PROJECT III

"Design Intervention for Clubfoot Abduction Orthosis"

By
Rajat
176130006

Guide
Prof. Avinash Shende

Industrial Design Centre
IIT-Bombay

ACKNOWLEGDMENT

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Chapter 1

Introduction to Clubfoot

FIG. 1.1
CLUB RIGHT FOOT [UNILATERAL CLUB FOOT]

WHAT IS CLUBFOOT?

Clubfoot is a birth deformity in which an infant's foot is curved towards the body internally, often so severely that the bottom of the foot faces sideways or even upward. The clubfoot can affect one foot or both feet. Club foot in both feet is called as *Bilateral Clubfoot* & in one foot is called as *Unilateral club foot.*

Quick identification and immediate treatment helps correcting it. The leg affected with club foot may be smaller than the normal foot. Normally, half of the affected children have Bilateral Clubfoot. Some cases can also be associated with other problems too.

This condition can be diagnosed at birth or before birth with ultrasound during 18 to 21 weeks of pregnancy. Normally, the Males are identified with this condition about twice as frequently as females.

CAUSE OF CLUBFOOT

There is no identified cause of club foot presently. However, Genetic and Environmental factors are considered responsible for this as per the medical experts.

Basic foot anatomy

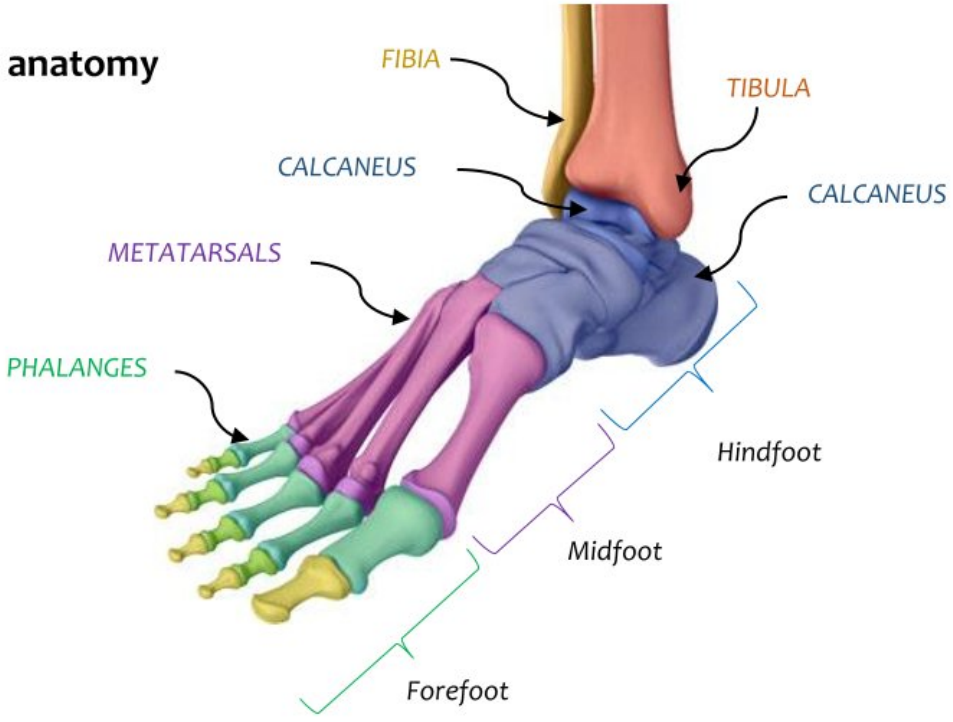


FIG 1.2. NORMAL FOOT

Figure 1.2 shows the general method of addressing the group of bones in the foot.

- The bones located from near tip of the foot [indicated in green and yellow color] are referred as *Front-foot*.
- The bones in the middle of the foot [indicated in purple color] are referred as *Mid-foot*.
- The bones located farthest from tip of the foot [indicated in blue color] are referred as *Hind-foot*.

Foot bone orientation in normal foot and club foot

- Figure 1.3 shows the difference between the normal foot and a club foot bone arrangement.
- The foot marked with red lines is affected by club foot and the angle between the red lines is an indication of the bone deviation from their original position.
- Though, the bones structure is not affected, the location & relative positions are.

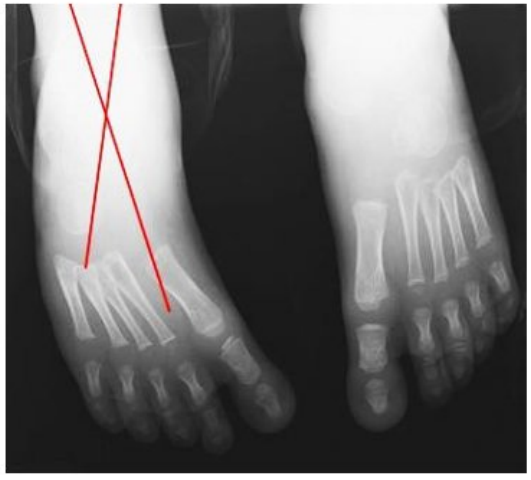


FIG 1.3. X-RAY IMAGE OF UNILATERAL CLUBFOOT

Statistics

As per WHO

- Clubfoot affects 1 lakh children worldwide, making it one of the most common birth defects in the world.
- Left untreated, the condition causes severe lifelong disability. *80% of untreated clubfoot are found in developing countries.*
- A patient who undergoes surgery will require two to three more surgeries over his lifetime.
- At 30 years old, a patient who underwent surgery will have a quality of life similar to a 50 year-old patient with Parkinson's Disease[8].

As per *Miracle Feet India*,
Estimated cases every year in India are around 35,000[11]

Treatment of Clubfoot

Following discussed are the three way of treating clubfoot.

1

Ponseti Method

Most clinically practised and efficient method.

2

French Method

This incorporates stretching, mobilization, and taping.

Done by a physical therapist who has specialized training and experience.

3

Surgery

In cases of severe deformities, which do not respond to stretching, surgery may be needed to adjust the tendons, ligaments, and joints in the foot and ankle.

FIG 1.4. CASTING PROCESS IN PONSETI METHOD

- The Ponseti method is a non-invasive, low-cost procedure to correct clubfoot with a 98% success rate.
- It consists of manually aligning the child's foot with the application of a series of casts over 6 to 8 weeks as shown in figure 1.4.
- It can take as little as 5 casts and 20 days to give a child a new chance at life.
- Once the inward bending is improved, the Achilles tendon is often cut, and braces are worn until the age of four. Initially, the brace is worn nearly continuously and then just at night. In about 20% of cases, further surgery is required.

Tenotomy

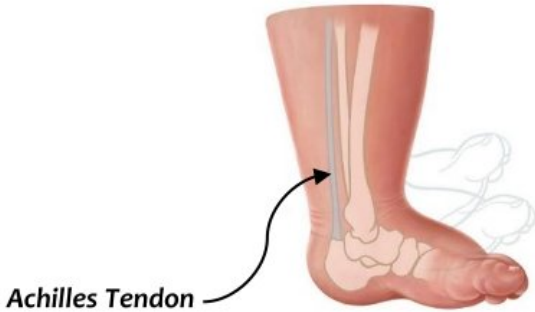


FIG.1.5. ACHILLES TENDON

FIG.1.6. TENOTOMY

- Tenotomy is the invasive procedure.
- It consist of cutting the Achilles tendon, as indicated in the figure 1.5, located around the hind-foot.
- It is performed by pricking the elastic tendon, as shown in figure 1.6, with a small blade to tear on its own creating a popping sound. The sound indicates that the tendon is torn.
- This procedure is performed only in few cases where the foot may not respond to the casting process.
- The child is again subjected to few cast after the Tenotomy.

What If Untreated ?

FIG.1.7. LIVELIHOOD OF A PERSON WITH CLUBFOOT

FIG.1.8. ACHILLES TENDON

The condition of clubfoot can be corrected at an early stage and becomes difficult to treat if neglected!
Further, Employment & social stigmas are life challenges especially in underdeveloped countries.
Irrespective of the type or severity, clubfoot will not improve on its own.
A child with an untreated clubfoot-

- Will walk on the outer edge of the foot as shown in figure 1.8
- Develops, sometimes, painful calluses
- Faces difficulties in wearing any foot wears even socks!
- Can have painful feet for lifetime that often severely limit physical activities.

Grading Of Clubfoot

- The clubfoot deformity can be grade as per the degree of deformity. The figure 1.9 indicates the range of deformity varying from benign to severe condition. A zero degree indicate the normal foot and a value of 90 degree and above indicates the severe clubfoot deformity.
- Every range of degree is assigned a score. And depending on the total score calculated, in 4 different manner as shown in fig. 1.9, the clubfoot is graded. Table 1.1 shows the score based classification of clubfoot. Figure 1.10 shows the method of approximately calculating the angle of deformity.

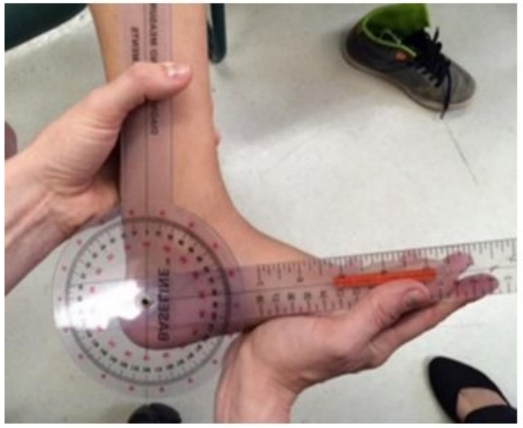
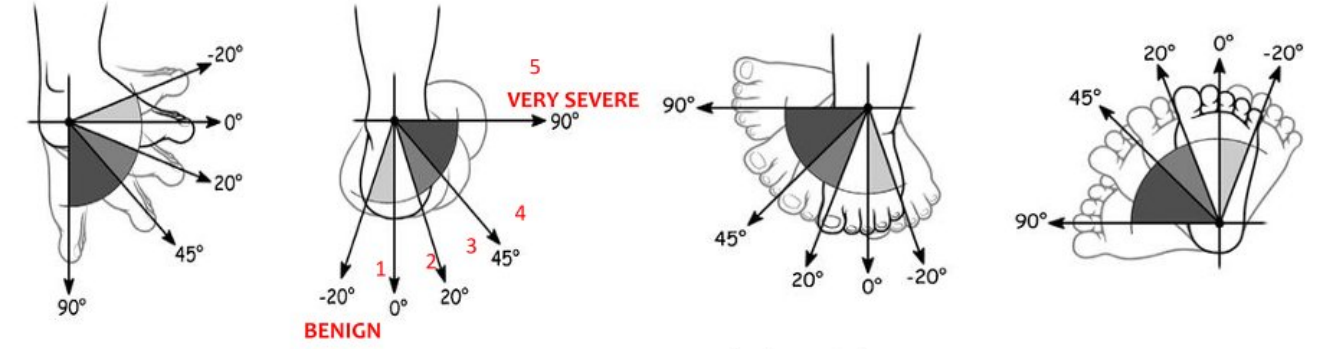


FIGURE 1.10 MEASURING THE ANGLE



sagittal plane evaluation by Equinus

LOOKING FROM RHIGT HAND SIDE OF LEFT FOOT

Frontal plane evaluation by Varus

LOOKING FROM BACK OF LEFT FOOT

horizontal plane evaluation of forefoot relative to hindfoot

LOOKING FROM TOP OF LEFT FOOT

Horizontal plane evaluation of Derotation of calcaneopedal block

LOOKING FROM BOTTOM OF LEFT FOOT

FIGURE 1.9 GRADING OF CLUBFOOT

TABLE 1.1 GRADE CLASSIFICATION

GRADE	TYPE	SCORE
1	BENIGN	<5
2	MODERATE	=5<10
3	SEVERE	=10<15
4	VERY SEVERE	=15<20

Scoring of Clubfoot

- The Pirani Scoring is a very simple and reliable way to determine severity and check on the progress in the examining and treatment of Clubfoot.
- A foot can be examined in a minute without use of any equipment.
- The measurements are taken while the examiner is gently correcting the foot with least possible efforts and no discomfort.
- Scoring the foot at each visit during treatment enables the health care worker treating the child to document how the foot is responding to manipulation and casting.

The Pirani Scoring System is based on following 6 Clinical Signs of Contracture as shown in chart 1.11.

3 Signs in Midfoot are
- Medial Crease
- Curved Lateral Border
- Lateral Head Talus

3 Signs in Hindfoot are
- Posterior Crease
- Empty Heel
- Rigid Equinus

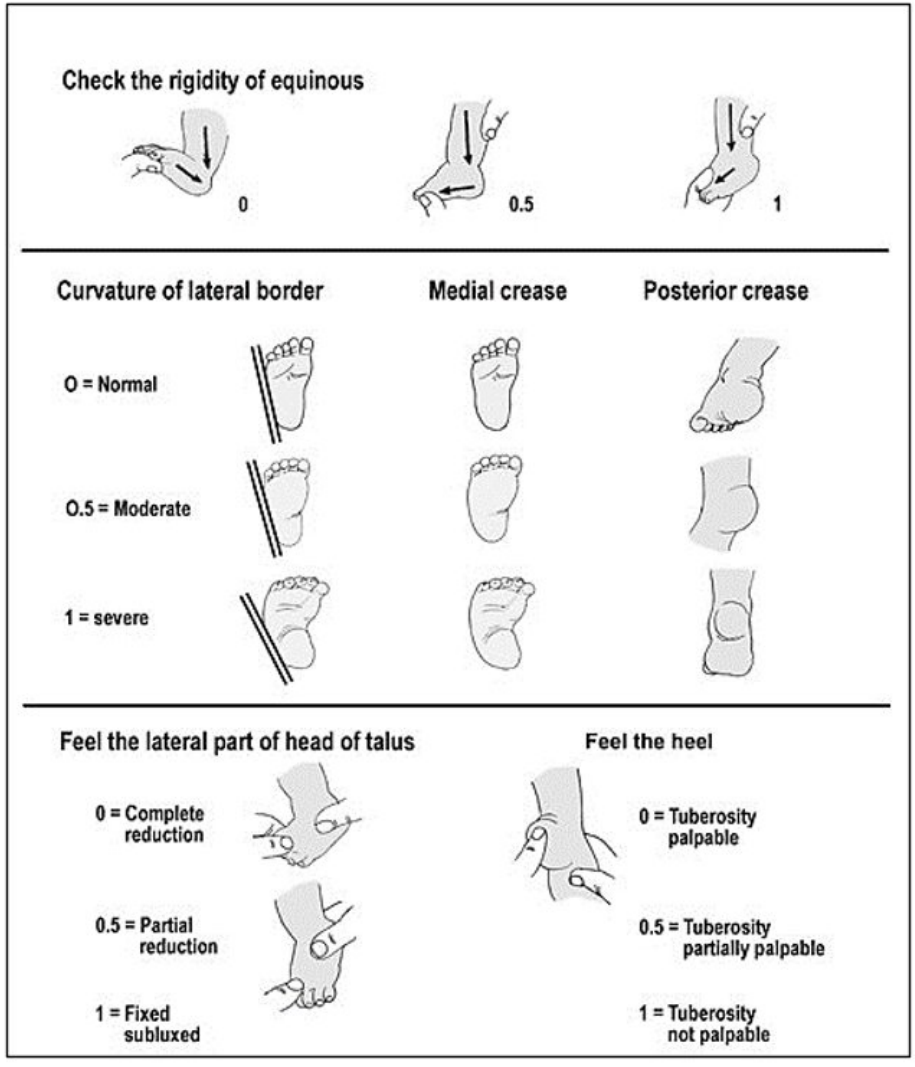


FIG. 1.11 CHART OF PIRANI'S SCORING SYSTEM

Pirani Score Record Sheet

- As per the record sheet shown in table 1.2, the child is scored depending on Severity from 0, 0.5, or 1.
- Total Score varies from 0 to 6 and is the sum of Midfoot and Hindfoot Contracture Scores.

DATE	VISIT 1		VISIT 2	
SIDE	*Right*	*Left*	*Right*	*Left*
Medial Crease				
Curved Lateral Border				
Lateral Head Talus				
MID FOOT CONTRACTURE SCORE(MFCS)				
Posterior Crease				
Empty Heel				
Rigid Equinus				
HIND FOOT CONTRACTURE SCORE(HFCS)				
TOTAL SCORE				

TABLE 1.2 PIRANI SCORE RECORD SHEET

Chapter 2

Child Growth & Motor Skills Development

This chapter constitutes some standard data as per sources mentioned, relevant to *children growth, development, child's color preferences and perception.*
The data was helpful for design the brace, footwear and the accessories.

The chart shows the motor skills development of a child during the growth in Months[4].

Age	Motor
1–1.5 months	• When held upright, holds head erect and steady.
1.6–2 months	• When prone, lifts self by arms; rolls from side to back.
2.1–2.5 months	• Rolls from tummy to side • Rests on elbows, lifts head 90 degrees • Sits propped up with hands, head steady for short time
3 months	• Prone: head held up for prolonged periods • No grasp reflex
5 months	• Holds head steady • **Goes for objects and gets them** • **Objects taken to mouth**
6 months	• **Transfers objects from one hand to the other** • **Pulls self up to sit and sits erect with supports** • **Palmar grasp of cube hand to hand eye coordination**
6-9 months	• **Teething starts. Try to bite/eat objects.**
7 months	• **Responds to their name**
9–10 months	• Wiggles and crawls • Sits unsupported • Picks up objects with pincer grasp • Learns to drop objects

This is the normal duration of age when the child is wearing brace for around 23 hours a day.

The chart addresses the sequence of activities, a child is capable of doing, during the aging process from 1 month to 6 years. This information was helpful in designing accessories for the brace.

Age	Motor
1 year	• Stands holding furniture • Stands alone for a second or two, then collapses with a bump
18 months	• Can walk alone • Picks up toy without falling over • Gets up/down stairs holding onto rail • Begins to jump with both feet • **Can build a tower of 3 or 4 cubes and throw a ball** • **Supinate grasping position usually seen as first grasping position utilized.**
2 years	• Able to run • Walks up and down stairs 2 feet (61 cm) per step • Builds tower of 6 cubes
4 years	• Goes down stairs one foot per step • Postural capacity needed to control balance in walking not attained yet • Skips on one foot • Imitates gate with cubes • Copies a cross • Between 4 and 6 years, the classic tripod grip develops and is made more efficient.
5 years	• Skips on both feet and hops. • Begins to be able to control balance not attained at 3–4 years of age • Begins to be able to control gravitational forces in walking • Draws a stick figure and copies a hexagonal based pyramid using graphing paper • Gives age
6 years	• At this age, until age 7, adult muscle activation pattern in walking is complete. • Leads to head control and trunk coordination while walking, by at least age 8. • Mechanical energy transfer exists • Knows right from left and number of fingers

AS PER AMERICAN OPTOMETRIC ASSOCIATIONS [24]

The following are some age-appropriate activities that can assist an infant's visual development.

Birth to four months

- Use a nightlight or other dim lamp in your baby's room.
- Change the crib's position frequently and change your child's position in it.
- **Keep reach-and-touch toys within your baby's focus, about eight to twelve inches.**
- **Talk to your baby as you walk around the room.**
- Alternate right and left sides with each feeding.

Five to eight months

- **Hang a mobile, crib gym or various objects across the crib for the baby to grab, pull and kick.**
- Give the baby plenty of time to play and explore on the floor.
- **Provide plastic or wooden blocks that can be held in the hands.**
- **Play patty cake and other games, moving the baby's hands throug**h the motions while saying the words aloud.

Nine to twelve months

- Play hide and seek games with toys or your face to help the baby develop visual memory.
- **Name objects when talking to encourage the baby's word association and vocabulary development skills.**
- Encourage crawling and creeping.

One to two years

- Roll a ball back and forth to help the child track objects with the eyes visually.
- Give the child building blocks and balls of all shapes and sizes to play with to boost fine motor skills and small muscle development.
- Read or tell stories to stimulate the child's ability to visualize and pave the way for learning and reading skills[24].

The above mentioned information was helpful to understand what parents/guardian should do to compliment their child's growth, as the child ages, enhancing their physical and mental development.

The Bright Color Appeal

As per AOA[American Optometric Association], USA

"At birth, babies' vision is abuzz with all kinds of visual stimulation. While they may look intently at a highly contrasted target, babies have not yet developed the ability to easily tell the difference between two targets or move their eyes between the two images[24]"

Children tend to be attracted to the bright block colors of the color wheel rather than pastels or muted blends. ***Primary colors red, yellow and blue, and secondary colors green, orange and purple, are more appealing than light shades of pink and beige or neutral shades of gray and brown***. For this reason, the food and beverage industries, as well as the toy industry, use bright colors to market children's products[5].

As per an article from *Sciencing.com,*
Children take in the world around them through their eyes, and bright colors are one of the first aspects of sight that help them distinguish form and categorize objects. These colors appeal to young children, as they are easier for them to see. **At about 5-months old, children can see colors with their still-developing vision, though distinguishing bright colors comes easier to them**. As children age, they continue to be drawn to brighter colors. **Bright colors catch young children's eyes because they help kids to distinguish objects from one another in their field of vision. Children spend more time looking at bright colors as opposed to looking at muted shades or pastels**[25].

The above mentioned information was helpful in deciding the choice of colors.

Chapter 3

Field visits and User Study

Creating Questionnaire

A basic questionnaire was made prior meeting the expert Doctors based on the initial theoretical enquiry about the Clubfoot as discussed in the Chapter 1.

What makes parents to take off the braces on their own?

What reason do parents tell when asked about them being impatient?

Why there is a need for continuous or real-time assessment of club foot in the treatment?

Do putting braces always follows the surgery or the braces also can be used prior surgery? Which one is better to follow?
Under which conditions the surgery is must for the patient?

Do the conduct of Ponseti Method has any relation with the growth of bones in infants? If yes, how the Bone growth and the treatment complements each other?

