08 KES/kWh (\$0.2029/kWh), which is the highest standardized rate for electricity in Kenya
128 based on January 2017 data⁵².

129 To calculate the total cost of producing the entire assembly, methodology from Laplume
130 *et al.*⁵³ was used and modified to include labor costs (Equations 1-5). Equation 1 shows the
131 components of the cost of the brace – electricity, materials, and labor.

132

133 $C = C_E + C_c + C_L + C_h$ **Equation 1**

134 Where

135 C = Total cost of producing the brace (\$)

136 C_E = Cost of electricity (\$)

137 C_c = Cost of filament consumed (\$)

138 C_L = Cost of labor (\$)

139 C_h = Cost of non-printed hardware (\$)

140 The cost of the electricity can be calculated with Equations 2 and 3.

141 $C_E = EC_u$ **Equation 2**

142 Where

143 E = Total energy usage (kWh)

144 C_u = unit energy costs (\$/kWh)

145 The energy used by the printer was measured directly with a multimeter (+/- 0.01 kWh)
146 and the value of C_u is dependent upon the cost of electricity fees at the site of manufacturing.

147 $E = P_p t + E_w$ **Equation 3**

148 Where

149 P_p = Average power use while printing (kW)

150 t = Time of print (hr)

151 E_w = Energy consumption for warming the printer (kWh)

152 The cost of filament consumed is calculated by looking at the cost of the filament per
153 kilogram and multiplying it by the number of kilograms used, as seen in Equation 4.

154 $C_c = m_p C_f$ **Equation 4**

155 Where

156 m_p = Mass of the filament used in print (kg)

157 C_f = unit cost of filament (\$/kg)

159 Finally, labor costs can be calculated with Equation 5. This assumes that the operator is
160 paid for the entire time the printer is in operation, though due to the automated nature of 3-D
161 printing, labor charges may only be incurred while preparing and completing prints.

162 $C_L = wt$ **Equation 5**

163 Where

164 w = Hourly wages (\$/hr)

165

166 **3. Results**

167 **3.1 Design and Biomechanics**

168 The final clubfoot brace, based upon the requirements discussed in section two, is shown
169 in Figure 3. There are 13 printed components in the clubfoot brace assembly (Figure 2). These
170 parts, their masses, their required printing time, and their estimated material costs (using PLA
171 costs of \$30/kg) can be seen in Table 3. The non-printed components can be seen in Table 4.
172 The total cost of the materials necessary to produce the clubfoot brace was found to be \$10.92
173 through totaling the values seen in Tables 3 and 4.

174 The base of the brace is comprised of top and bottom sliders together held together by
175 the closing bracket, two carriage bolts, and two nuts press-fit into printed flattened knob pieces.
176 The tightening and loosening of these knobs allows for adjusting the feet width. The minimum
177 width of the braces is 18 cm, and it can be extended to 27 cm according to the notches along
178 the edge of the slider piece. The brace should be adjusted to place the feet shoulder width apart,
179 and the distance between the feet should be increased as the child grows.

180 At the far end of the slider pieces are attachment points for the two angle brackets. These
181 brackets (Figure 3) can be printed at different angles to allow for dorsiflexion (included in the
182 source code are predefined angle brackets with angles of 90, 95, 100, 105, and 110 degrees).

183 As shown here they are at 90 degrees, which provides a dorsiflexion of 0 degrees. They are able
184 to be locked into place or, if reversed (Figure 4), allow for motion of the legs as the footpads
185 are not locked relative to the slider pieces.

186 The footpads are also able to be tightened onto the angle brackets with carriage bolts
187 and locked into place by securing them onto interlocking ridges on the angle brackets (Figure
188 5). Figure 6 shows the fully assembled clubfoot brace and highlights the degrees of motion that
189 it is able to be moved and locked into. Due to the simplicity of the assembly, the infant's shoes
190 can be first attached to the footpad via Velcro straps before attaching the footpad to the bar. The
191 shoes employed should be "low rise" at the heel to allow observation that the heel remains
192 against the foot pad, which is lost if a "high top" shoe is employed.

193 This open-source clubfoot brace detailed here was evaluated based for the positive
194 presence of FAO design features outlined in Table 1 above. The results of this evaluation and a
195 comparison of the features, cost, and manufacturability of the open-source 3-D printed brace
196 and four other existing FAOs can be seen in Table 5.

197 The design of the FAO is such that the affected feet maintain hip abduction of 70
198 degrees and dorsiflexion of 15 degrees (with a 105 degree L bracket) to maintain static stretch
199 on the posteromedial ligamentous structures of the hindfoot and (tibialis anterior, tibialis
200 posterior, flexor digitorum longus, flexor hallucis longus and the deltoid and spring
201 ligaments)⁵⁴. These posteromedial soft tissue structures are thought to be the main etiology of
202 recurrence of deformity when the maintenance phase of the deformity correction is not
203 complied with. Fibrosis and contracture of these tissues that have been stretched out in the
204 active deformity correction phase allows recurrence of the deformity. To maintain correction,
205 compliance with the bracing protocol is critical. The ability of parents to comply with the
206 bracing treatment is made possible by having an affordable and seemingly comfortable brace
207 with which the parents can treat their children. The parents must understand the reason for
208 the bracing and must be able to easily fit a well-sized brace to their child. As the components
209 of the 3-D printed brace are individually printed, sizing the brace to the child, even as the
210 child grows is economical and it is possible to achieve a custom fit. The 3-D printed brace
211 described herein is modelled after the Dobb's dynamic brace to allow flexion and extension of
212 each leg independently while maintaining the feet in the abducted and dorsiflexed position⁵⁵.

213 It should be noted that the customization and degrees of freedom possible with this
214 open-source design requires education of the people providing and fitting the braces so that the
215 feet are placed and maintained in an optimal position. It should also be noted that the brace is
216 designed and made of hard plastic and as such, the shoes worn by the child need to provide
217 protection to the child's skin from developing pressure points and sores. The use of the child's
218 own shoes within the brace also allows an additional degree of customization of the brace. If
219 shoes are not to be worn with the brace, the brace would need to be padded to provide protection
220 to the skin. However, it should be pointed out that common shoes may not achieve the desired
221 biomechanical principles, and infant / toddler shoes also may slip, with the inability to hold a
222 child's foot in a desired position for a prolonged amount of time. Users should carefully consider
223 the shoes to ensure that the Velcro straps are adequate to hold the positions over extended
224 periods.

225 226 **3.2 Cost Analysis**

227 While the open-source 3-D printed brace is in the same cost range as the Steenbeck⁵⁶
228 and Miraclefeet⁵⁷ braces, the open-source brace was more comparable in features to the
229 commercially available models. Its ability to be locally manufactured also presents an
230 advantage over commercial models and the Miraclefeet in allowing for point-of-use
231 customization and creating local employment opportunities similar to the Steenbeck model.

232 Using Equations 1-5 and the values seen in Table 6, a cost sensitivity analysis was

233 performed. The mass of the filament used (m_p) and the time used to print the parts (t) were
234 calculated using the open-source 3-D printing software Cura. The power usage (P_p) and energy
235 consumption (E_w) were monitored using a multimeter during the printing.

236 Using the inputs from Table 6, a starting scenario was created with the following
237 assumptions:

238 1. Printing is considered to be mostly automated and done by professional while
239 working on other tasks (labor cost of \$0/hr). This estimate is relevant when there is no
240 opportunity cost to using existing salaried employee (e.g., the use of a lab technician or
241 other position that is paid a fixed cost, and for which there is no opportunity cost for
242 them working on the fabrication of the device). It should be noted that with the STL
243 files provided by this study enable anyone familiar with FFF-based 3-D printing
244 operation to begin the prints in less than one minute. Although the actual printing will
245 take over 20 hours, 3-D printers operate unattended and no labor is involved in the
246 printing process itself. The operator then needs to remove the printed components from
247 the bed and assemble them in a process that takes only a few minutes depending on the
248 experience of the individual. The base case used here does not include the labor cost as
249 setting up prints, removing them and assembly are roughly equivalently time consuming
250 to placing an order, inputting payment information, acquiring and unpacking/removing
251 packaging from a commercial brace.

252 2. There is an electrical fee of \$0.19/kWh (Kenyan electricity costs for domestic usage⁵²)

253 3. Filament is purchased at \$30/kg (least expensive commercial option found in Nairobi
254 although filament is available less expensively elsewhere).