What is the proper way of plastering the cast on the foot?

In what way the bones are arranged during casting a plaster?

Is there any pressure exerted on the thigh bones during casting a plaster?

Is thigh/calf bone considered as a reference during casting a plaster?

How advantageous would it be to consider the thigh/calf bone as a reference for setting angles in designing the brace ?

Why the present method of measuring club angels is clinically inefficient to measure the progress in a patient with braces?

Any kind of complain/feedback/advice/difficulties/insight presented by parents for the present design of braces?

Meeting Doctors

Expertise dealing with clubfoot are few. So, initially Dr Nisha, CMO at IIT B Hospital, was approached to help find an expertise practising in paediatric orthopaedics.

With some reference from BeTic IIT Bombay, team of Doctors at clubfoot clinic at B J Wadia Hospital was approached for further study.

Later, Dr Sourabh Sinha from B J Wadia Hospital appeared to be the consulting expert for this project and this project work further was continued with his Support and supervision.

Also, Dr Atul Bhaskar, paediatric specialist at Hiranandani Hospital, help with interacting with a lot of parents at his clinic in Andheri West. He also shared some of his Brace collection for understanding the Brace as a product.

Visits

DR. NISHA

CMO
IIT-B HOSPITAL

DR. ATUL BHASKAR

Visiting consultant
HIRANANDANI HOSPITAL

DR. SOURABH SINHA

Visiting Consultant
BETIC, IIT-B

DR. ALERIC & TEAM

Paediatric Specialist
B J WADIA HOSPITAL, PAREL

DR. SURESH CHAND

Asst. Paediatric Specialist
B J WADIA HOSPITAL, PAREL

DR. BHUSHAN

Asst. Paediatric Specialist
B J WADIA HOSPITAL, PAREL

During initially visits to Dr Atul Bhaskar, paediatric specialist at Hiranandani Hospital, I was invited to his clinic for further study. At his clinic I got to see two patients of age around 24 days and 8 weeks old. The figure refers to the 24 days old baby girl being put on plaster.

USER 1

CLINIC – Children's Orthopaedic Clinic

CLINICIAN – Dr Atul Bhaskar

LOCATION - Andheri West.

AGE – 24 days old

CONDITION – Unilateral Clubfoot [Right]

The girl was diagnosed with clubfoot soon after her birth on the right foot.
A weeks gap was given to consult and inform parents about the situation, so that they cooperate well during the initial phase of treatment, which is the most crucial phase.
During this initial phase the babies normally cry a lot. But, the Ponseti method do not cause any pain to the baby during treatment.

FIG. 3.1

Holding the leg at toe and knee

FIG. 3.2

Start from the foot by holding it in a desired way

FIG. 3.3

2-3 layers are casted one by one

FIG. 3.4

Done !

Dr Atul demonstrated the whole procedure of holding the affected foot, examining the foot and plastering the foot. He also informed me and the family members of the baby about how to take care of the baby after the plastering is done , timely checking and indications if the baby is really facing some problem in the plastered foot.

USER 2

CLINIC – Children's Orthopaedic Clinic

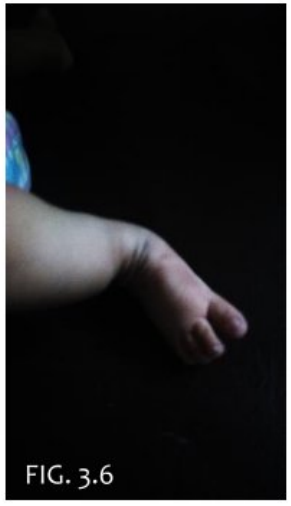
CLINICIAN – Dr Atul Bhaskar

LOCATION -- Andheri West.

AGE – 8 months old

CONDITION – Bilateral Clubfoot [Both Left & Right foot]

It take very long to tie all laces & Baby kicks with other leg while putting braces



Baby cries a lot after change !

Black Marks on Skin

Previous injury & History of Bleeding

- The above shown figures refer to the second patient who was 8 weeks old.
- The plastering was over for this patient and she was on brace since last 3 months. She was given a steinbeek brace by Dr. Atul.
- The parents while sharing their experience of using this orthosis.
- They reported about the black marks on skin of the foot that were caused due to the exposed joinery in the footwear, some stress points on the foot where the baby faced bleeding due rough contact as shown in figure 3.8, skin blackening as shown in figure 3.7 and swelling due to tight small bands used for fastening the orthosis.
- The crude appearance of the brace was not liked by the parents as it evoked a sense of pain and punishment they said.
- The mother of the child informed me about the difficulties she face during putting the brace on to the child. The child looses or kicks out the foot during she try to shoe the second foot after the first shoe is done.

FIG. 3.9

FIG. 3.10

USER 3

CLINIC – Clubfoot clinic at B J WADIA Hospital

CLINICIAN – Dr Alaric Arijoos, Dr Bhushan

LOCATION – Parel

AGE – 8 yrs. Old

CONDITION – Relapse of Clubfoot [Left]

- The 8 years old boy had gone through all the procedures of treatment right from he was diagnosed with clubfoot.
- It was almost an year later he completed the treatment, the neighbours and school teachers started noticing his improper way of walking and running all of a sudden.
- His mother was informed by them and he was brought to B J WADIA hospital for further treatment.
- A condition of relapse was identified in his left foot. A surgery was scheduled to deal the condition.
- The boy was not operated earlier and Tenotomy sometimes is required in such cases.
- Till then he was put on plaster on left leg as show in figure 3.9 and 3.10.

USER 4

LOCATION – Bangalore

AGE – 25 years

CONDITION – Bilateral Clubfoot

- The user was operated when he was 10 days old.
- He was never put to any brace during his treatment at Bangalore hospital.
- He was prescribed to wear shoe custom made after surgery for several years.
- He reported about the shoe being very rugged and painful.
- He has been suffering from painful feet and cannot stand for more than 2 hours even now.
- He has been facing difficulty in walking and running if done over a long period of time.
- Sometimes his pain stays over two days, making it difficult to commute.
- He prefers the pain caused due to shoes over the pain caused due to painful-feet as it helps him step well.

Key Insights

- Any kind of leniency in bracing can lead to relapse.
- Child takes around a week to adjust to the brace once the bracing protocol starts [as per the steinbeek orthosis Users and doctors recommending].
- Braces are circulated among the patients either when parents cannot afford the treatment or the no. of braces available is less.
- Visual inspection of exposed foot is must to avoid/realise any kind of damage/problems in plastered or braced foot.

Chapter 4

Market study

Ankle Foot Orthosis [AFO]

Figure 4.1 and 4.2 shows the AOF Orthosis.

PROs

- Light in weight
- Easy to Manufacture
- Cost Effective
- Best suited for holding foot in a neutral position

CONs

- Restricts Dorsiflexion as resembled in fig 4.3.
- Not suitable in walking kids as it keeps the foot in neutral position

Costs around Rs. 400 -800.
It Is Globally Used.

FIG. 4.1

FIG. 4.2

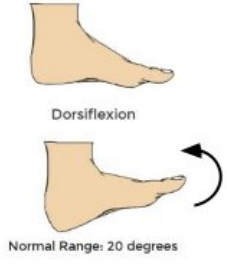


FIG. 4.3 DORSIFLEXION

Stanford Orthosis

Figure 4.4 and 4.5 shows the Stanford Orthosis.

PROs

- Light weight
- Easy to Manufacture
- Cost Effective
- Easy to Use as Shoes clip on and off
- Bars can be reused and recycled
- Injection-molded for global mass production

CONs

- Extremely difficult to clean
- Distant between the feet is constant

Costs around $ 25

FIG. 4.4

FIG. 4.5

Iowa Orthosis

FIG. 4.6 IOWA BAR

Figure 4.6 shows the Iowa Orthosis.

PROs
- Less clutter
- Mechanical joints are not exposed to child
- Has 2 point flexibility – 30 & 60 degrees position

CONs
- Restricts Dorsiflexion
- Not suitable in walking kids as it keeps the foot in neutral position
- Has more weight due to use of metal.

Costs around 200 $
Its is popularly used in China & USA

Dobb's Orthosis

Figure 4.9 shows the Dobb's bar

- Dobbs Bar enterprises sells three kind of braces.
- Its is popularly used in Canada, UK, Brazil & Japan.
- The brace itself cost around 120 $.
- Its has flexibility to change angle of abduction length adjustment as per shoulder width.

FIG. 4.7 DOBB'S BAR

MARKELL SHOES
BY
MARKELL SHOE COMPANY

FIG. 4.8 MARKELL SHOE

FIG. 4.9 MARKELL SHOE

- This braces are to be wore with Markell's shoes which costs around $ 100.
- To avoid kid's interaction with the mechanical joints, they are provide with cover costing around $18.

FIG. 4.10 BAR COVER

The Denis Browne Bar

The figure 4.11 and 4.12 shows the Dennis Brown Bar
PROs

- Light weight
- Easy to Manufacture
- Change of distance between the shoes is possible
- Most flexible in terms of changing angle of Abduction

CONs

- Uncomfortable while holding the kid.
- Very Expensive

Costs around $ 100.
It Is Very Popularly used in UK

FIG. 4.11

FIG. 4.12 DENIS BROWN BAR

Steinbeek Orthosis

The figure 4.13 shows the Steinbeek Orthosis

PROs

- Light weight
- Easy to Manufacture
- Cheaper as compared to other braces

CONs

- Uncomfortable while holding the kid.
- Very Uncomfortable to wear on to kids and for kids to wear.
- Correction is made by bending the rod manual.
- Change of distance between the shoes is possible

Costs around Rs 1000
It Is globally used and is well accepted by clinicians

FIG. 4.13 STEIN BEEK ORTHOSIS

Key Insights

- With the increasing size of brace, it becomes less portable.
- Metallic and edgy braces are difficult to handle.
- Any sort of exposed joinery is unsafe for growing kids.
- Lacing the shoe is time taking and often needs assistance.

Product Positioning

- The figure 4.17 shows a matrix of orthosis mapped orthogonal over cost and usability/compliance.
- The area, shaded inside the red lines, indicates a niche for the desired orthosis.

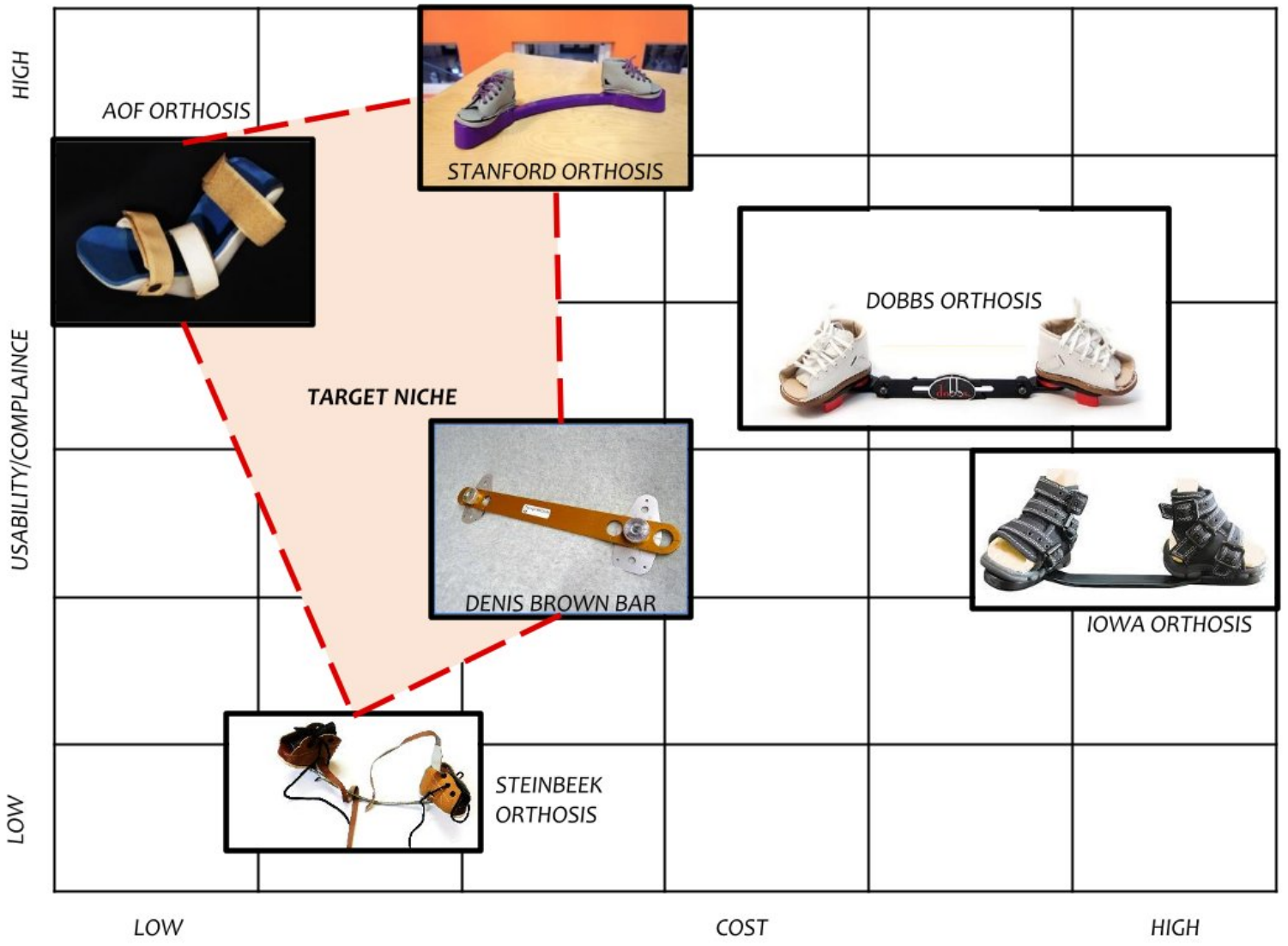


FIG. 4.14 PRODUCT POSITIONING

Chapter 5

User-Product Interaction

Parent-Child Interaction

Fig. 5.1 CLUB FOOT CLINIC AT B J WADI HOSPITAL

Another round of visiting and meeting Users was conducted, during the User study at B J WADIA hospital, focused at the parents child interaction during:

- *Travelling*
- *Feeding the child*
- *Playing*
- *How they manage to put child to sleep*

USER 5

CLINIC – Clubfoot clinic at B J WADIA Hospital

CLINICIAN – Dr Alaric Arijoos, Dr Bhushan

LOCATION – Parel

AGE – 1.5 years

CONDITION – Bilateral Clubfoot

FIG. 5.2

FIG. 5.3

FIG. 5.4

FIG. 5.5

FIG. 5.6

- The father used to carry child during in Local trains and for walks in busy places as shown in the figure 5.2
- At home and for walks around their home he would hold the child as shown in figure 5.3
- For any instance, if the baby needs to be made standing for short span of time around 10 minutes, then he was made to stand like as shown in figure 5.4
- The mother of the child used to carry him as shown in figure 5.5.
- The kid used to play sitting sometimes and was made to sit while feeding as shown in figure 5.6.

FIG. 5.7

FIG. 5.8

FIG. 5.9

FIG. 5.10

- The father reported of child observing the shoelace while they put on to his foot as shown in the figure 5.7
- The parent , both, use to assist each other to brace the child as shown in figure 5.8 and 5.9
- The father told that he used to be fascinated with the bright blue lace and tries to access them as shown in figure 5.10
- The kid used to play sitting with his other toys interacting with brace bar as shown in figure 5.11 and 5.12

FIG. 5.11

FIG. 5.12

USER 6

CLINIC – Clubfoot clinic at B J WADIA Hospital

CLINICIAN – Dr Alaric Arijoos, Dr Bhushan

LOCATION – Parel

AGE – 1.5 years

CONDITION – Bilateral Clubfoot

FIG. 5.13

FIG. 5.14

FIG. 5.15

- The mother use to feed and play with the child as shown in the figure 5.13
- She would talk him to small walks and out to sleep as shown in figure 5.14
- For any instance requiring for the child to stand, grand mother would assist and hold him as shown in figure 5.15

FIG. 5.16

FIG. 5.17

The was fond of playing by sitting as shown in the figure 5.16 and 5.17 . He played most with colored objects as per his Mother. He was curiously observing the brochure given to him.

FIG. 5.18

FIG. 5.19

FIG. 5.20

FIG. 5.21

FIG. 5.22

- The child use to cry a lot while being braced. The mother tries to put shoe on left foot as shown in the figure 5.2
- The mother always needed assistance from her mother-in-law for bracing the child as shown in figure 5.19 and 5.20
- The child was made to stand if required as shown in figure 5.21
- The kid suffered some skin infection over the ankle because of old circulated brace, as shown in figure 5.22.

USER 7

CLINIC – Clubfoot clinic at B J WADIA Hospital

CLINICIAN – Dr Alaric Arijoos, Dr Bhushan

LOCATION – Parel

AGE – 1.5 years

CONDITION – Bilateral Clubfoot

- The child was visited to clinic by his Mother.
- The kid used to play sitting as shown in figure 5.23.
- The mother used to put him to sleep and fed the baby in her lap as shown in figure 5.25
- The mother of the child used to carry him while walking as shown in figure 5.24.

FIG. 5.23

FIG. 5.24

FIG. 5.25

USER 3

CLINIC – Clubfoot clinic at B J WADIA Hospital

CLINICIAN – Dr Alaric Arijoos, Dr Bhushan

LOCATION – Parel

AGE – 2.5 yrs. Old

CONDITION – Bilateral clubfoot

FIG. 5.26

FIG. 5.27

FIG. 5.28

- The child was visited to clinic by his father.
- The father report that, they made child sit on small stool during feeding, playing and putting brace as shown in figure 5.26 and 5.27.
- The child was made to stand as shown in figure 5.29 if required.
- The father did the lacing in a different way, as shown in figure 5.28, to make sure that it is tighter.

FIG. 5.29

USER 7

CLINIC – Clubfoot clinic at B J WADIA Hospital

DESIGNATION– Cure NGO Worker

LOCATION – Parel

- There is a NGO Desk run by Cure NGO, which works for the facilitating the treatment to unprivileged people at B J Wadia Hospital and collaborates with the Miracle feet Organization for free distribution of clubfoot orthosis to the patients visiting B J Wadia Hospital.
- One of the desk member is responsible to allot orthosis to the patients depending upon their stage of treatment, progress and most importantly the fit/size of the shoe.
- The NGO circulates steinbeek orthosis among the patients as shown in figure 5.5 and the angle setting is done manual by this worker by bending the metallic rod around the table corner as shown in figure 5.6

FIG. 5.30

FIG. 5.31

FIG. 5.32

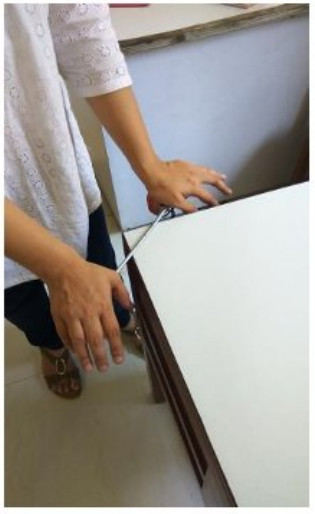


FIG. 5.33

Anthropometric considerations

Figure 5.34 show a comparative study of available data for an average height of an adult and the child, performed to identify the possibilities of how differently the brace can make contact on parents body or any one carrying a braced baby.

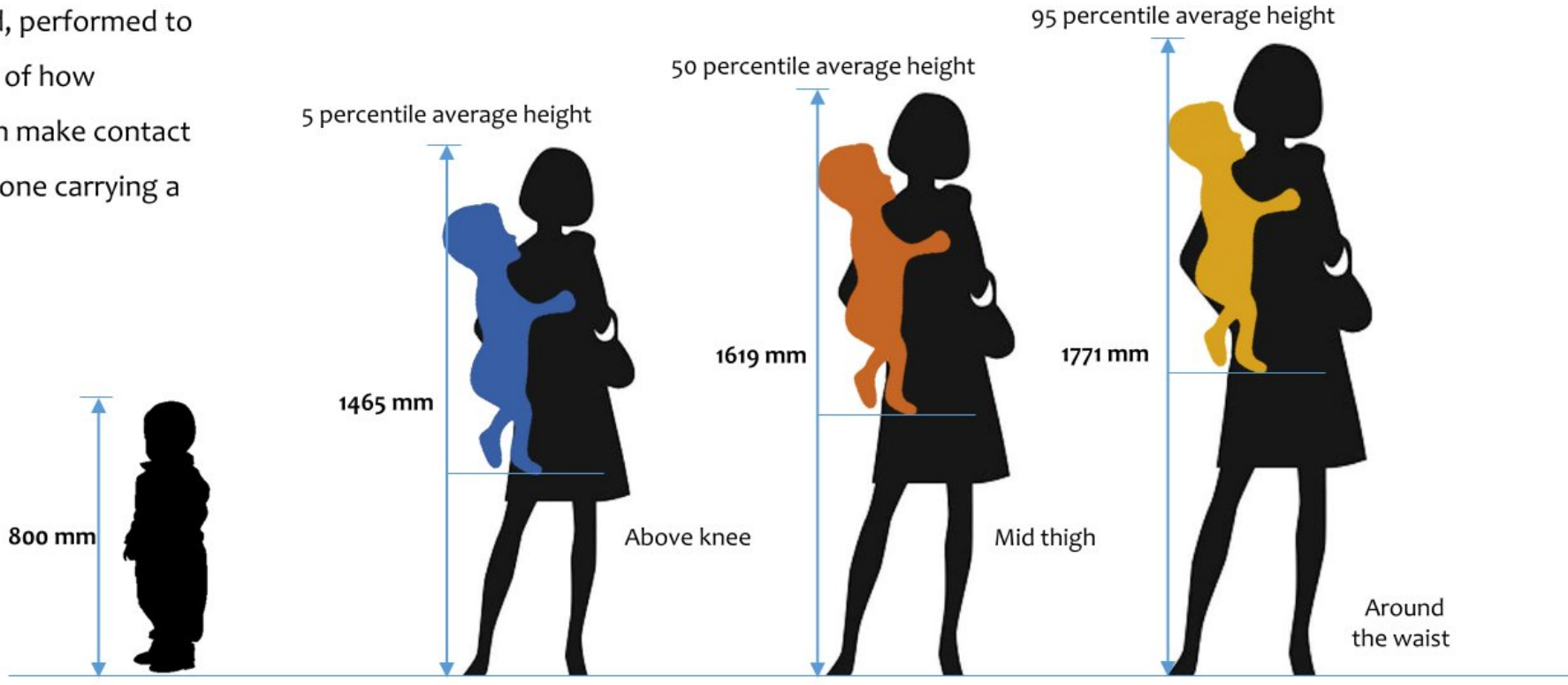


FIG. 5.34 POINT OF CONTACT OF BRACE WITH THE BODY

Ergonomics of Bracing

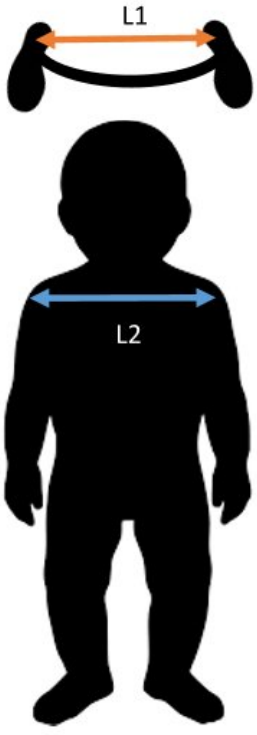


FIG. 5.35 BRACE LENGTH NORM

Brace size

The size of the brace is specified by its distance between the centre of rotation of the feet. This distance should approximately equal the shoulder breadth of the child as specified by the Doctors.

The sizes suggested by the Doctors are:

- 180 mm for age below 2 yrs.
- And 220 mm age above 2 yrs.

Center of rotation of foot

The figure 5.36 shows the approximate division of foot length into three equal parts such that the line of load passes through the distance of one-third of foot length from towards the hind foot. This is a standard data used in Transtibial Prosthetics Engineering [as per the reference 26]

This data was consider for referring to the center of rotation for foot abduction angle adjustment on the sole.

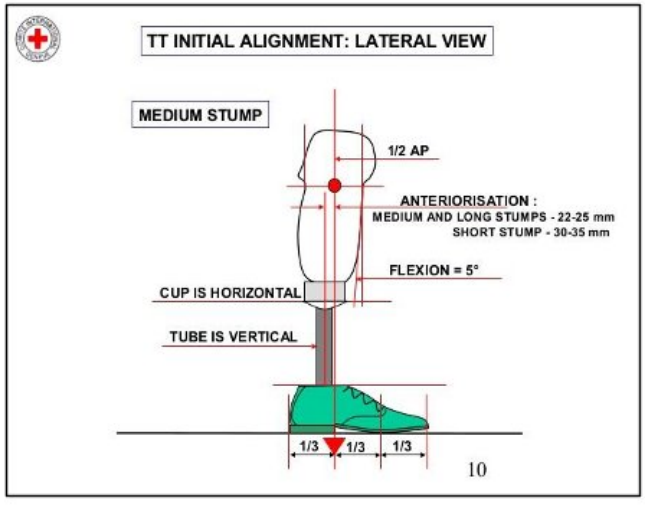


FIG. 5.36 THE CENTER OF ROTATION OF FOOT

Key Insights

- A closed Orthosis (shoe) makes it difficult to know the foot position within the shoe.
- Over-lacing the shoe creates discomfort to Child & Parents together.
- Most Parents lacks the idea of how exactly they followed the given instruction.
- Most clinically popular Orthosis lacks compliance with the Users.

Chapter 6

Proof of Concept

Biomedical Engineering and Technology (Incubation) Center Lab, IIT Bombay, has developed the technology supporting the need for monitoring of usage of brace and data collection. Figure 6.1 shows the schematic of circuit.

As per the schematic:

- There are piezo sensors placed in the shoe-sole.
- The bottom of the sole has a contact point to transfer signal from sensor to PCB module located at one end of the Brace.
- The is a power supply [Lipo battery] located on other side of the brace.
- The PCB module hubs a slot for the Micro SD card, used for data collection.
- The shoe when attached on the brace, the contact points on shoe and brace respectively, should always maintain contact with each other for proper data collection.

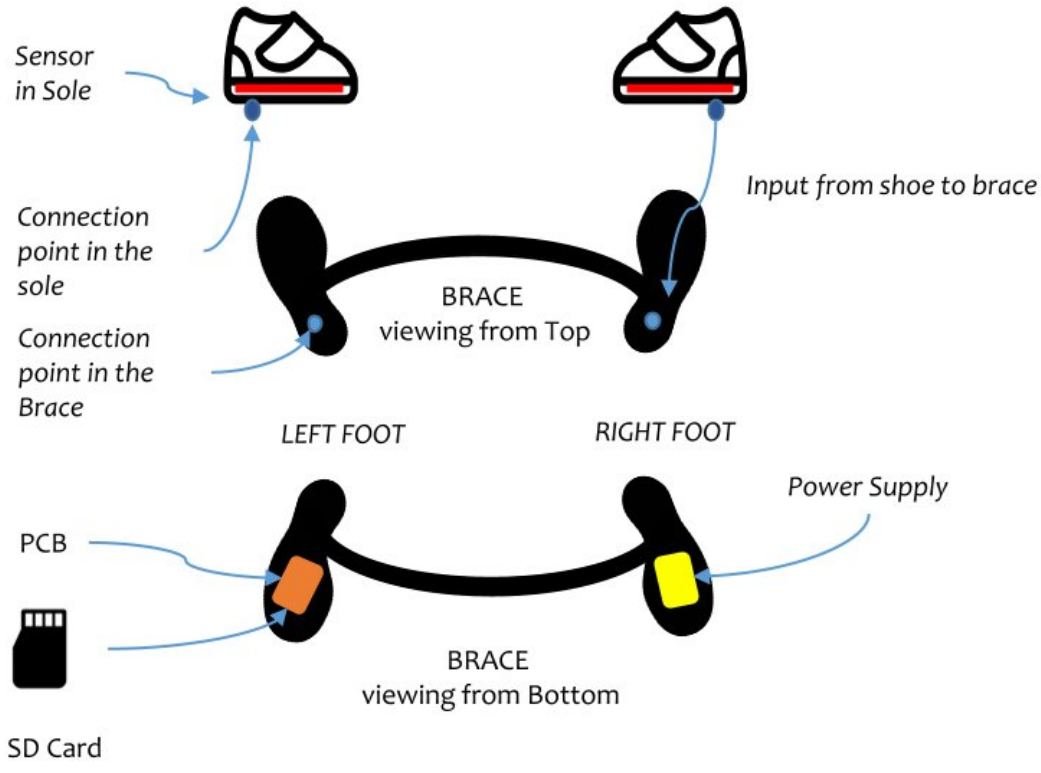


FIG. 6.1 CIRCUIT SCHEMATIC

Proof of Concept

- The circuitry was installed on a Stanford brace to demonstrate and conduct trial.
- The FSR sensors, as shown in figure 6.2, are put into shoe sole, the sensors are connected to main circuit running through the brace.
- The input from sensor is translated through the contact points, as shown in figure 6.3, below the shoe sole to the SIM receiver attached on the brace as shown in figure 6.4.
- The data is stored in the Micro SD card in Micro Data Logger and the whole circuit is powered by a Lipo Battery as shown in figure 6.5.

[FSR]Pressure sensor

FIG. 6.2

Connection points

FIG. 6.3

Unmodified brace

SIM Receiver [used as contact point]

FIG. 6.4

Modified brace

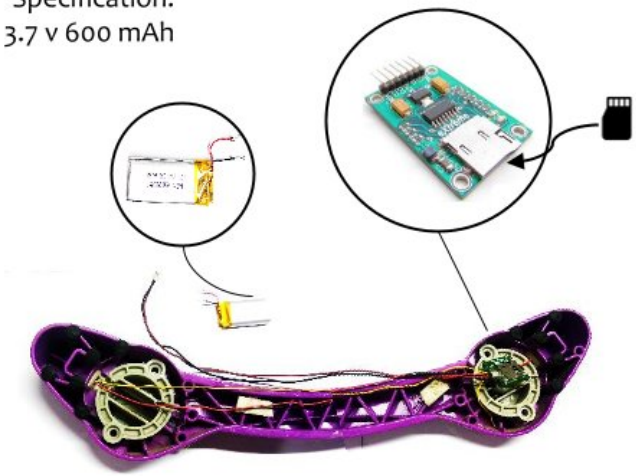
Lipo Battery

Dimensions:
35 x 17 x 5mm

Spécification:
3.7 v 600 mAh

Micro Data Logger For SD Card

Dimensions:
35 x 35 x 5mm



Left End's Bottom View

FIG. 6.5

Right End's Bottom View

Present procedure *[Scenario]*

- When the child is brought to clinic, he/she is allotted with a steinbeek or Stanford brace depending upon his/her condition.
- In the next visit, the parents will have to report the conduct of bracing, prescribed in previous appointment.
- Sometimes, the reporting of follow up by parents is not reliable as per clinicians, due to which the given treatment can prove to be false/incorrect. This is more prominent in case were the child may not show any improvement with respect what parents are reporting.
- The child is subjected to change of size of brace and shoe depending upon the his/her progress.

Expected procedure after adopting the technology

When the child is visited to clinic

The local data storage from the brace is taken out to collect the follow up report.

An assistant would transfer the data to the computer system to generate readable data of the follow up.

The local data storage is put back to the brace.

There can be a changed of shoe for the better fit. The child is now expected to visit on next visit

Bracing Protocol

In a meeting with Dr. Suresh Chand at B J Wadia Hospital, the bracing protocol was explained as

- The shoes are put first
- And then the brace is put on the shoes
- The step between the angle of abduction should be equal to or more than 20 degrees and the angle of dorsiflexion can maintain between 10 to 15 degrees.

Chapter 7

Design Brief

Design statement

To design a Club-foot Abduction Orthosis for Better User Compliance and True Monitoring of Prescribed Usage.

Design Brief

FUNCTIONAL REQUIREMENTS

UNOBSTRUSIVE
No electrical circuitry component should be visible

LIGHT IN WEIGHT
Not more than 500 mgs

DATA COLLECTION
Should facilitate realistic data collection

SAFETY
The orthosis should be water proof & electrical shock proof

USER COMFORT
The orthosis should be easy to adapt by child & during mother child interaction

COST EFFECTIVE
The cost should not be more than $ 25

TARGET USER

PRIMARY USER
Child

SECONDARY USER
Parents/ Guardian

TERTIARY USER
Clinicians and NGO staff

MAINTAINANCE

BATTERY REPLACEMENT
Every 3 months
By clinicians

EASE OF CLEANING
the orthosis should be easy to clean of particulate and fluid dirt

USAGE PATTERN

INITIALLY

Braces to be used 23 hrs. a day (for first 4 months)

REGULAR

Then 12 hrs. a day (for next 3-4years)

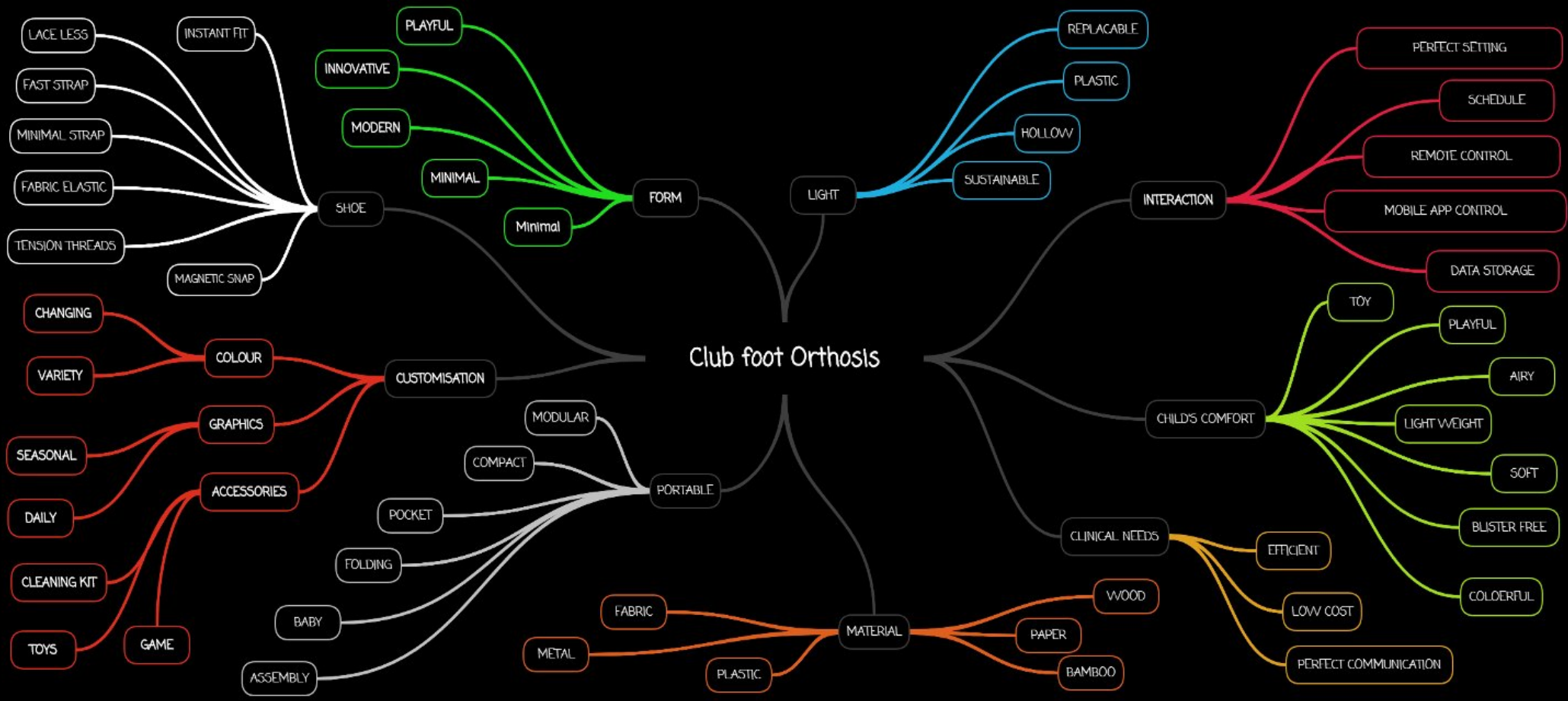
MAY HAVESs

Provision of Child-brace interaction.

Chapter 8

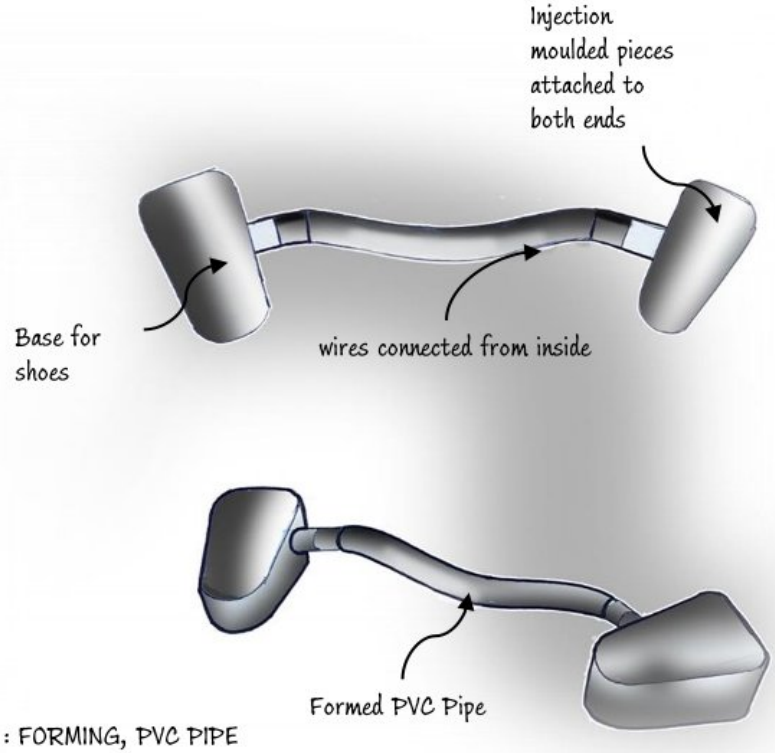
Ideation

MINDMAP

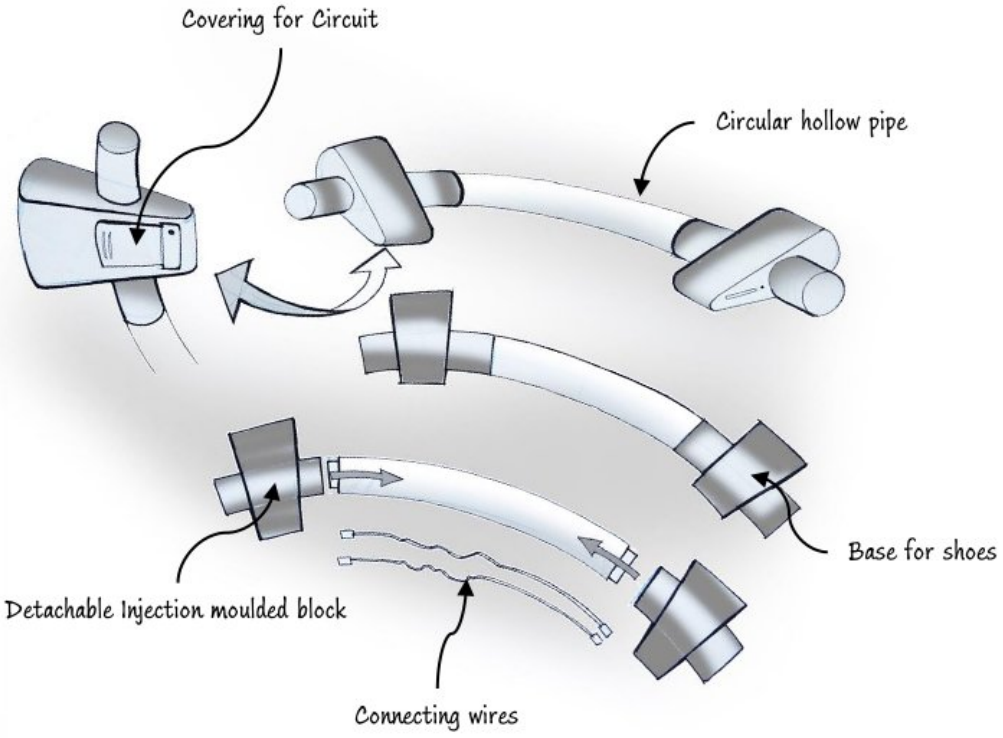

Club foot Orthosis
SHOE
LACE LESS
INSTANT FIT
FAST STRAP
MINIMAL STRAP
FABRIC ELASTIC
TENSION THREADS
MAGNETIC SNAP
FORM
PLAYFUL
INNOVATIVE
MODERN
MINIMAL
Minimal
LIGHT
REPLACABLE
PLASTIC
HOLLOW
SUSTAINABLE
INTERACTION
PERFECT SETTING
SCHEDULE
REMOTE CONTROL
MOBILE APP CONTROL
DATA STORAGE
CUSTOMISATION
COLOUR
CHANGING
VARIETY
GRAPHICS
SEASONAL
DAILY
ACCESSORIES
CLEANING KIT
TOYS
GAME
PORTABLE
MODULAR
COMPACT
POCKET
FOLDING
BABY
ASSEMBLY
MATERIAL
FABRIC
METAL
PLASTIC
WOOD
PAPER
BAMBOO
CHILD'S COMFORT
TOY
PLAYFUL
AIRY
LIGHT WEIGHT
SOFT
BLISTER FREE
COLOERFUL
CLINICAL NEEDS
EFFICIENT
LOW COST
PERFECT COMMUNICATION