255 Using these assumptions and Equations 2-5 yields a cost of electricity (C_E) of \$0.16, a cost of
256 filament consumed (C_c) of \$8.22, a cost of labor (C_L) of \$0, and a cost of non-printed hardware
257 (C_H) of \$2.70. Summing these values together using Equation 1, the total material cost of the
258 brace is calculated to be \$11.08.

259 By varying each one of three variable inputs (C_u , C_f , w) in the ranges specified in Table
260 7, while keeping the other two variables constant (e.g. varying C_u while keeping C_f and w
261 constant), a sensitivity analysis was conducted to show how the price of the 3-D printed brace
262 varies. Figure 6 shows the range of costs that can be incurred with variations in the electrical,
263 material, and labor costs. Figure 7 also highlights each of the filament sources listed in Table 2
264 above.

266 The cost of the 3-D printed brace can be seen to vary significantly depending upon the
267 source of filament, electricity costs, and any costs that may be incurred from labor. As seen in
268 Figure 6, the variable with the most potential for affecting the final cost of the brace is the labor.
269 In the extreme case, the labor cost is set at a local machinist's wages (\$1.30/hour) for the entirety
270 of the print time and results in a final cost for the brace of over \$37. It should be made clear
271 that this is an unrealistic scenario as the '3-D printer operator' would use the vast majority of
272 the 20 hours on other tasks, while only spending a few minutes focused on brace manufacture.
273 Realistically the labor costs in this market are well under one U.S. dollar with all actual
274 opportunity time cost included.

275 The cost of the filament also has significant effects on the final cost of the brace, with
276 the most expensive filament source resulting in a brace costing over \$30. On the other hand,
277 using recycled filament produces a brace costing less than \$5 in total to manufacture. Electricity
278 costs vary the least, with a total fluctuation in cost being \$0.17.

279 Finally, when comparing this method of distributed manufacturing to conventional
280 manufacturing the cost of tooling is often included in the manufacturers cost analysis. In this
281 case, the tooling cost was \$500 for the 3-D printer and follows previous estimates of a minimum
282 of a five-year lifetime⁶¹ as the most likely components to fail on the printer can be manufactured

283 by the printer itself. Although it could be used to manufacture a wide range of medical devices
284 with substantial economic savings⁶²⁻⁶⁴, it is instructive to determine the tooling cost for an
285 individual FAO. If it is conservatively assumed that 1 FAO can be manufactured per day with
286 a printer over 5 years, 1825 FAOs can be made with a machine resulting in a tooling cost of
287 27.4 cents/FAO. One 3-D printer operator can of course manage many 3-D printers
288 simultaneously so if a given medical facility needed more FAOs/day additional printers could
289 be used. One person working full time with hand tools manufacturing low-cost Steenbeek
290 braces can produce about 100 braces per month.⁶⁵ Thus, 3-4 conventional 3-D printers under a
291 single operator would be needed to produce the same number of 3-D printed FAOs/month. It
292 should be noted that the values given in this study are not the maximum production speed, but
293 those that should be able to be achieved widely. With 3-D printing, the number of FAOs
294 produced per month could be increased by increasing print speed and/or layer height, but there
295 are physical limits to the fabrication speed of a single headed printer. However, for production
296 of many of the same parts, 3-D printer manufacturing can be scaled by using a 3-D printer with
297 multiple heads. So, for example, this can be done vertically with a quad-delta style 3-D printer
298 that could produce four identical FAOs per day⁶⁶ or a multi-head (5 head) Cartesian style
299 printer⁶⁷ on an open source Gigabot platform⁶⁸ that could produce five identical FAOs per day.

300 In addition to offering greater functionality at lower costs, this approach to FAOs also
301 has the advantage of reducing the environmental impact (albeit small) from the manufacturing
302 process due to the decrease in shipping embodied energy and the ability to print with partial
303 infill^{69,70}. Finally, these cost estimations for the device can be considered conservative as
304 recycling post-consumer thermoplastic waste into 3-D printing filament using recyclebots
305 (waste plastic extruders) has already been shown to be feasible^{49,50,71-76}, which indicates that
306 the cost of the printed parts could be significantly reduced as shown in Table 5.