Ideations for Brace

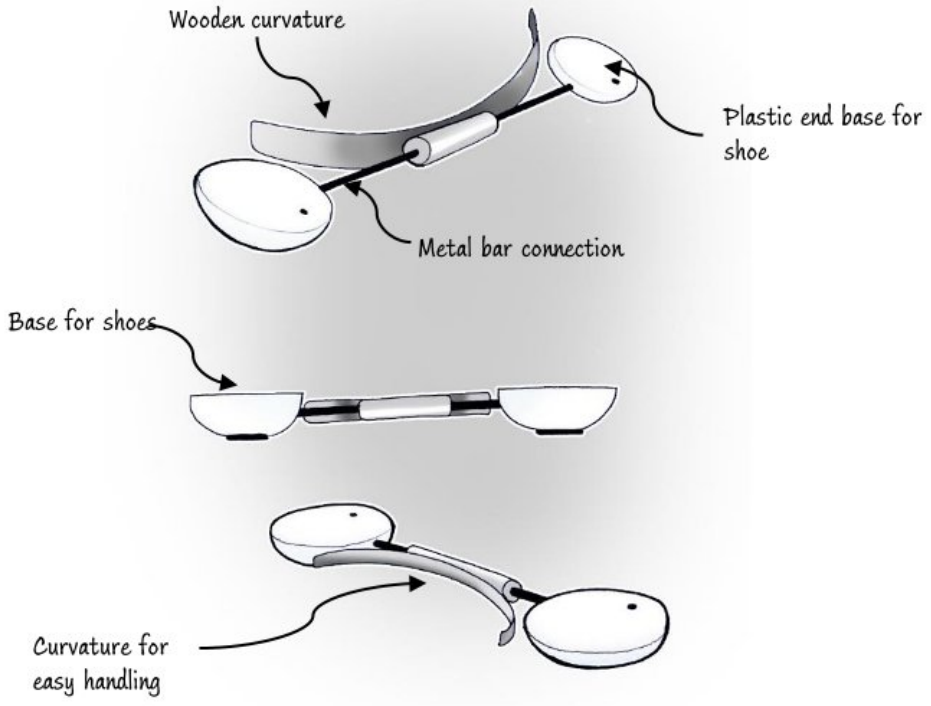
GROUP 1- FRUGAL MANUFACTURING



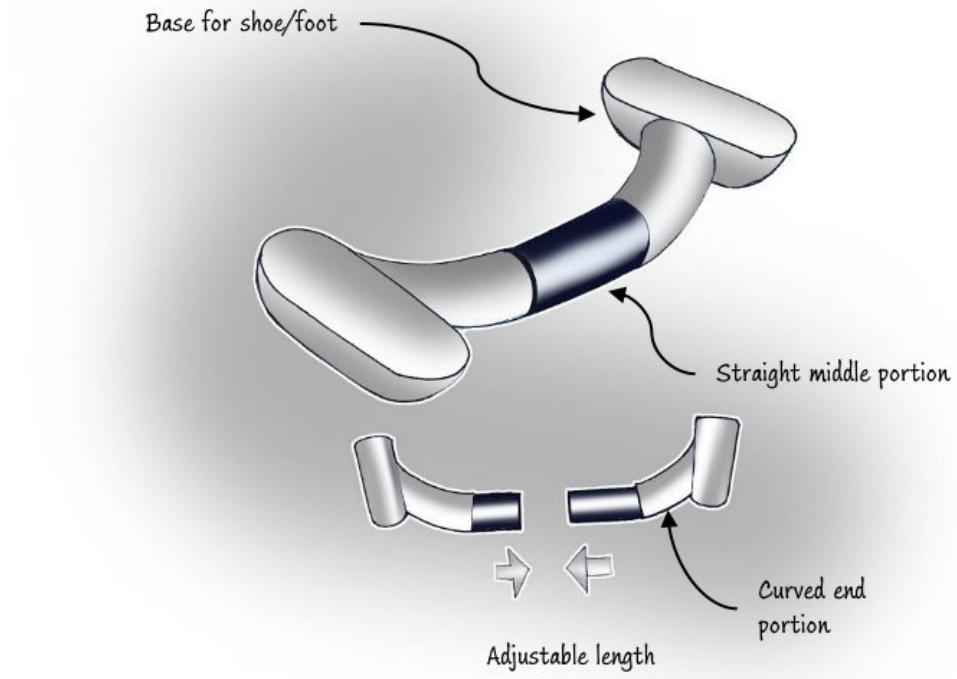
KEYWORDS : FORMING, PVC PIPE



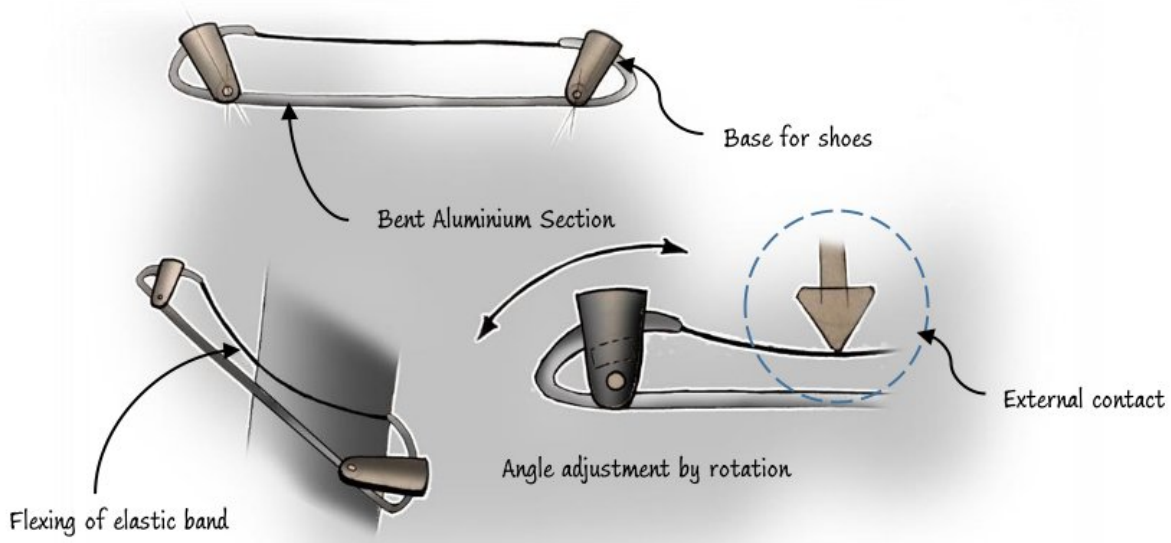
KEYWORDS :
FORMING, PVC PIPE, DETACHMENT