307

308 **3.3 Open Source Designs and Future Work**

309 The open source design was intended to be printed in PLA on any number of FFF-based
310 3-D printers. Previous work⁷⁷ has shown that increasing the thickness of a 3-D printed polymer
311 based mechanical component as compared to an aluminum component was sufficient to match
312 the strength as was done here. However, it has been pointed out that in addition to the changes
313 in strength expected from slicing^{78,79}, materials⁸⁰, and color³⁶, there is also variability due to
314 different realistic environmental conditions³⁵. To ensure that the designed mechanical
315 properties, are realized when printed the two step process outlined in ref. 80 is recommend,
316 which has a reasonably high expectation that a part will have the desired tensile strengths. First,
317 the exterior of the 3-D printed object is inspected visually for sub-optimal layers. Then, on
318 critical components that will undergo substantial loads to determine if there has been under-
319 extrusion in the interior, the mass of the sample is measured. This mass is compared to the
320 theoretical value using densities for the material and the volume of the object. As the infill
321 density used in this study is 80% and the forces expected from a young child using the brace
322 are relatively small, exterior observation is adequate unless there is a concern about filament of
323 inconsistent diameter or properties (e.g. recycled waste used for filament without quality
324 control⁸¹⁻⁸⁴).

325 This article discusses both the distributed manufacturing cost and the FAO systems
326 design and function, which enables but fails to address outcomes of the treatment of clubfoot
327 itself. For this, future clinical work is needed using the 3-D printed FAOs. To enable this for
328 researchers anywhere in the world, all 3-D printable designs shown here (both the FreeCAD
329 models and STL files) are available for free at the Open Science Framework under a GNU
330 General Public License 3.0.⁸⁵

331 **4. Conclusions**

332 While treatable, clubfoot continues to prove to be a challenge to many throughout the

333 developing world, and the cost of necessary orthotics can be prohibitively expensive and
334 difficult to obtain. This study has shown that through the use of 3-D printing, it is possible to
335 manufacture a low-cost children's foot abduction orthosis. When compared to existing
336 alternatives for the treatment of clubfoot in the developing world, the open-source 3-D printed
337 orthosis presented in this paper is able to have the same physical features of all of the
338 commercial alternatives while significantly reducing the cost and allowing improved
339 customization to occur locally. Future work is needed to test the efficacy and outcomes of these
340 devices in the clinical environment. With continued growth of 3-D printing technology and
341 improved material sourcing, 3-D printing can provide a cost-effective way to provide FAOs and
342 other orthotic devices to the developing world.
343