KEYWORDS : SUSTAINABLE, ABUNDANCE, MATERIALS

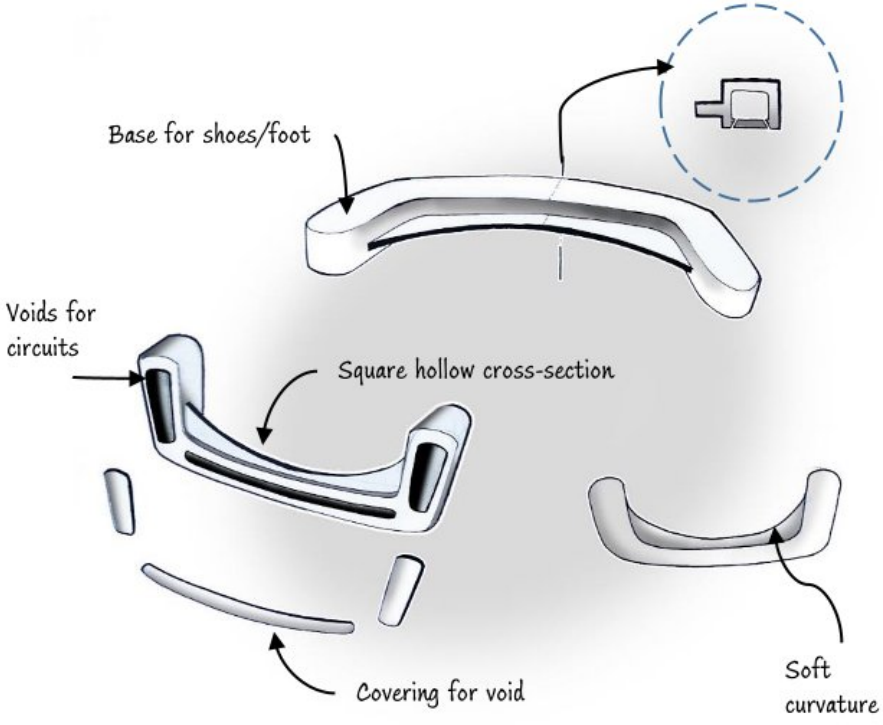


KEYWORDS : LENGTH ADJUSTMENT

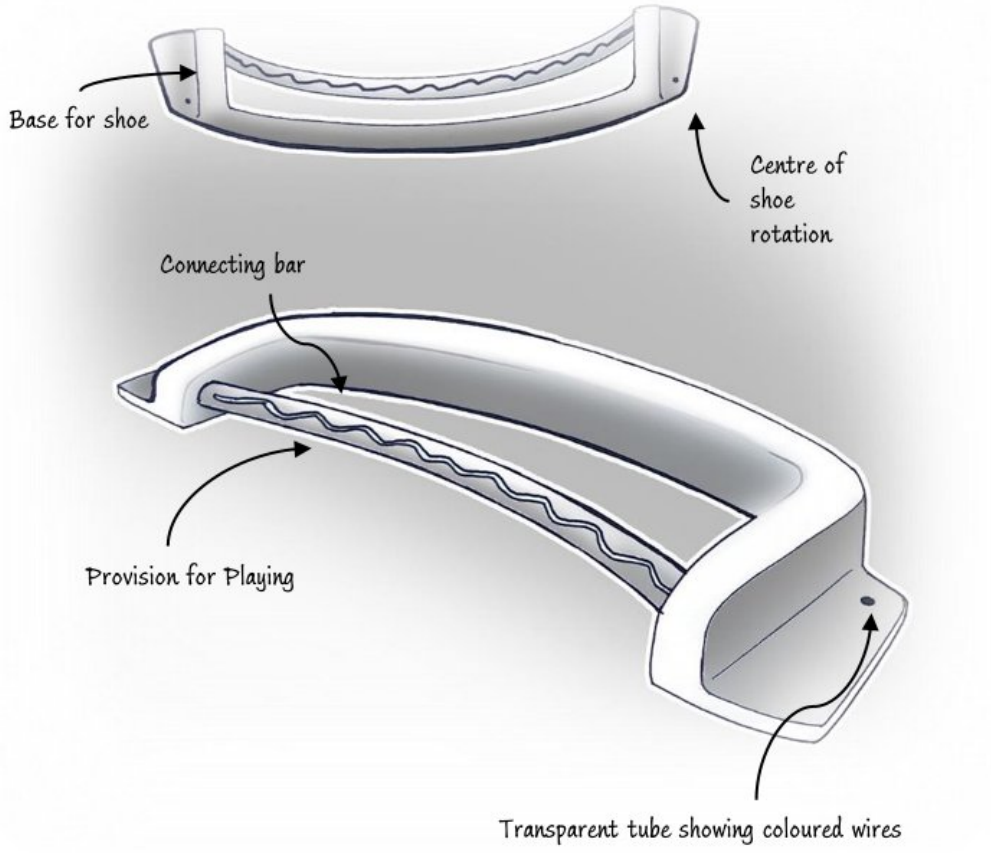


KEYWORDS :
EXTRUSION, BENDING, LIGHT, STRONG

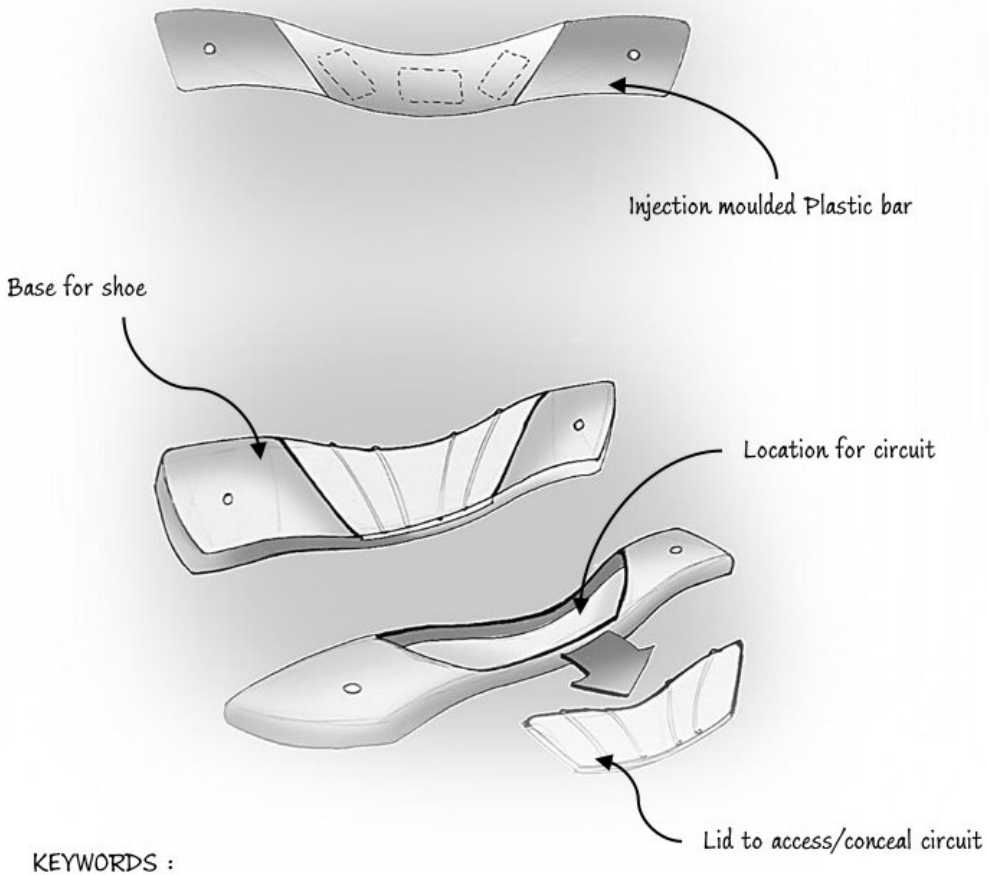
GROUP 2- INTEGRAL BODY



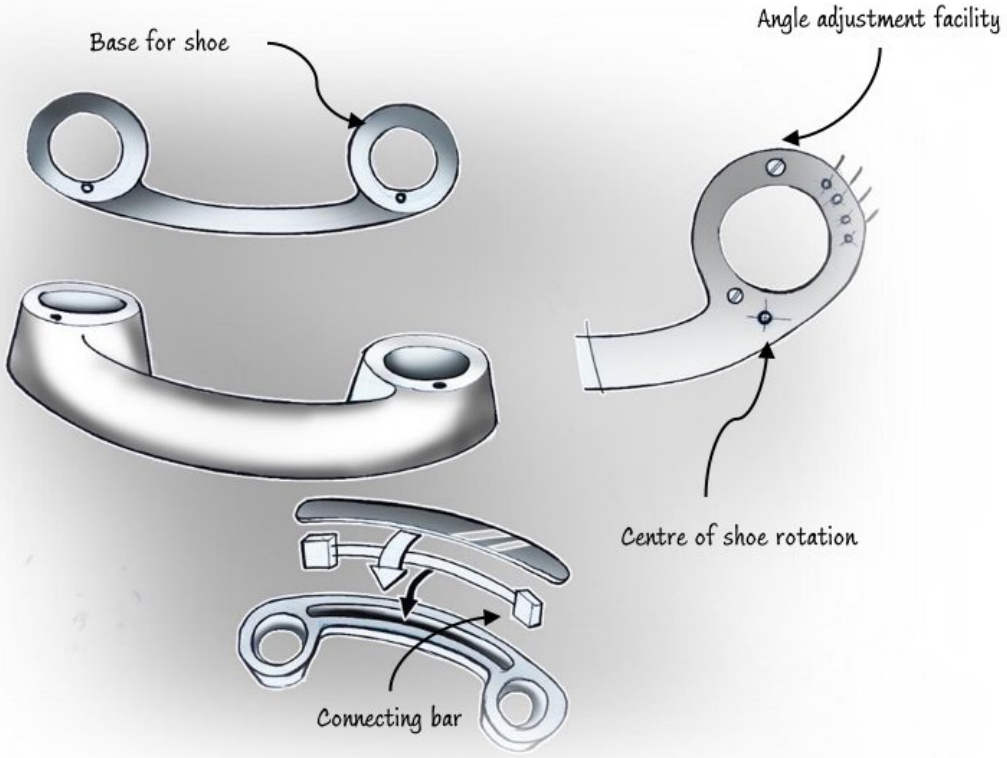
KEYWORDS : RIGID, UNIBODY



KEYWORDS :
SURPRISE, TRANSPERANT, COIL, PEDAL

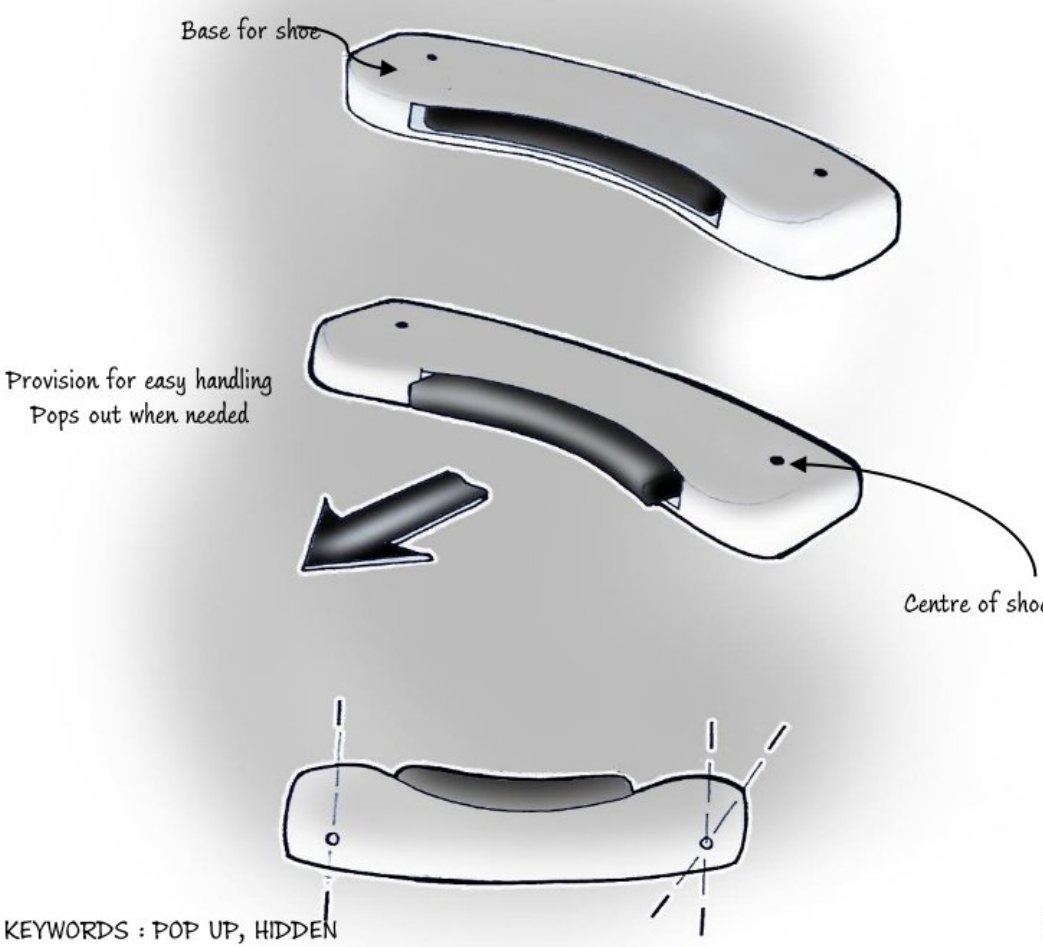


KEYWORDS :
UNIBODY, COMPACT SOFT, CLARITY

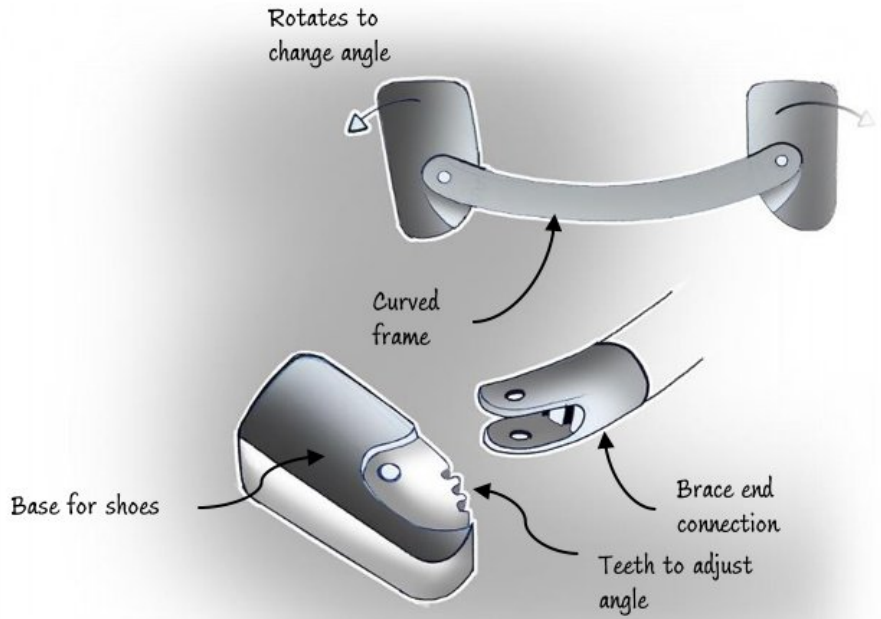


KEYWORDS :
HOLLOW, SOFT, TELEPHONE

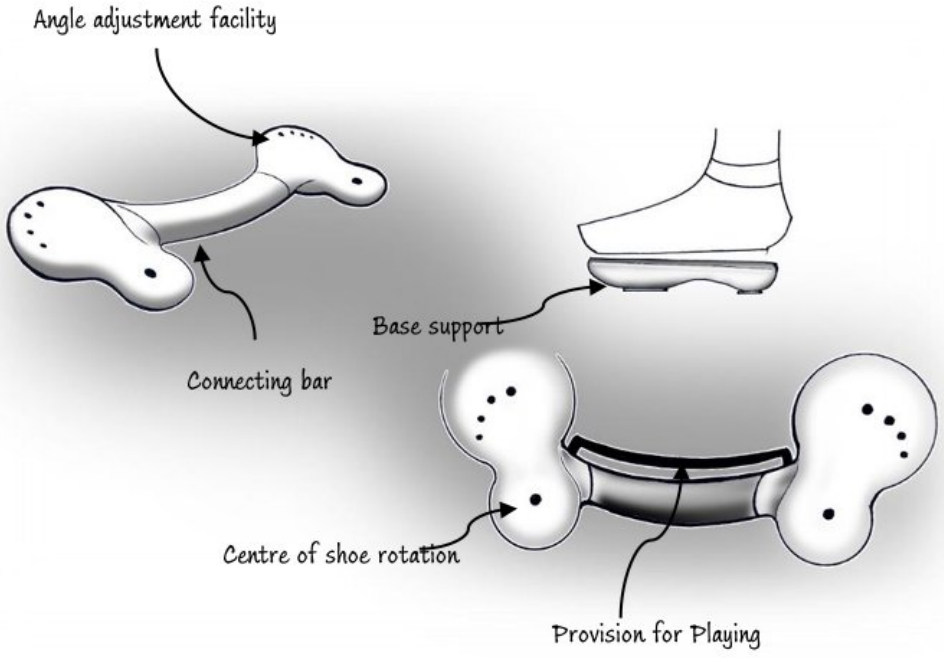
GROUP 3- ADDED FUNCTIONALITY



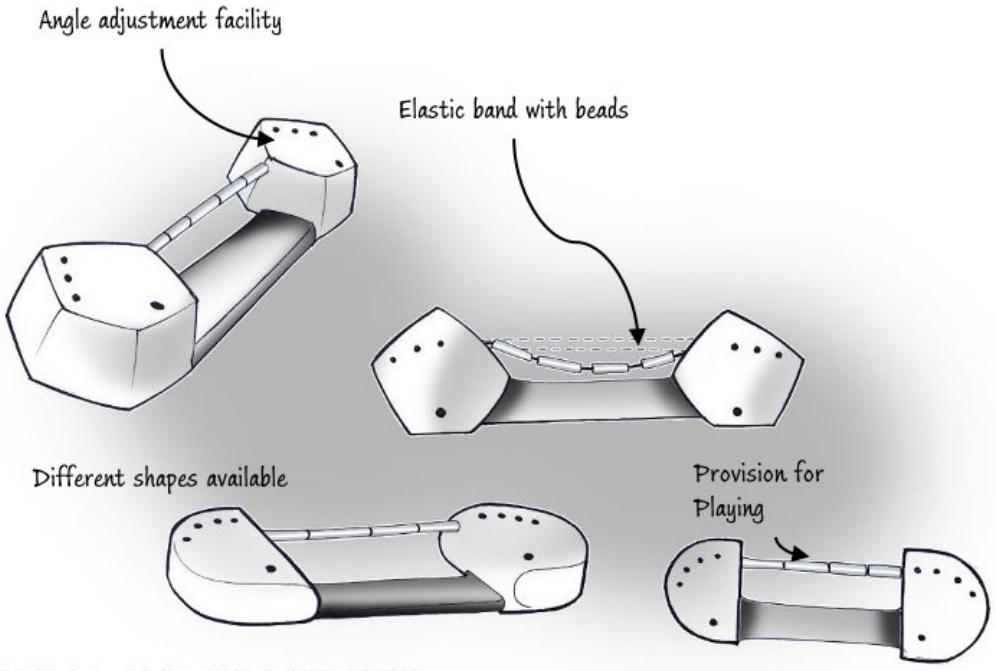
KEYWORDS : POP UP, HIDDEN



KEYWORDS : PIVOT, RATCHET



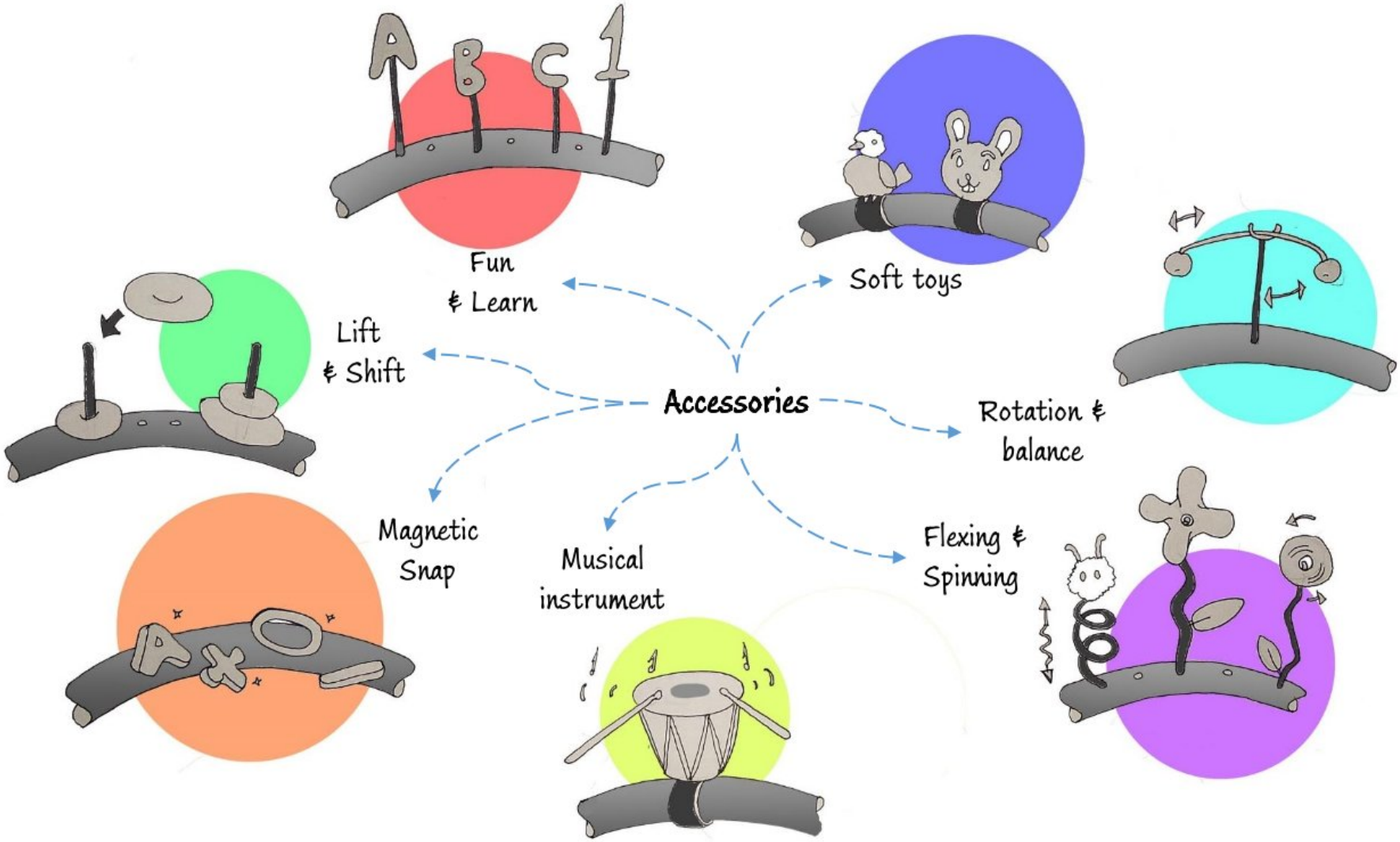
KEYWORDS : BONE, CONNECTION, STRENGTH, LINK

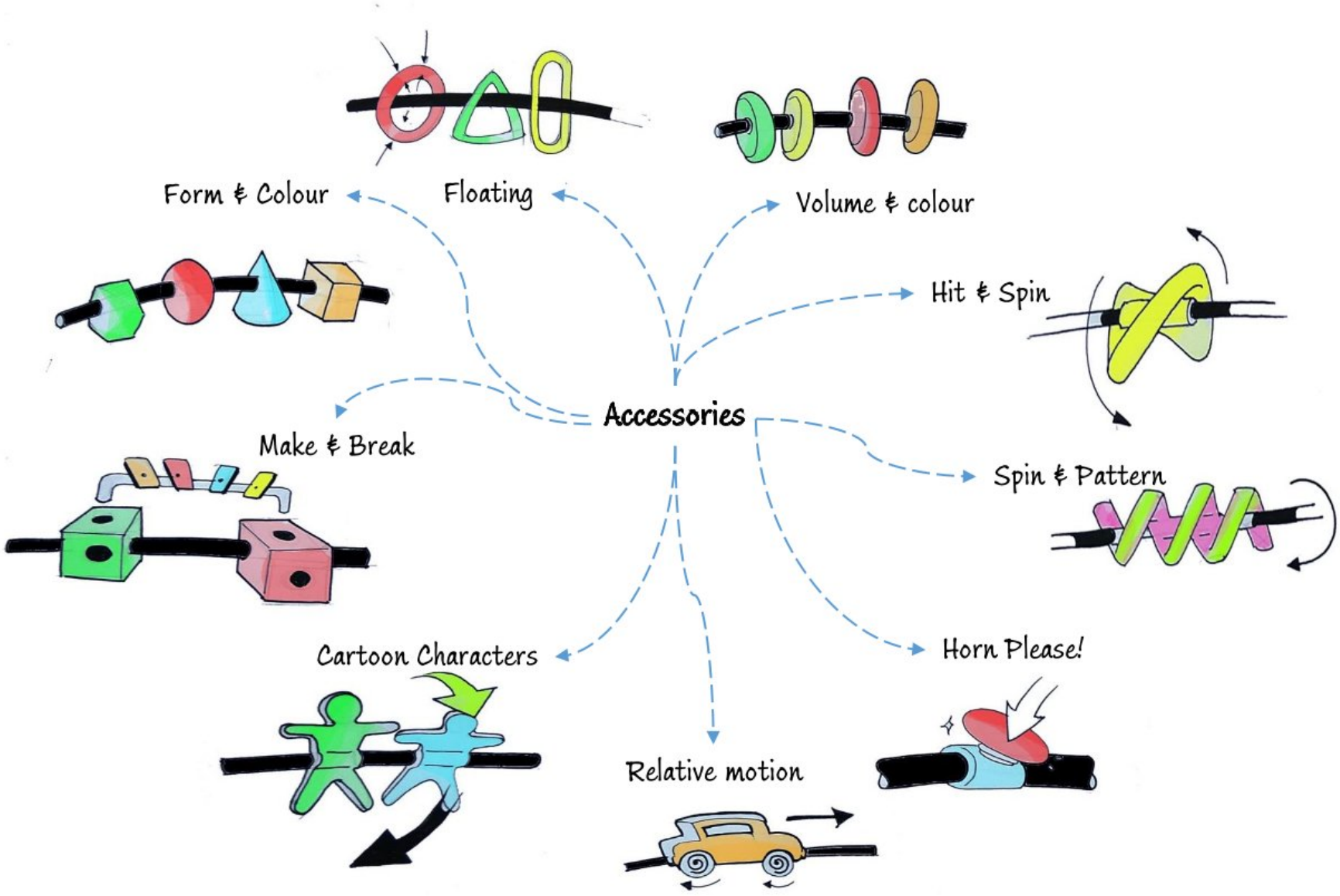


KEYWORDS : PLAY, SHAPE, ATTRACTIVE

Ideations

For accessories


Accessories
Fun & Learn
Soft toys
Lift & Shift
Rotation & balance
Magnetic Snap
Musical instrument
Flexing & Spinning


Form & Colour
Floating
Volume & colour
Hit & Spin
Accessories
Make & Break
Spin & Pattern
Cartoon Characters
Horn Please!
Relative motion

Chapter 9

Design of Brace footwear

Locating the Foot

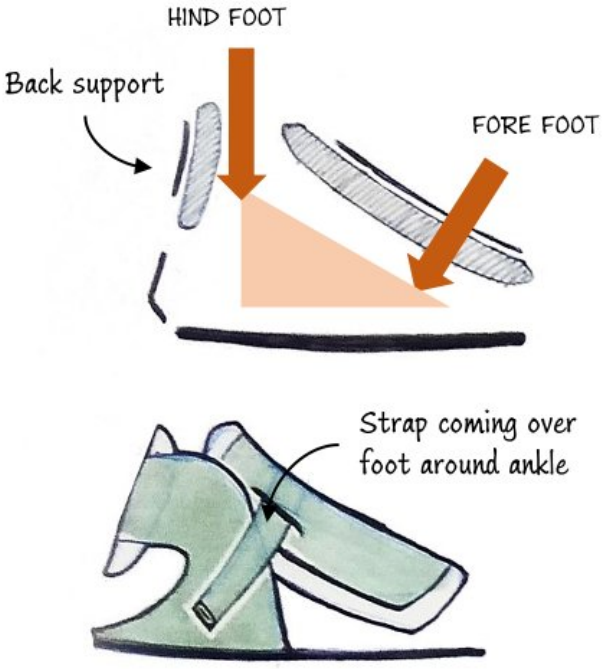


FIG. 9.1 REQUIRED FASTENING FOR FOOT

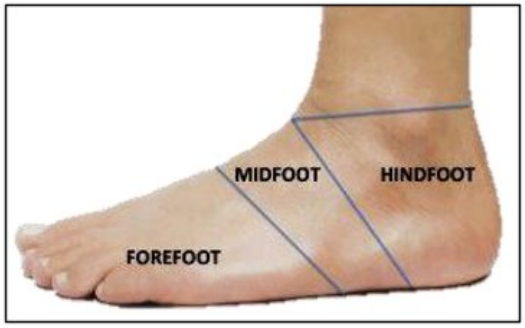


FIG. 9.2 FOOT DIVISION

- One of the key considerations for designing the foot wear for orthosis was to locate the foot properly.
- From the study of other orthosis and discussions with clinicians, it was found that, the foot needs to be located on the sole such that the hind foot and the fore foot as indicated in figure 9.2, should make firm contact on the sole.
- To assign a controlling detail to the foot wear, the least required no. of fastening forces/tension should strap the foot about the hind and fore portions as indicated in figure 9.1.

Ways to Strap

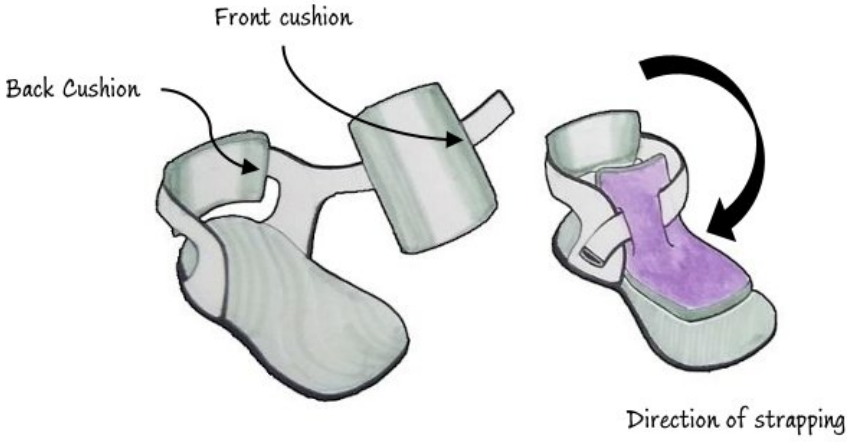


FIG. 9.3

FIG. 9.4 Velcro

FIG. 9.5 Lace

FIG. 9.6 Combination of Elastics & button

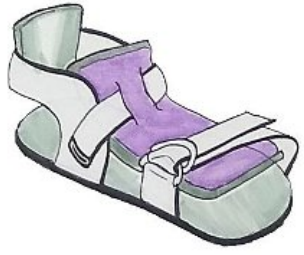


FIG. 9.7 Combination of Buckle with Velcro

Adding to the strapping further, the major two stress points; first, where the tightening makes mark on the foot as found from user study, two cushioning was required. One for front and other for back side as shown in figure 9.3
Further, for fastening the strap, options like Velcro, lace, elastic band , buttons and buckles were considered, based on the present trends in shoe design, as shown in the figure 9.4,9.5,9.6 and 9.7 respectively.

Static anthropometry data for Leg & Foot
AGE GROUP 3 TO 4 YEARS

As per
SECTION 1.5
Hand book of Child Measurement & Capabilities
By Norris & Wilson

Indicated dimensions in figures 9.8 to 9.16 were taken into consideration for designing a footwear.
The age group 3-4 years was chosen initially.

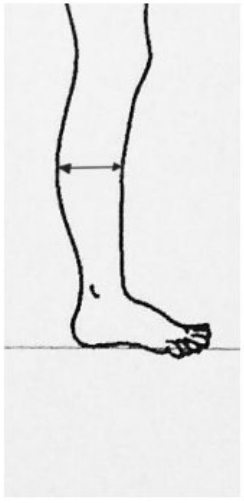


FIG. 9.8 *Calf Depth*
6.5 cm

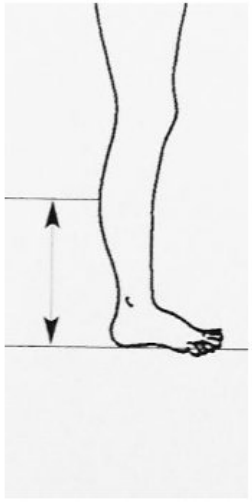


FIG. 9.9 *Calf height*
18.6 cm

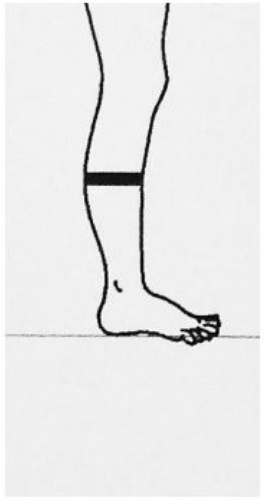


FIG. 9.10 *Calf circumference*
20.6 cm

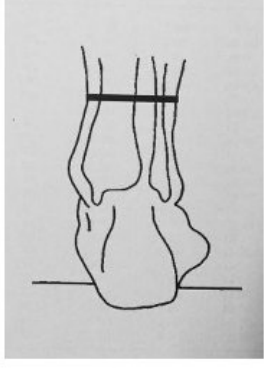


FIG. 9.11 *Ankle circumference*
15.4 cm

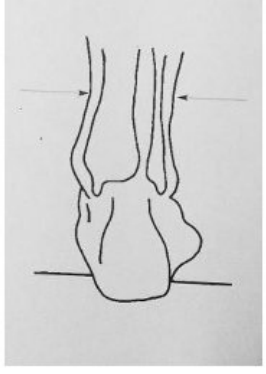


FIG. 9.12 *Ankle breadth*
3.8 cm

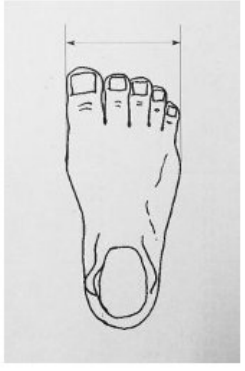


FIG. 9.13 *Foot breadth*
6.8 cm

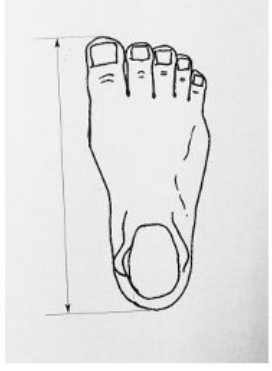


FIG. 9.14 *Foot length*
15.5 cm

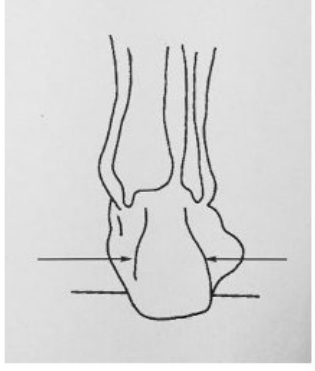


FIG. 9.15 *Heel breadth*
4.6 cm

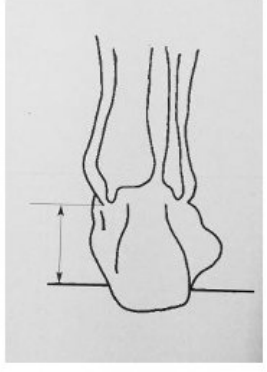


FIG. 9.16 *Ankle height*
3.9 cm

Mock Up And Iterations

FIG. 9.17 MAKING OF MOCK-UP MODEL FOR A REFERENCE

FIG. 9.18 VELCRO

FIG. 9.19 COMBINATION OF ELASTICS & BUTTON

FIG. 9.20 LACE

FIG. 9.21 COMBINATION OF BUCKLE WITH VELCRO

As the figure 9.17 shows, a reference model was made to construct a synergetic strapping around it. Using which, four different mock ups, as shown in figure 9.18 to 9.21, were made to test the best suiting way to fasten the straps.

MODEL-Front strapping with Velcro

FIG. 9.22

FIG. 9.23

FIG. 9.24

MODEL-Front strapping with Buckle

FIG. 9.25

FIG. 9.26

FIG. 9.27

MODEL-Front strapping with Lace

FIG. 9.28

FIG. 9.29

FIG. 9.30

MODEL-Front strapping with Elastic band , Button & Velcro

FIG. 9.31

FIG. 9.32

FIG. 9.33

All the mocks were tested, as shown in above images, by kids of age group 3-4 years. The key insights from the testing were:

- Strapping with only Velcro was preferred by all parents [as children wore sandals for sports activities, parents were confident about using Velcro]
- Visual accessibility of foot and Inspection was easier with present way of strapping & flat sole.
- Wider front strap would be better.

Static anthropometry data for Leg & Foot
AGE GROUP 18 TO 24 MONTHS

As per
SECTION 1.5
Hand book of Child Measurement & Capabilities
By Norris & Wilson

The age group was later changed to 18 to 24 month considering the frequency of appointment and age of the patients visiting clinic.

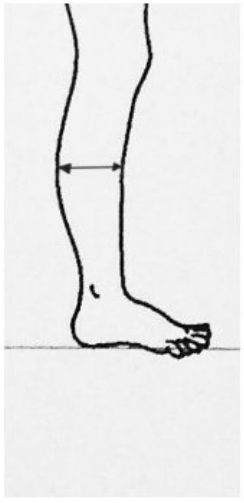


FIG. 9.34 *Calf Depth*
6.2 cm

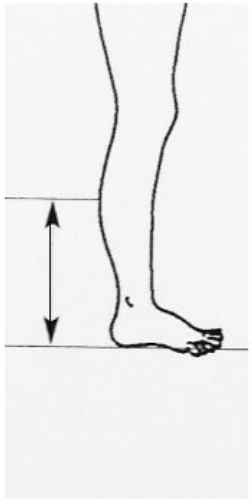


FIG. 9.35 *Calf height*
16.8 cm

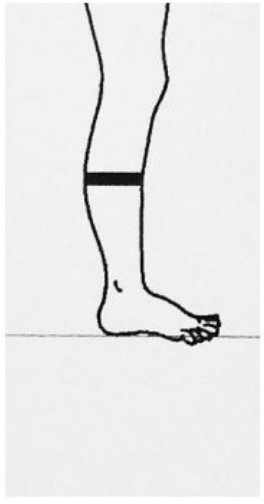


FIG. 9.36 *Calf circumference*
19 cm

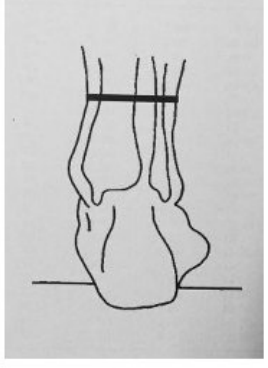


FIG. 9.37 *Ankle circumference*
14.3 cm

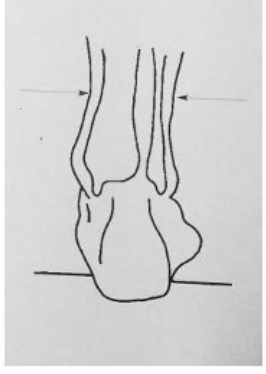


FIG. 9.38 *Ankle breadth*
3.8 cm

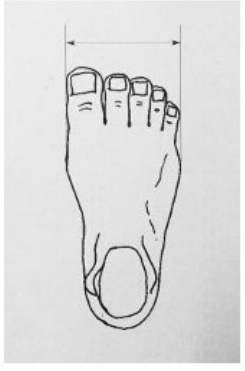


FIG. 9.39 *Foot breadth*
5.5 cm

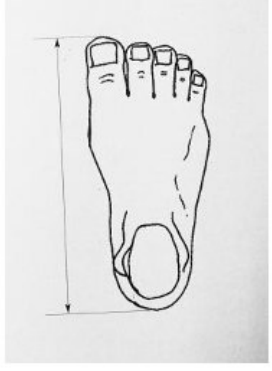


FIG. 9.40 *Foot length*
12.5 cm

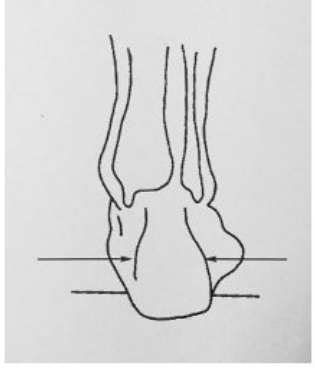


FIG. 9.41 *Heel breadth*
3.5 cm

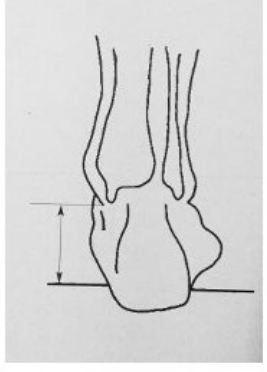


FIG. 9.42 *Ankle height*
3.9 cm

Trial 1

FIG. 9.43

FIG. 9.44

FIG. 9.45

FIG. 9.46

FIG. 9.47

FIG. 9.48

FIG. 9.49

After the change in the target age group, another mocks up for foot were created to design the Velcro based foot wear. Figures above indicates the first trial.

Trial 2

FIG. 9.50

FIG. 9.51

Another trial [second], as shown in figure 9.50 and 9.51, with change of strapping direction was done. The strapping here comes from one side of the foot and turns back through an eye/loop for to be fasten by Velcro.

Trial 3

The initial trials were conducted considering that the whole foot wear can be constructed out of straps only for the ease of manufacturing as shown in figure 9.52 and figure 9.53 and 9.54 shows the trial 3.

FIG. 9.52

FIG. 9.53

FIG. 9.54

Trial 4

FIG. 9.55

FIG. 9.56

FIG. 9.57

FIG. 9.58

FIG. 9.59

Figure above shows another trial, were the width of Velcro band was different in straps. After this a feedback session was conducted, in which Dr. Sourabh Sinha and Dr. Suresh Chand from B J Wadia Hospital reviewed the work and the given feedback was-

- *To keep the edge on the internal side of the foot straight and harder*
- *Increase the span of cushion from behind the heel.*

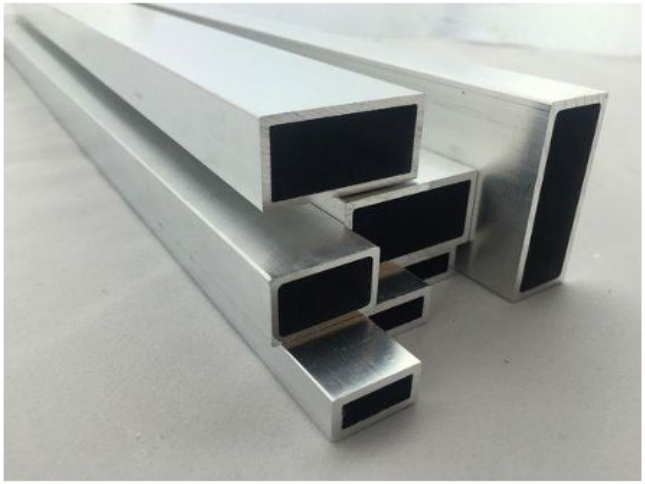
Chapter 10

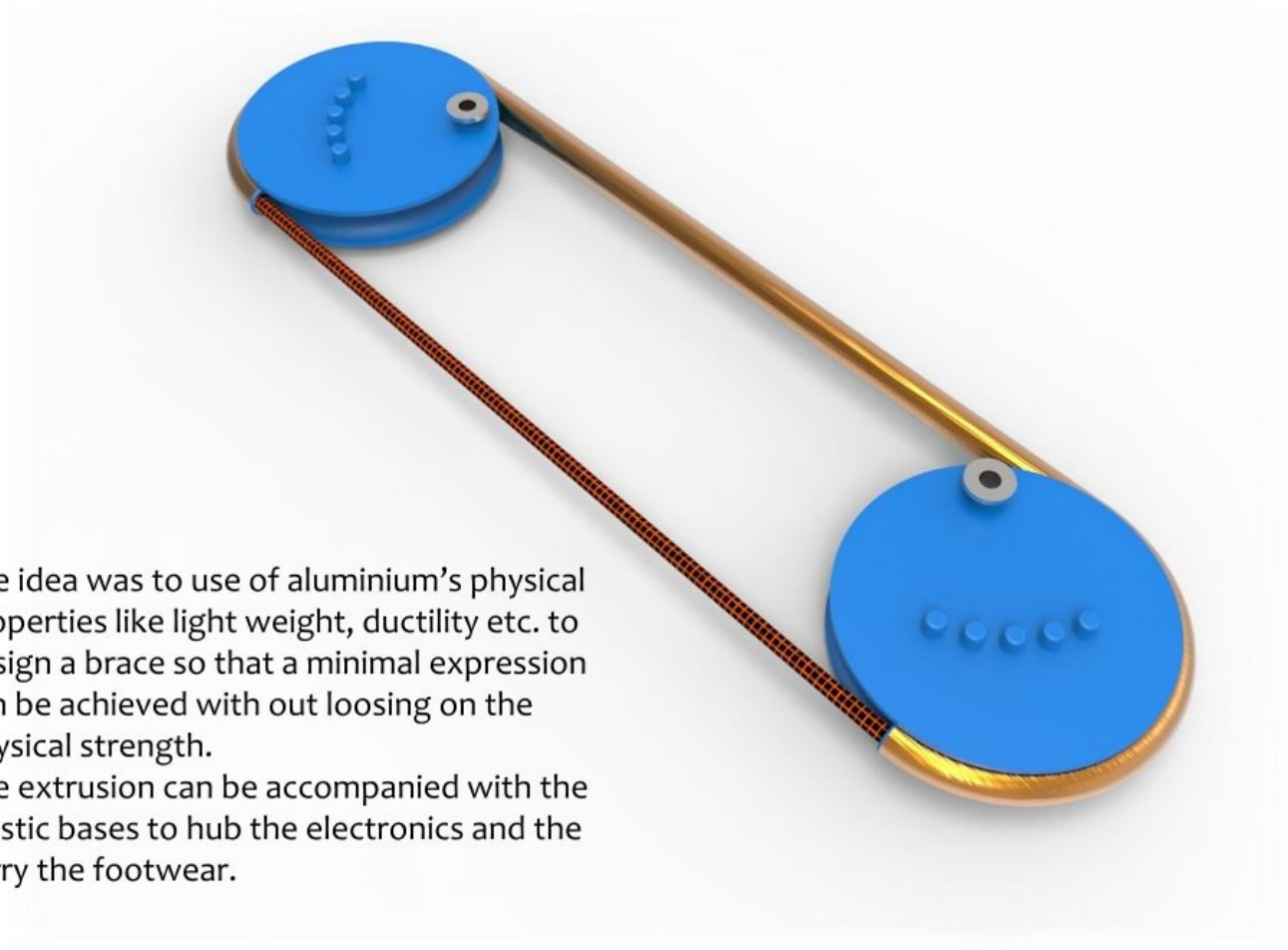
Design Concepts for Orthosis

Concept 1

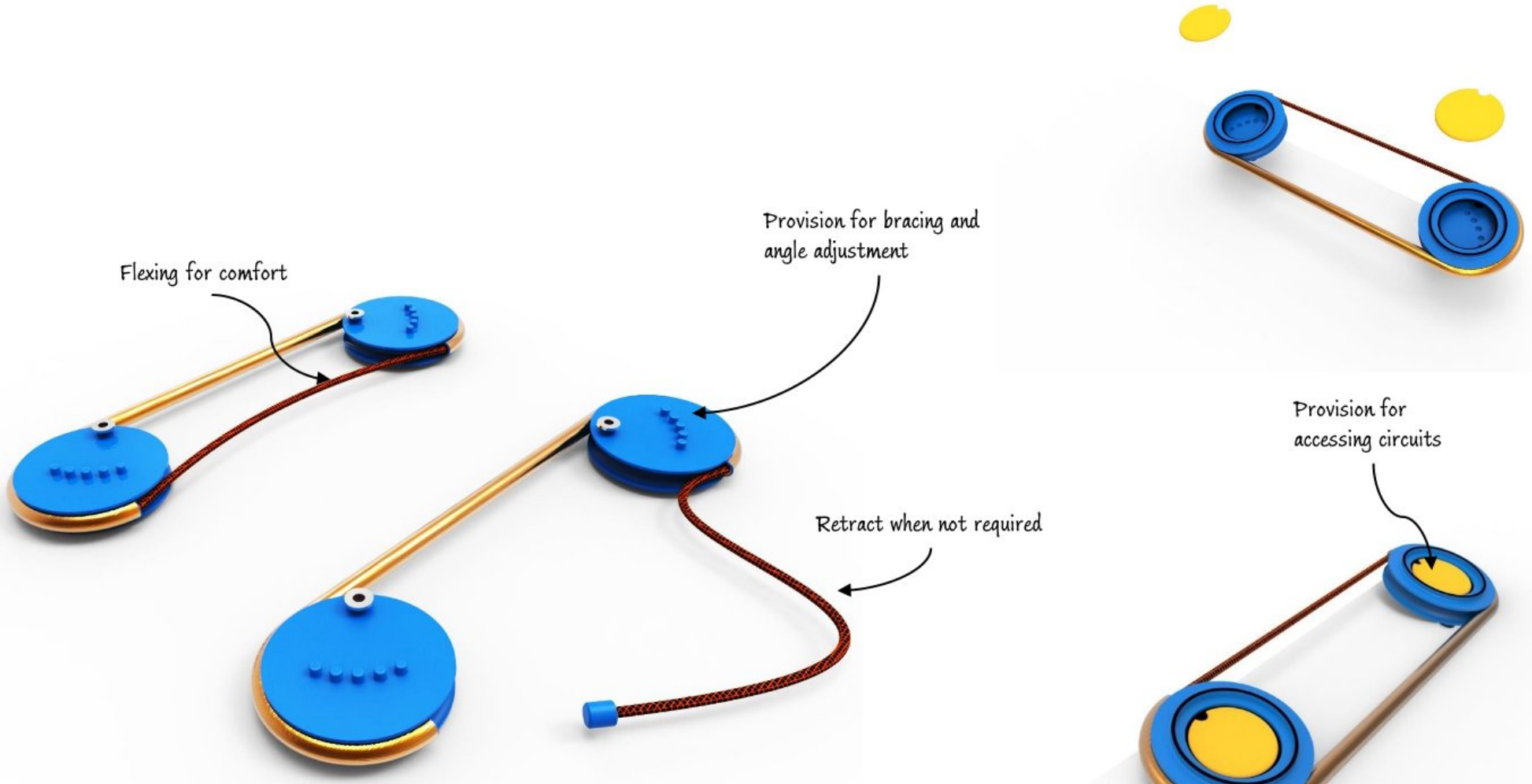
Inspiration

An Aluminium sections





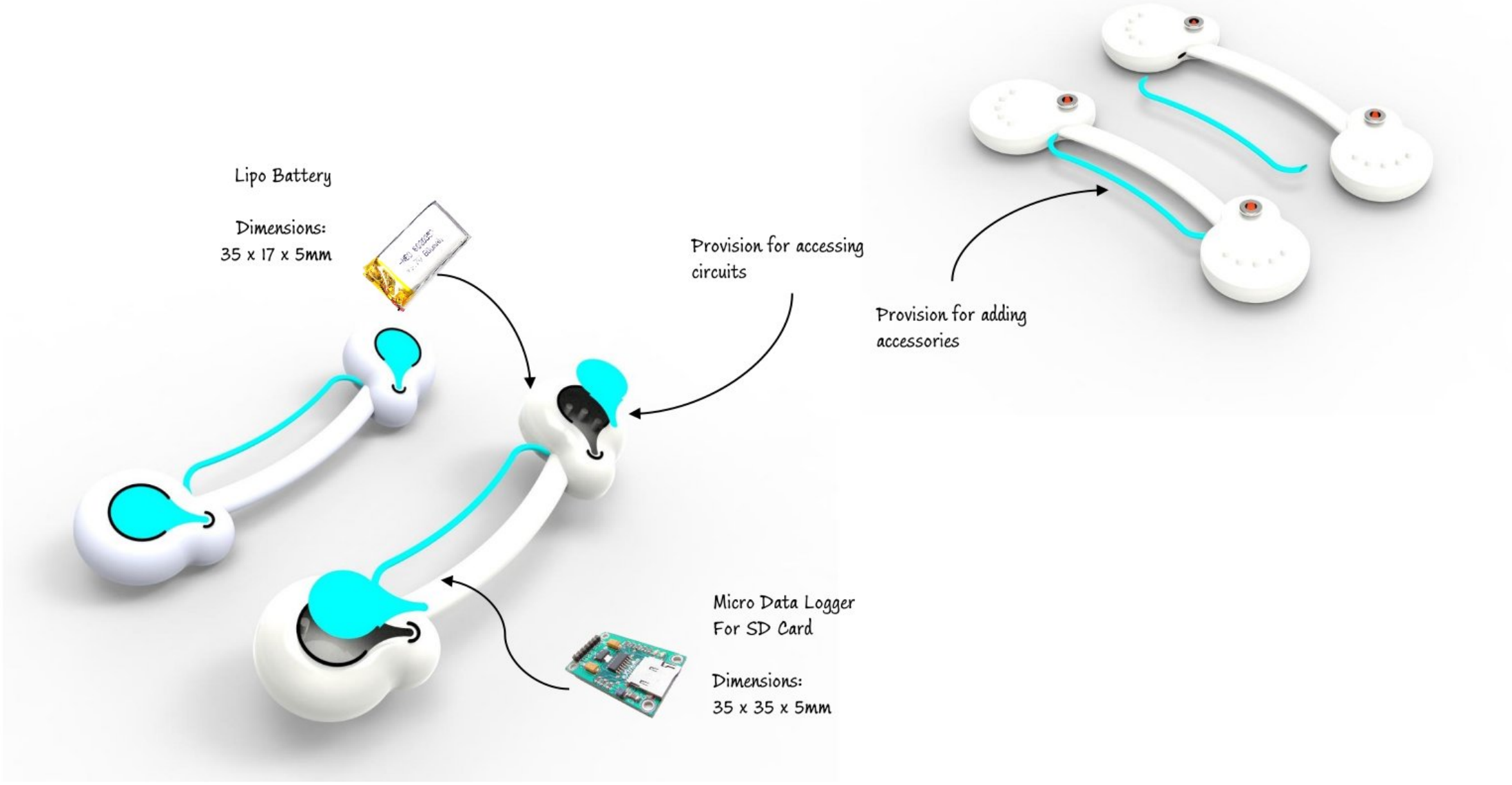
The idea was to use of aluminium's physical properties like light weight, ductility etc. to design a brace so that a minimal expression can be achieved with out loosing on the physical strength.
The extrusion can be accompanied with the plastic bases to hub the electronics and the carry the footwear.


Flexing for comfort
Provision for bracing and angle adjustment
Retract when not required
Provision for accessing circuits

Concept 2

Inspiration
A Bone

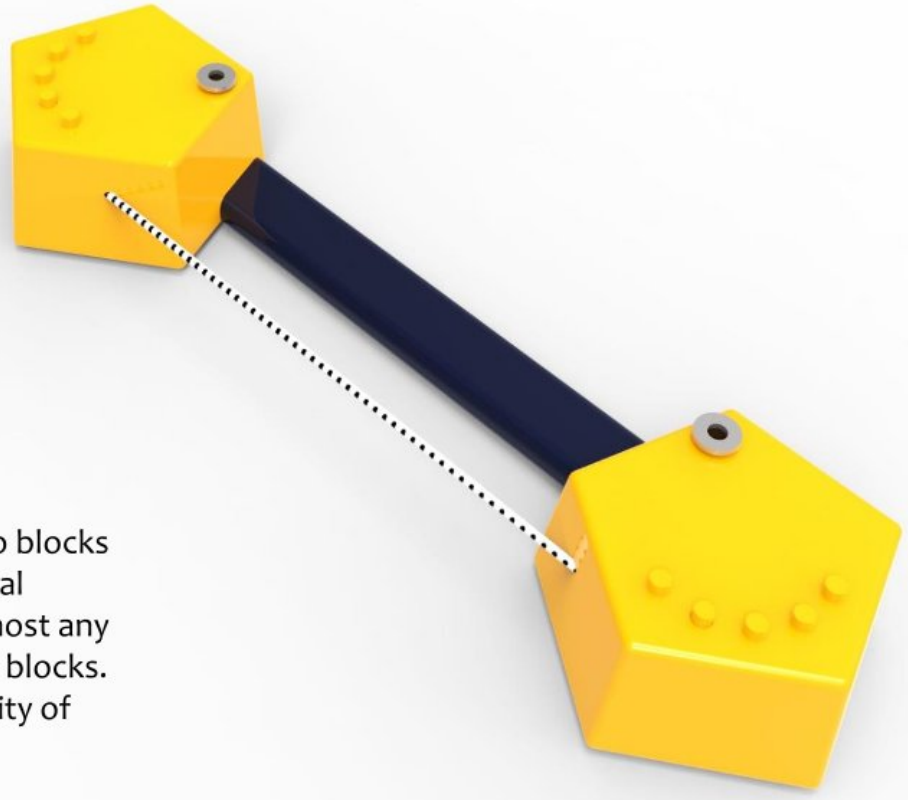
The idea was to create a uni-body structure inspired from the Bones. A uni-body structure like bone, retains better strength hence, the notion that *the brace is stronger as bones* is validated by a *simile.*
Also, the Bone as Object is quite popularly cartooned in many animated shows for children.