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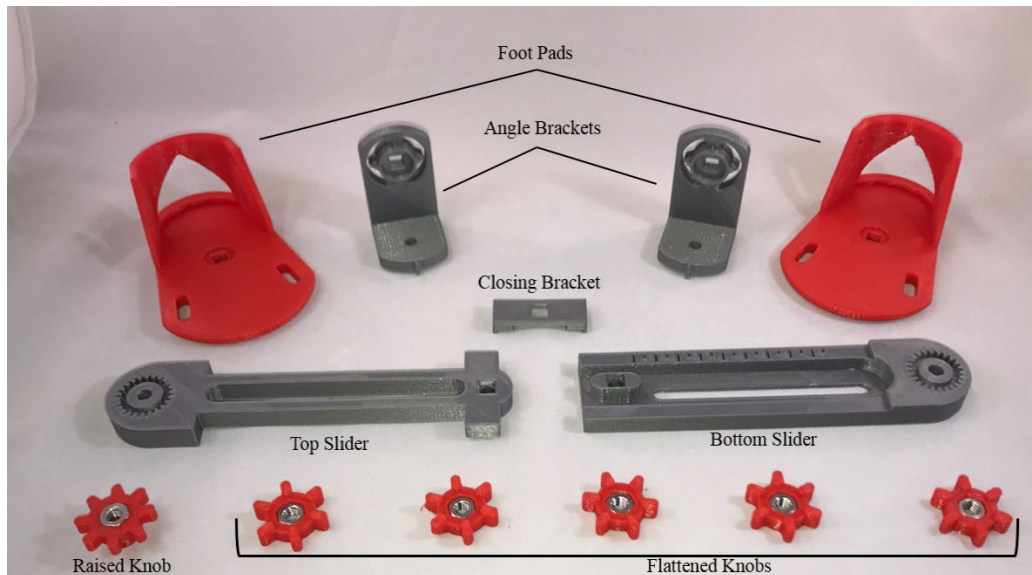
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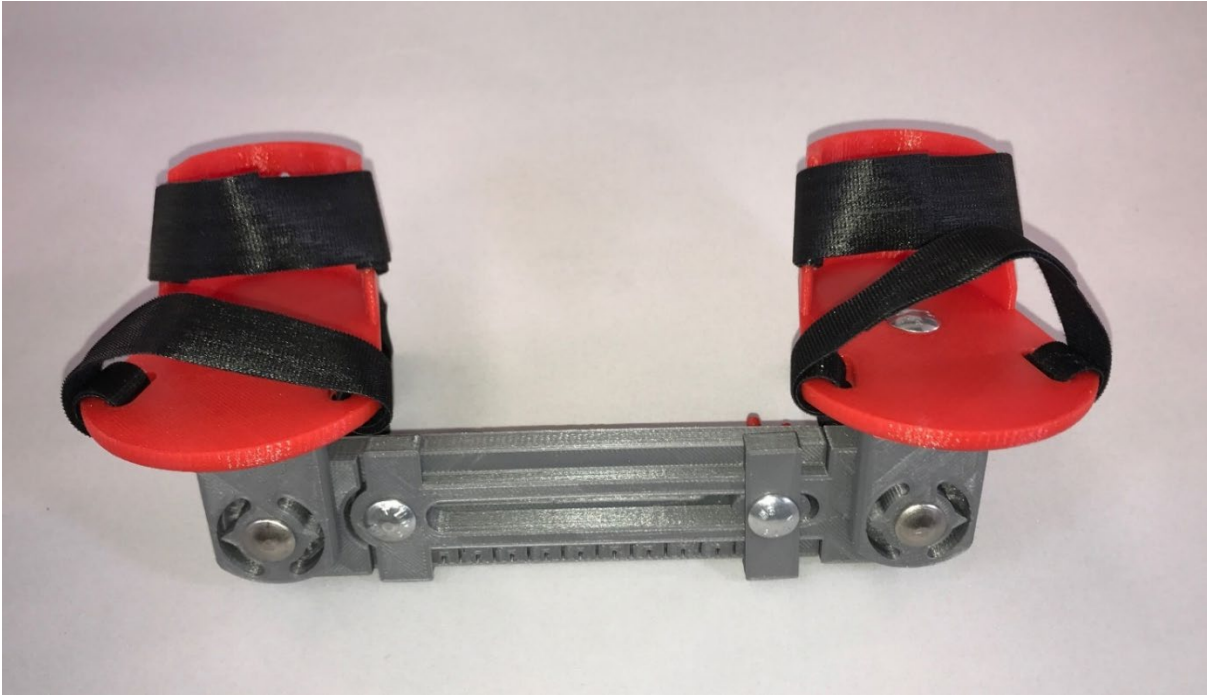
569 **Figure Captions**



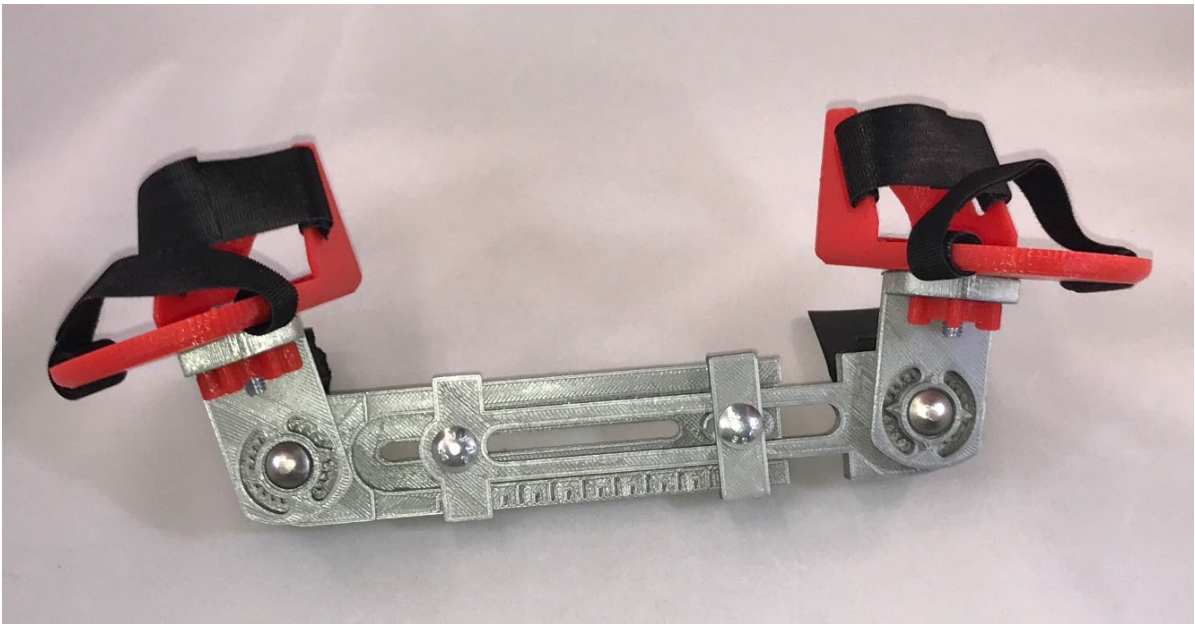
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571 Figure 1 - Simple FAO using the Denis Browne bar (Source:
572 <https://commons.wikimedia.org/wiki/File:Botas.JPG>)
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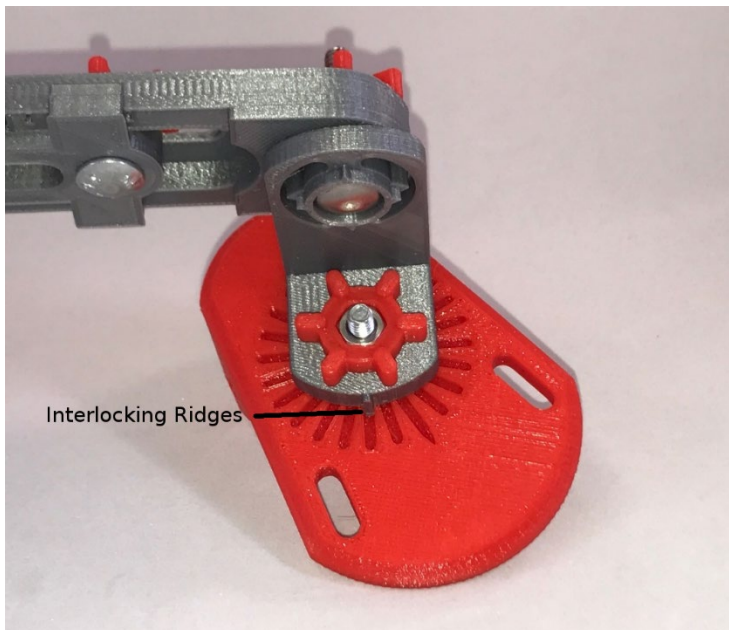
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577 Figure 2 – Bill of Materials all 3-D printed components laid out and labeled.
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580 Figure 3 - Angle brackets locked into place.
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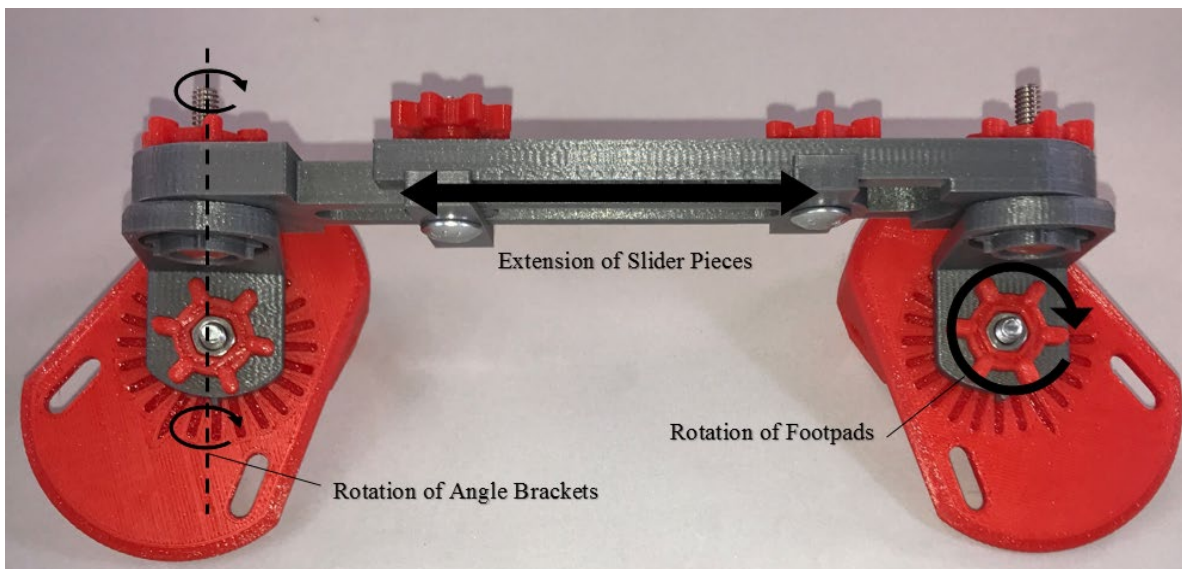