Lipo Battery
Dimensions:
35 x 17 x 5mm
Provision for accessing
circuits
Micro Data Logger
For SD Card
Dimensions:
35 x 35 x 5mm
Provision for adding
accessories

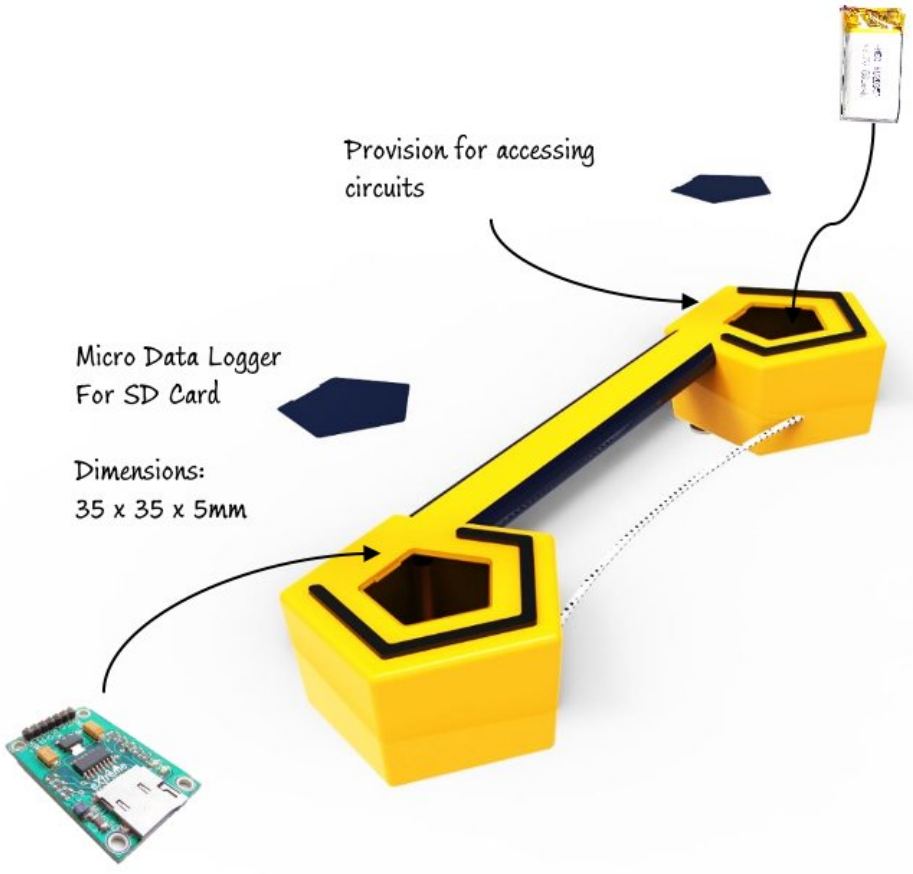
Concept 3

Inspiration

The Lego block



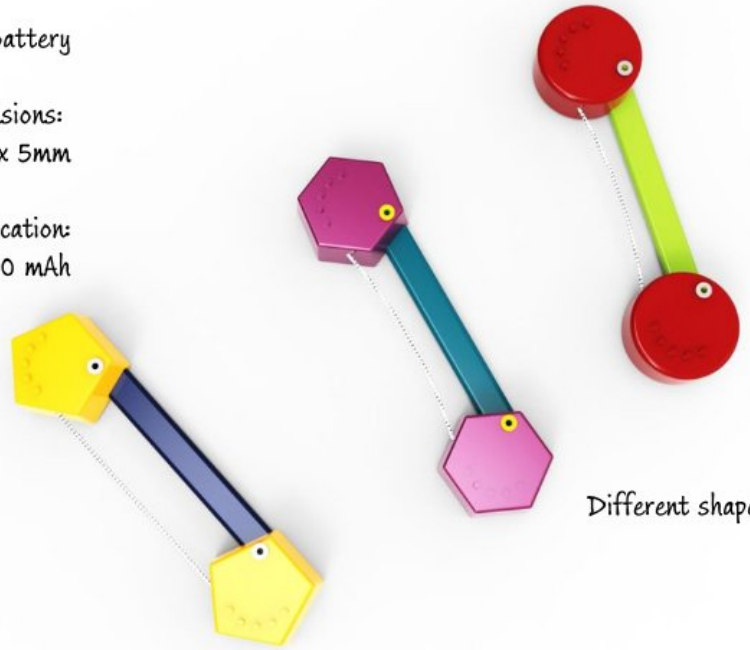
The colorful and vibrant Lego blocks are popular for their structural flexibility of constructing almost any thing out of strong and edgy blocks. The idea was to use this quality of Legos to bring in some customizability in brace.



Lipo Battery

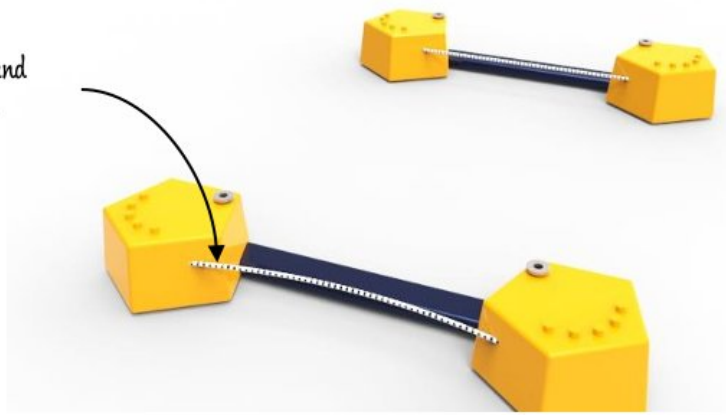
Dimensions:
35 x 17 x 5mm

Specification:
3.7 v 600 mAh



Different shape and colour
every visit

Flexing for comfort and
mounting accessories



Concept 4

Inspiration
The Telephone toy

One of the most popular and imitated toy of all time- Telephone.
The idea was to bring in similar visual language to make it appeal like a just another toy to play around.

Lipo Battery

Dimensions:
35 x 17 x 5mm

Specification:
3.7 v 600 mAh

Micro Data Logger
For SD Card

Dimensions:
35 x 35 x 5mm

Provision for
accessing circuits

Hollow structure to add
strength

Provision for bracing and
angle adjustment

Chapter 11

Final Concept

Concept Analysis

	CONCEPT 1	*CONCEPT 2*	*CONCEPT 3*	*CONCEPT 4*
LIGHT WEIGHT	Using metal extrusion can increase the weight . Thinner sections would make it sonorous. Thicker section would make it heavier.	There is a functional distribution of volume that can help achieving lightest possible design with suitable grade of plastic.	The customization by use of basic geometric shapes calls for a bulkier ends of the brace.	The connection bar of the brace is biggest of all concepts making it consume more material to get manufactured and visually heavier
CUSTOMISATION	The flexing band and the anodizing of extrusion can be customized for color textures and patterns on them.	The subtle curved form can compliment physical well with a platform like attachment where the child can play and the brace can become more interactive.	This concept allows for customization of shape of the brace ends , color and flexing band for color, pattern, texture.	The color of the brace can changed.
FORM FACTOR	The integrity of two different material creates a three piece configuration because of which it feels as though it lacks physical integrity	The form here is most functional of all the concepts.	The ideal of using shapes for inculcating customization into the brace would not necessarily come up with a good formal statement. This approach has randomness to it.	The intermediate connection is way stronger visually and overall the formal appeal is quite similar to the toys
MAINTENANCE	As this would be a three piece brace, cleaning would be an issue at joints	There is a possibility of accessing electronics from top. The defined shape and the mating with shoe can take care of the exposure of lid openings to foreign particles	There is a possibility that lids to access electronics can be shifted on the top. This would still can expose the openings to foreign particles because of undefined and bigger surface area.	The wide accessible cap at bottom can collect lot of dust and dirt.
SAFETY	Users would always be skeptical as metal extrusion will be carrying the connecting wires. Water proofing might fail at joints.	There is a defined bifurcation of space in this concept so it would help confining the circuit from any kind of leakage.	Like concept 2, this also has bifurcation of space but the addition of flexing band can permit moisture inside the brace body. There is a risk that it also might carry electric current if moist.	There is high risk of failing [of water proofing and electrical isolation] due large perimeter of the opening lid located at the bottom. This facilitates increased permeability for foreign particles

Concept Evaluation

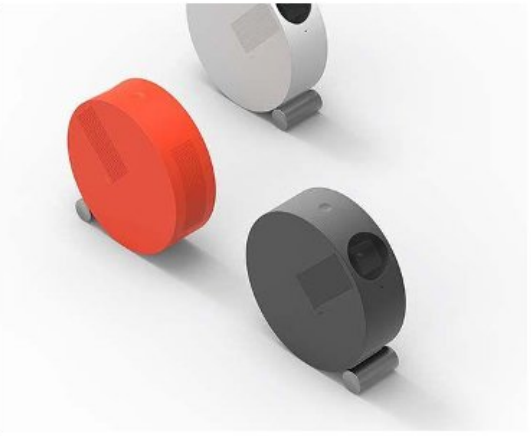
Concept evaluation was done on the basis of functional requirement after a discussion with Dr. Sourabh Sinha. Following are the factors considered :

- *LIGHT IN WEIGHT*
- *CUSTOMIZATION –color, shape, and attachments.*
- *SAFETY --water proof and electrical circuit isolation.*
- *FORM FACTOR*
- *MAINTENANCE --Ease of cleaning and accessibility of electronics*

Criterion	*CONCEPT 1*	*CONCEPT 2*	*CONCEPT 3*	*CONCEPT 4*
LIGHT WEIGHT	4	1	2	3
CUSTOMISATION	2	3	1	4
SAFETY	3	1	2	4
FORM FACTOR	4	1	3	2
MAINTENANCE	4	1	2	3
Average rank	3.4	**1.4**	2	3.2

Mood Boards



PLAYFUL

Mood board 1





SOFT

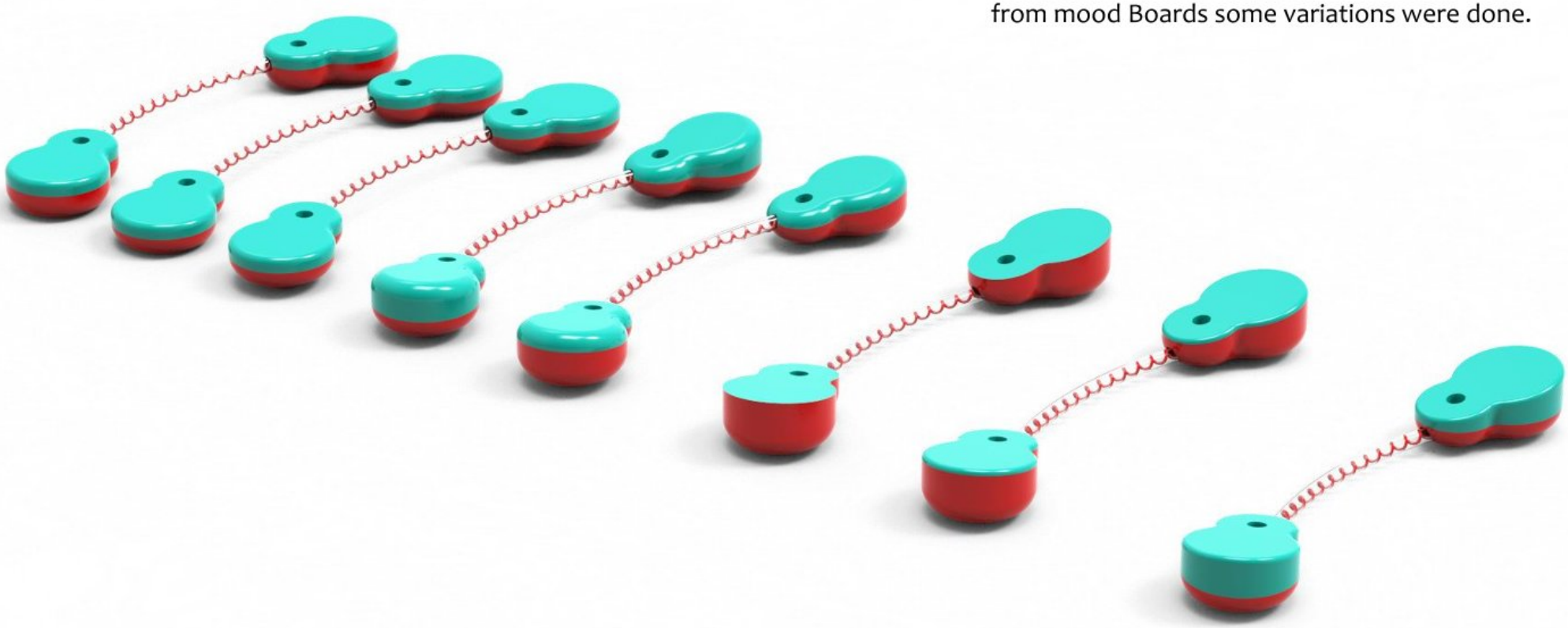
Mood board 2

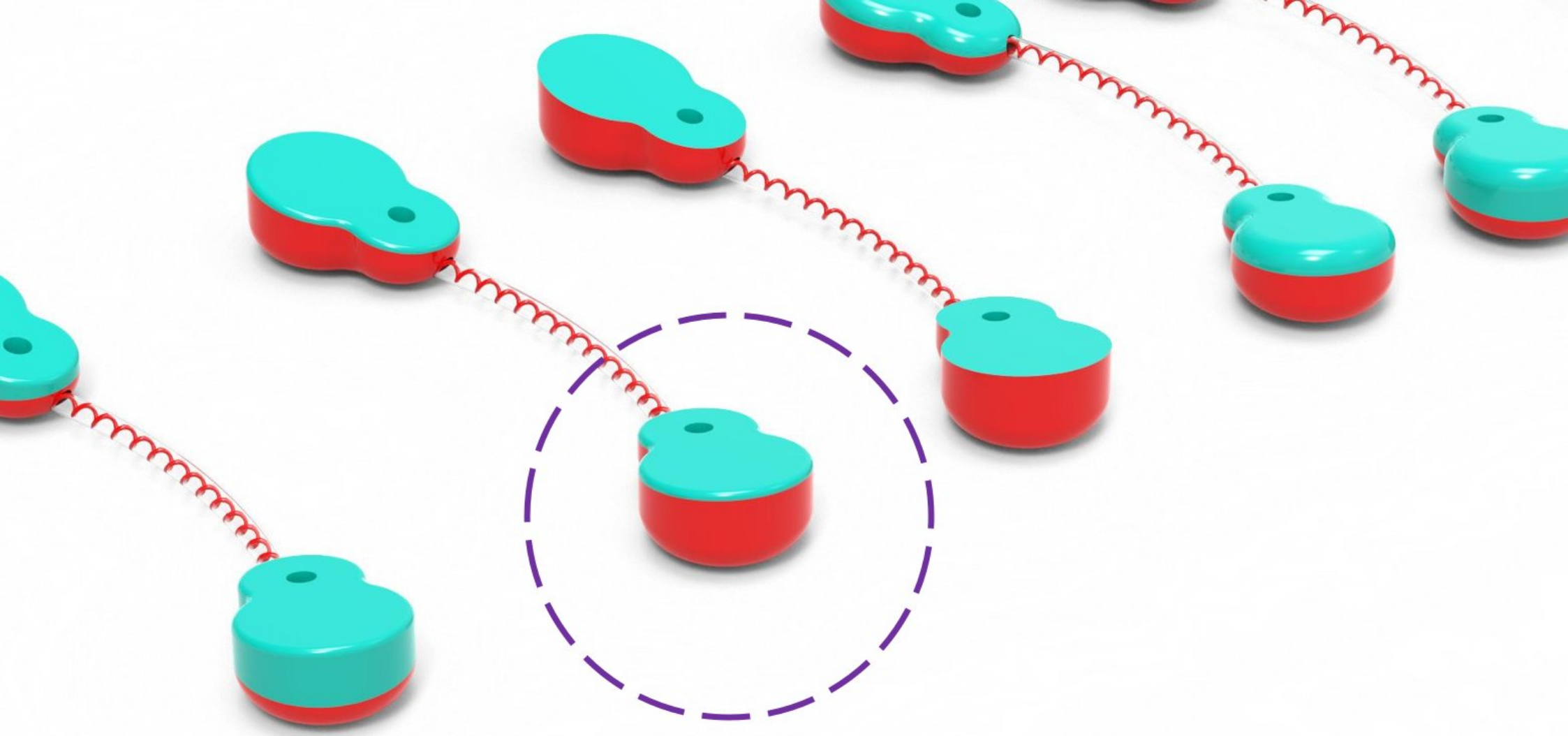
MINIMAL

Mood board 3

Formal Exploration

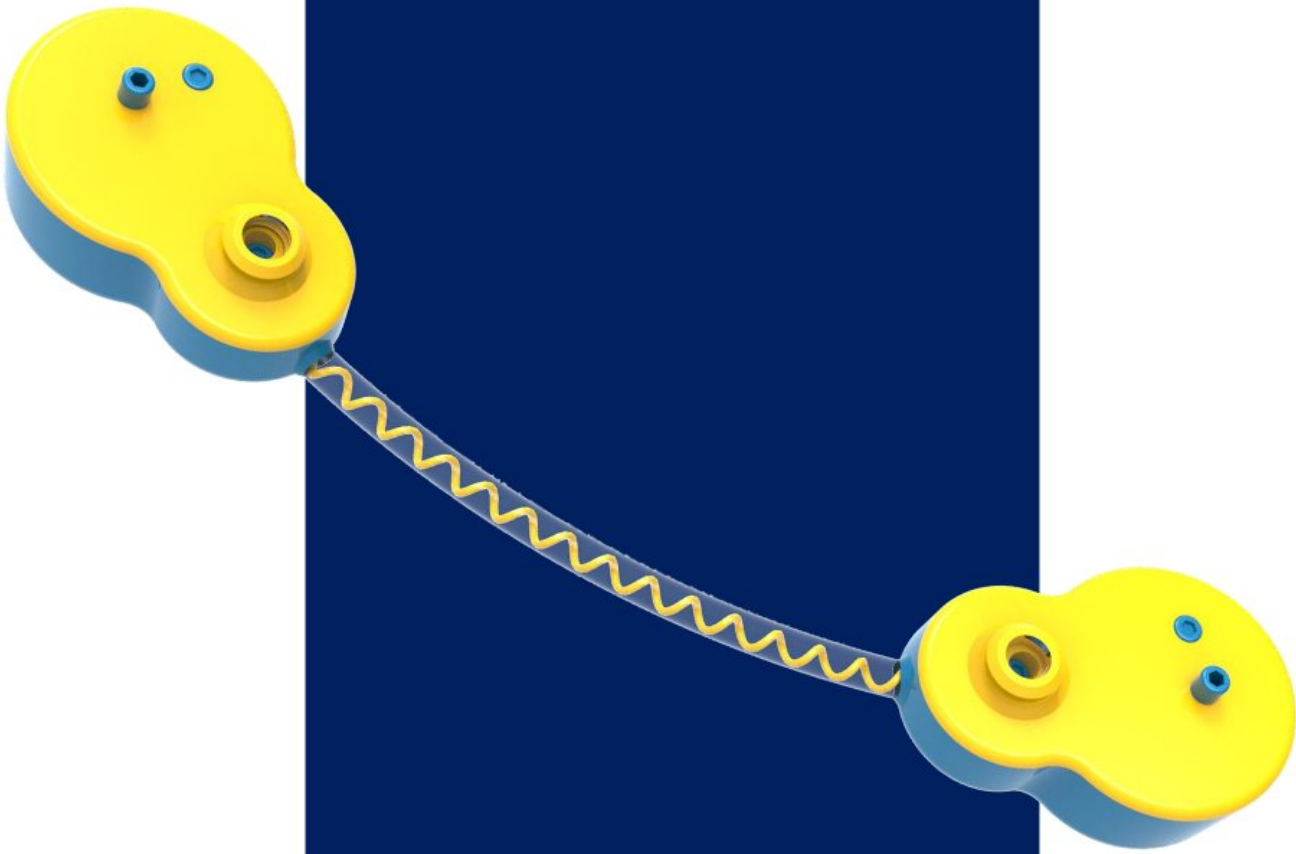
Considering the parting of parts in plastic, provision of dorsiflexion, structural integrity, height of partition above the ground and expression from mood Boards some variations were done.





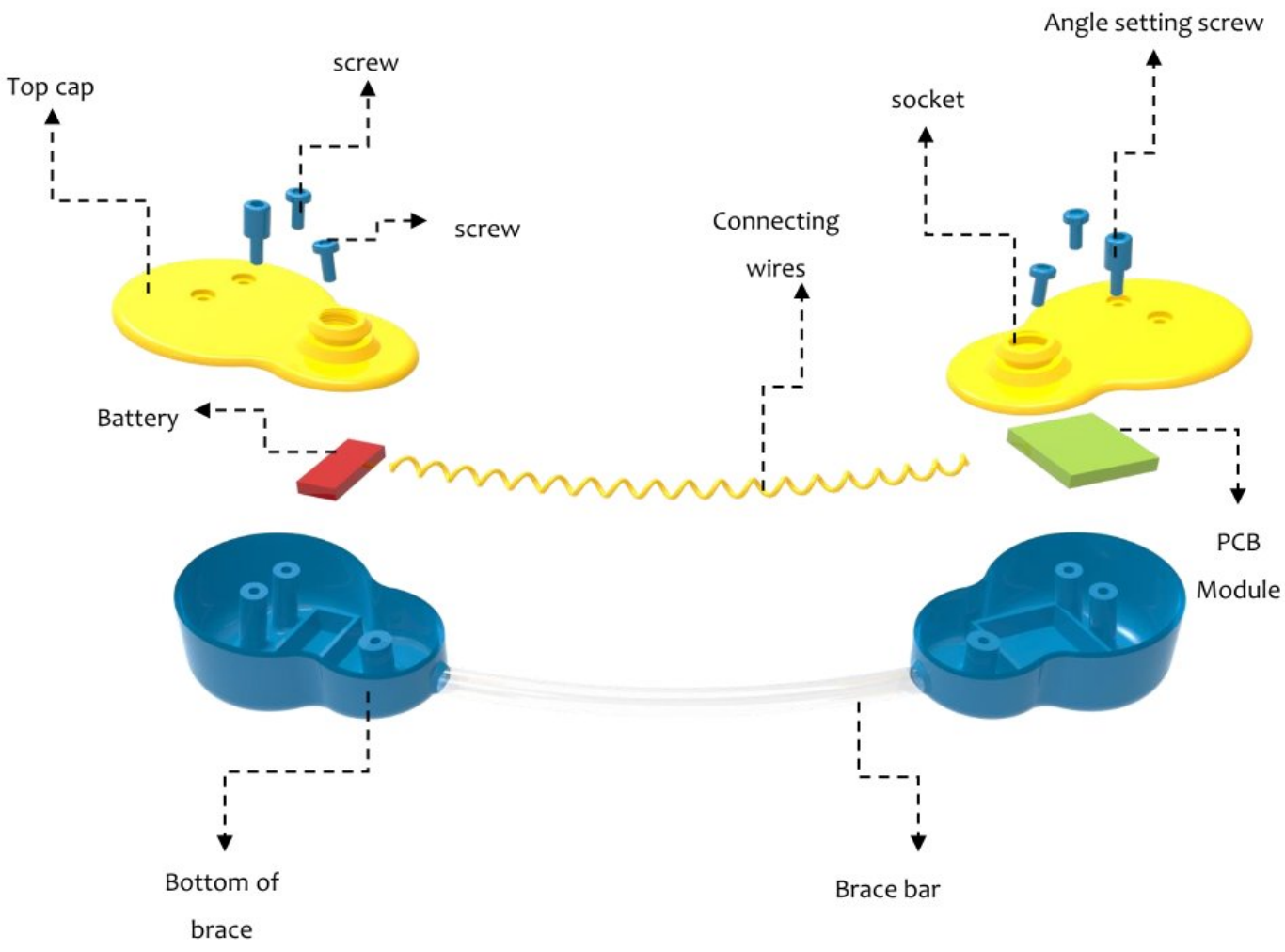
High lighted form was chosen as it was best suited for the considerations mentioned previously.