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584 Figure 4 - Angle brackets reversed to allow for increased leg motion.
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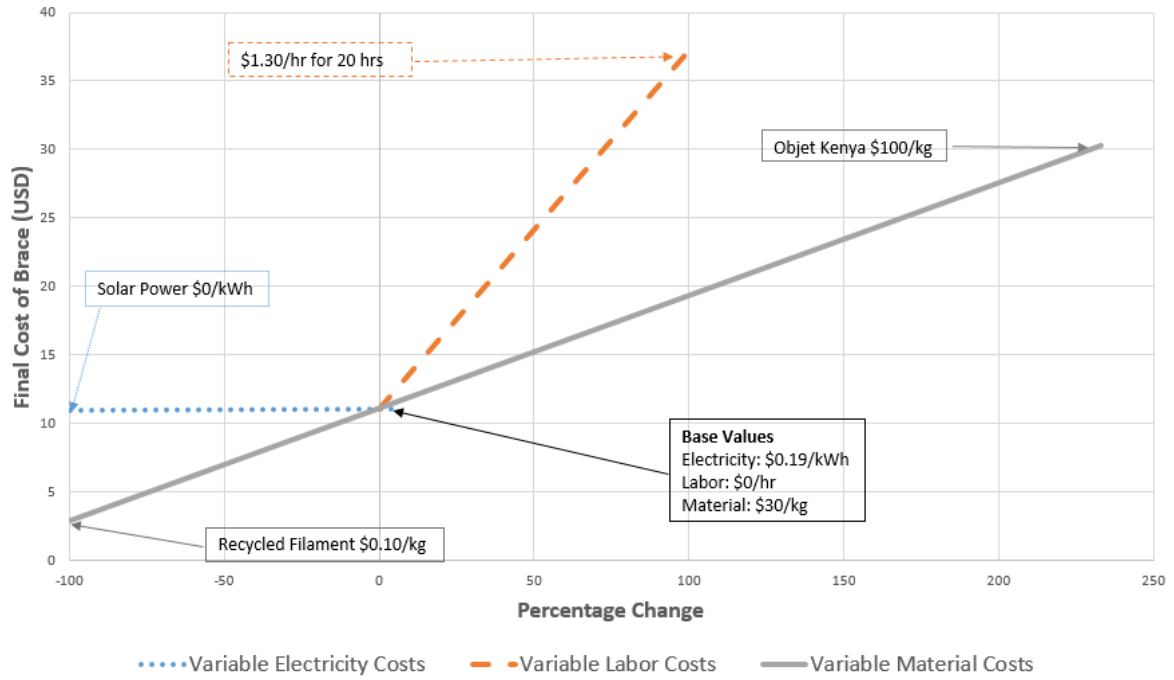
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Figure 5 - Attachment of the footpads to the assembly via angle brackets with interlocking ridges to lock footpads into place.



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Figure 6 - Fully assembled, showing ranges of motion.



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Figure 7. Cost sensitivity analysis: Cost of manufacturing brace vs percentage change in variable costs.

600 **Table 1. Design criteria for FAOs seen in literature**

Design Criteria	Description
Ability to adjust angle of abduction ^{12,39-41}	The feet pads/boots, should be able to be locked into 60-90 degrees of external rotation for affected feet and 20-45 degrees for non-affected feet.
Ability to dorsiflex the feet ^{12,39-41}	When wearing the brace, the feet should be able to be dorsiflexed to an angle of 0-20 degrees.
Ability to adjust feet width ^{12,39-41}	When wearing the brace, the heels of the feet should be adjusted to be the same distance apart as the width of the infant's shoulders.
Allow feet to move independently ⁴²	Each foot can move relative to the other foot while maintaining the necessary outward angle for correction.
Removable footpads ^{12,39-41}	Footpads are large enough to accommodate children wearing shoes. Footpads can be removed for easier application.

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603 **Table 2. Sources of commercial 3-D printer filament (PLA) available in Kenya**

Filament Source	Cost (USD/kg), including shipping and VAT	Source of Data
ESun	30	Mitchell, B., 2016, personal communication, August 5
AB3D	~50	AB3D-African Born 3D Printing ⁵¹
Objet Kenya Limited	100	Shah, A., 2016, personal communication, August 12

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606 **Table 3. Bill of Materials 3-D printed components**

Component	Quantity	Print Time (hrs:min)	Mass (gm)	Cost
Angle Bracket	2	1:39	24	\$0.72
Bottom Slider	1	3:36	47	\$1.41
Closing Bracket	1	0:16	4	\$0.12
Foot Pad	2	4:20	59	\$1.77
Knob (Flat)	5	0:14	3	\$0.09
Knob (Raised)	1	0:14	2	\$0.06
Top Slider	1	2:57	40	\$1.20
Total	13	20:11	274	\$8.22

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610 **Table 4. Prices of Non-printed hardware BOM⁵⁸**

Component	Quantity	Cost
1/4-20 1" carriage bolt, 18-8 stainless steel	2	\$0.20
1/4-20 1.25" carriage bolt, 18-8 stainless steel	1	\$0.24
1/4-20 0.75" carriage bolt, 18-8 stainless steel	3	\$0.14
1/4-20 hex nut, 18-8 stainless steel	6	\$0.04
Velcro	1m	\$1.40
Total Cost		\$2.70

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613 **Table 5: Comparison of FAO alternatives**

FAO Type	3-D Printed Brace	Ponseti AFO ⁵⁹	Dobbs Bar ⁶⁰	Steenbeek ⁵⁶	Miraclefeet ⁵⁷
Cost	\$11.08 (without labor commercial filament) ~\$37 (with max labor and commercial filament) <\$5 (with recycled filament and realistic labor)	~\$300	>\$300	\$10	<\$20
Description	Low-cost brace designed for 3-D printing with open-source hardware and software.	The standard commercial foot abduction orthotic for children with clubfoot. Consists of two boots connected by a laterally adjustable bar.	Modification of Ponseti AFO that allows for increased mobility through semi-independent motion of the feet.	Brace specifically designed for local manufacture in Uganda. Uses local materials (steel and leather) and local craftsmen for manufacture.	Low-cost, plastic orthotic designed by Stanford team for use in the developing world.
Locally manufactured	Yes, with distributed 3-D printing	No	No	Yes, with local materials	No
Ability to adjust angle of abduction	Yes	Yes	Yes	Yes to a degree as the angle can be adjusted by contouring the bar	Yes
Allows for dorsiflexion of feet	Yes	Yes	Yes	Yes	Yes
Ability to adjust feet width	Yes	Yes	Yes	No	No
Allows feet to move independently	Yes	No	Yes	No	No
Removable footpads	Yes	Yes	Yes	No	Yes

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618 **Table 6. Values used in cost estimation and sensitivity analysis**

Fixed Inputs	Value	Variable Inputs	Low Value	High Value
Mass of filament used, m_p (from Table 3)	0.274kg	Unit energy costs, C_u	\$0/kWh	\$0.20/kWh
Average power usage during print, P_p	43W	Unit cost of filament, C_f	\$0.10/kg	\$100/kg
Energy consumption for warming the printer, E_w	0.0014kWh	Hourly wages, w	\$0.00/hr	\$1.30/hr
Time to print, t	20.11hr			
Cost of additional hardware, C_h	\$2.70			

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