The Brace



The Exploded View

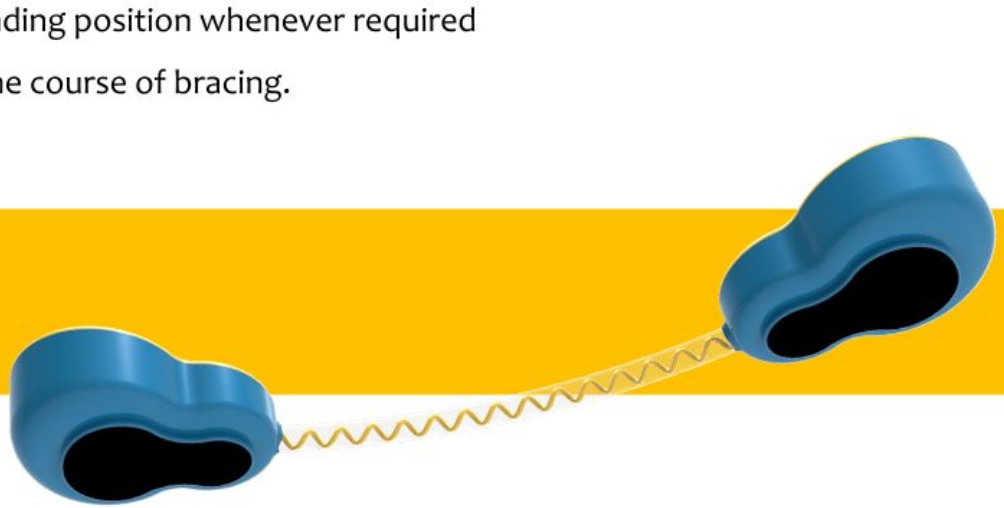
- The brace is parted at the interface of the top cap and the bottom of the brace.
- The two pieces at the end of the brace bar hubs the PCB Module and the battery.
- The transparent brace bar would be a Clear PVC extrude pieces formed to a curvature. The end pieces be then injection molded on the brace bar creating a one piece configuration.
- The two top caps would be completing the assembly after fastened with three screws on each side.
- Top cap and the bottom of the brace to be manufactured in ABS by injection molding.



Stable Base

- The brace bottom would be padded by rubber sheet, pasted or press fitted, providing for better stiction on the ground.

- This will help baby/child to be in a standing position whenever required in the course of bracing.



The Foot wear

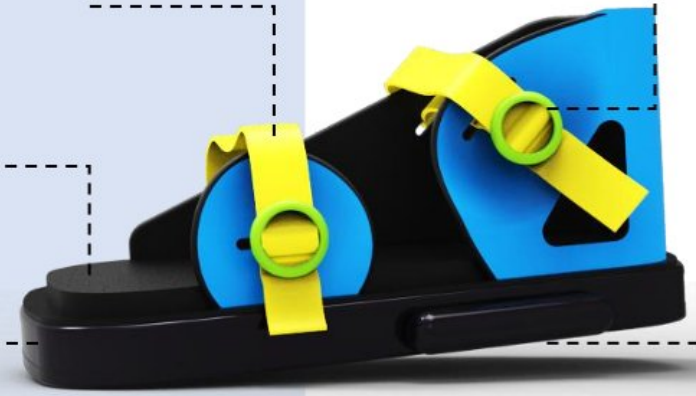
Tongue/cushion

Belts

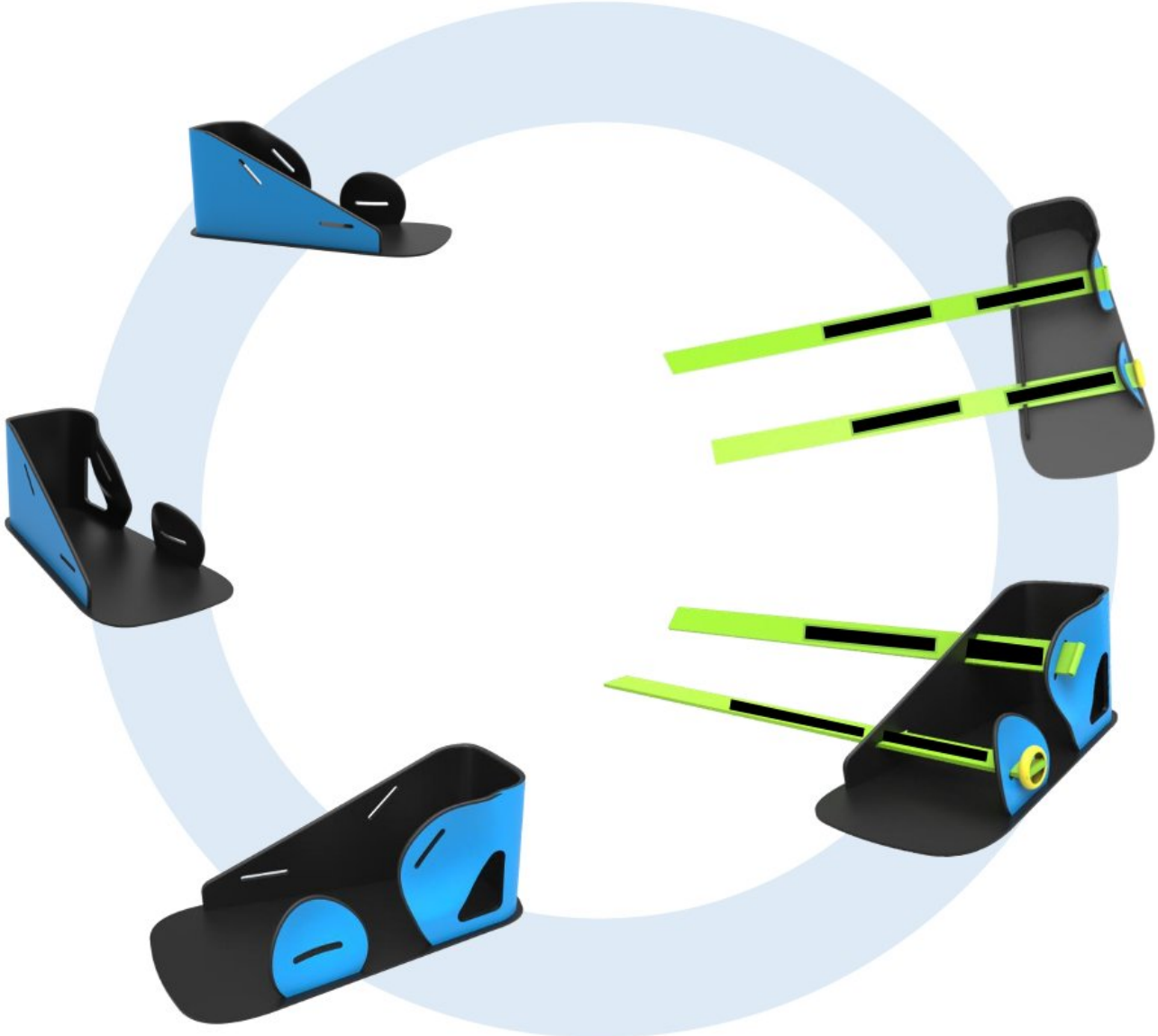
Buckle

Sole

Insole



Unlocking handle



- The shoe walls are constructed in two pieces, thus, breaking the wall to aid visual accessibility for foot and for more permeability of air for soothing skin irritation.

- The straps comes separate and are Velcro fastened before buckles are used to tighten the straps.

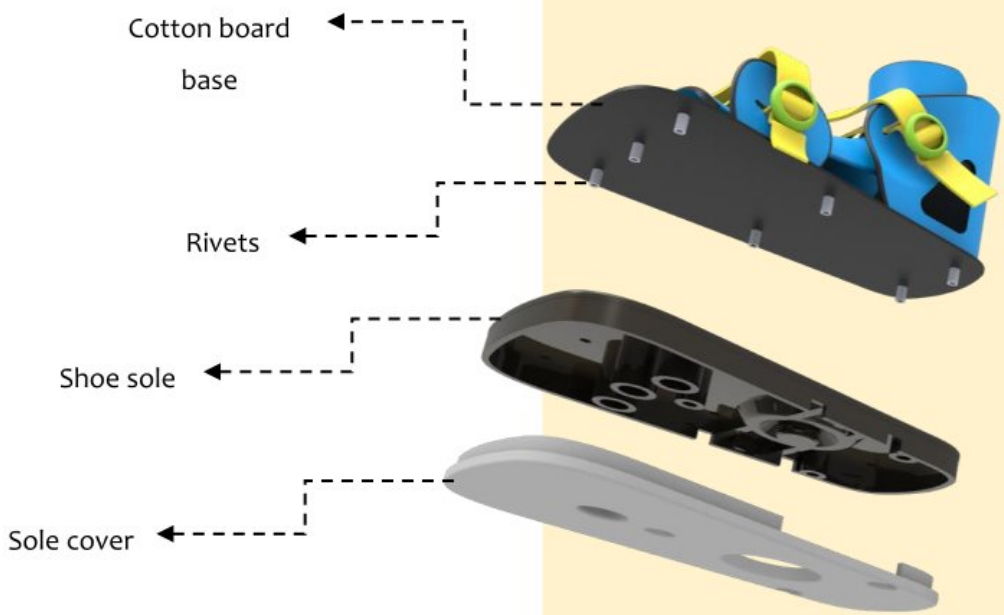
- The shoe is to be made out of canvas as material with the inner lining of cushioning for comfort.

- The shoe would then be stitched on the cotton board base.

- The stitched shoe now can be riveted upon the sole by aluminium rivets. This provides for easy replacement of the shoe if damaged or when needs to be discarded/ or sterilize.

- The sole be then assembled with the locking mechanism and closed with a cover by three stainless steel screws.

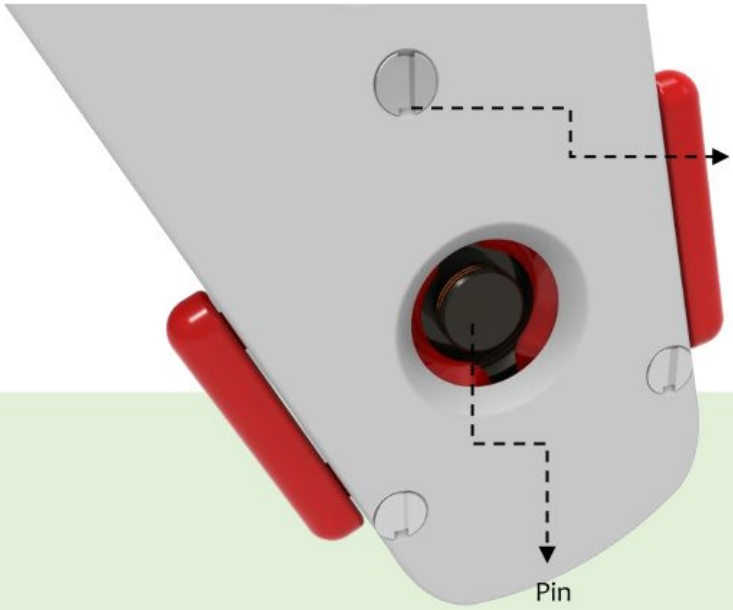
- The shoe sole, inherently during manufacturing, be incorporated by the sensor from the top.



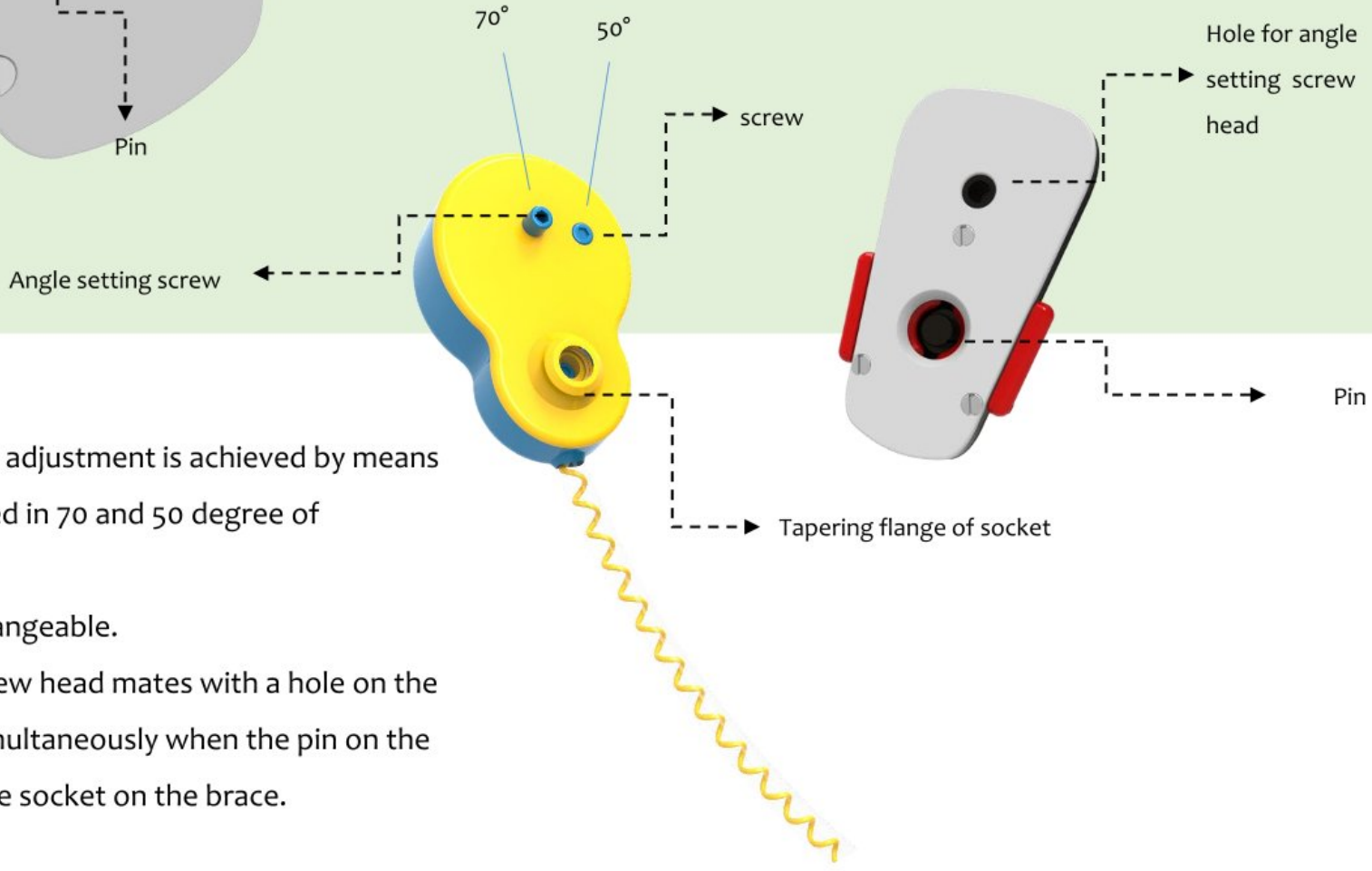
- The shoe is provided with a large tongue to cover up the foot from top for comfort against the tightness of belts.

- The shoe is supported by the a sole that hubs a mechanism to lock on the brace. The sole may also be subjected to the body weight of baby partially or fully for smaller or longer durations.

- Hence, the material of sole and the sole cover should be strong and sturdy. Also, it should be impact resistance. So, it can be manufactured from ABS [acrylonitrile butadiene styrene] by injection molding as a production process.

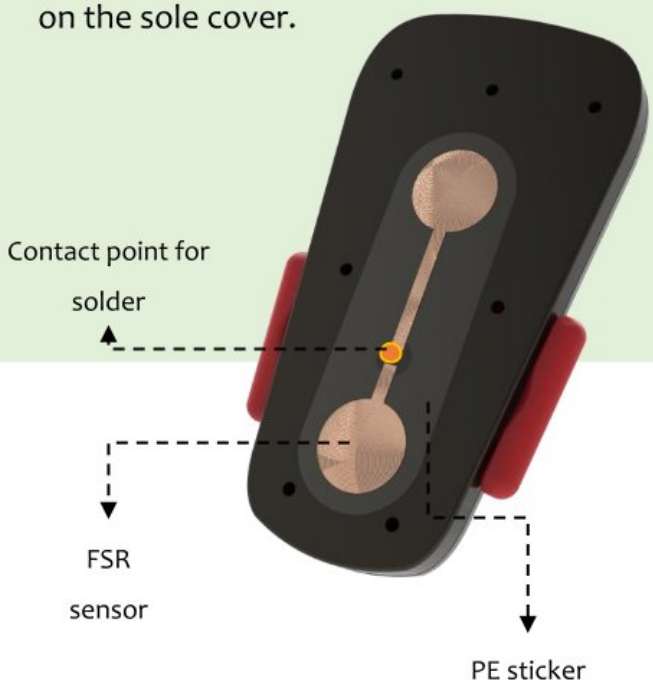


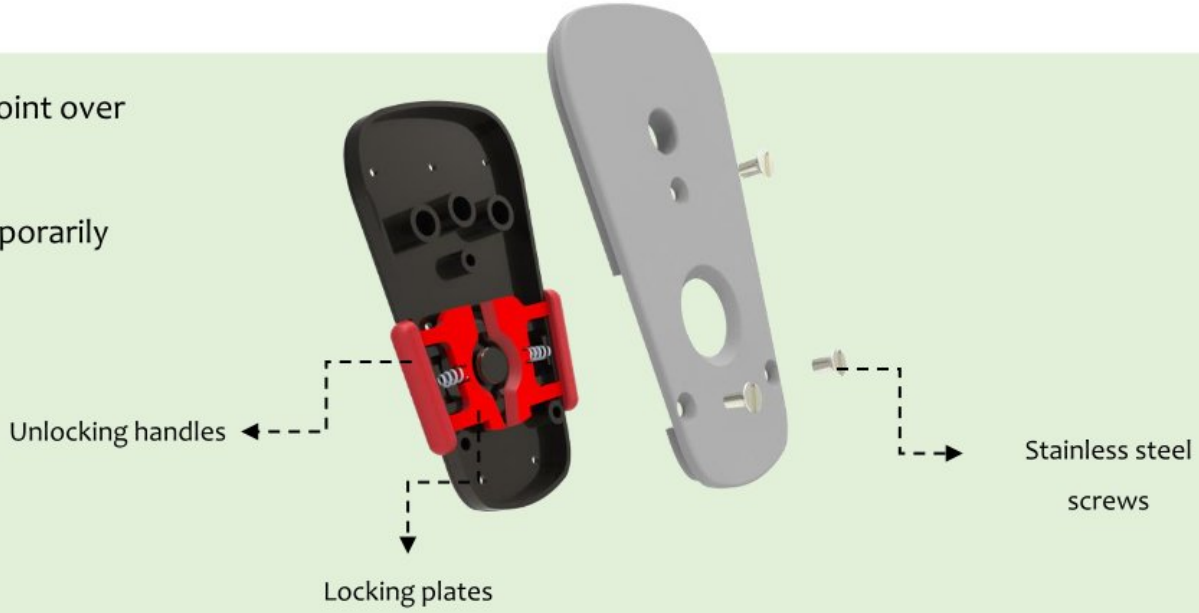
- The pin and the socket are coupled together to establish a connection for inputs from sensor.
- Pin and socket connection maintains the contact at connection point irrespective of any angular dislocation.



- The provision of angle adjustment is achieved by means of two screws oriented in 70 and 50 degree of abduction angle.
- The screw are interchangeable.
- The angle locating screw head mates with a hole on the bottom of the sole simultaneously when the pin on the sole is inserted into the socket on the brace.

- The FSR sensors are to be soldered on a contact point over the sole. The sensor then would be coated with a transparent PE [poly-ethylene] sticker to fix it temporarily on the sole cover.





- The sole hubs the mechanism for locking upon the brace and the whole assembly is covered with a lid, put in position by 3 Stainless steel screws.
- The proposed mechanism of spring loaded sliding plates involves simple locking against a tapering flange of socket provided on the brace.
- The sliding locking plate would be manufacture by injection molding from Nylon as material for its excellent abrasion resistance. The plates can be unlocked by pulling outward the Unlocking handles

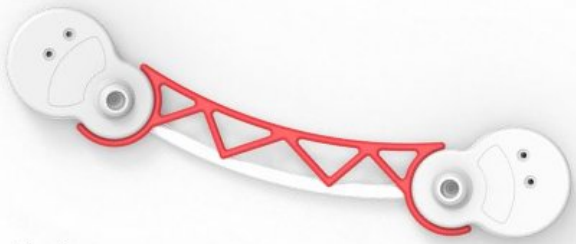
Exploring *Space-bar*

The rationale behind this attachment comes from the child's miss on relating with the present orthosis as an opportunity to interact with and Parent's discomfort of handling the braced babies.

Initially I was trying to play around with the brace shape to achieve an easy wearing of bar on brace with shoes coming over it to keep in its position.

Then I flattened the bar at centre for increasing the parent's comfort while they would carry the baby, but this would not go good with the toys.

So I then unlooped the loopy bar ends at brace ends. This would help parents to put on some hollow toys over the flat band. It was looking very strong and lacked playfulness.

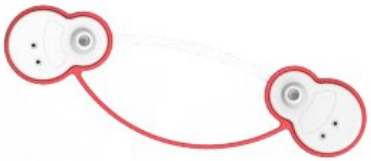


I tried here creating some drama out of its structure, but it was expressing lot of restrictive or fence like resemblance!

Then I tried making it simple and minimal, but here the flexibility was missing.

To add some flexing ability to the bar , I tried curving it back at the point where it connects on its ends.

But it still did not looked playful or happy enough.



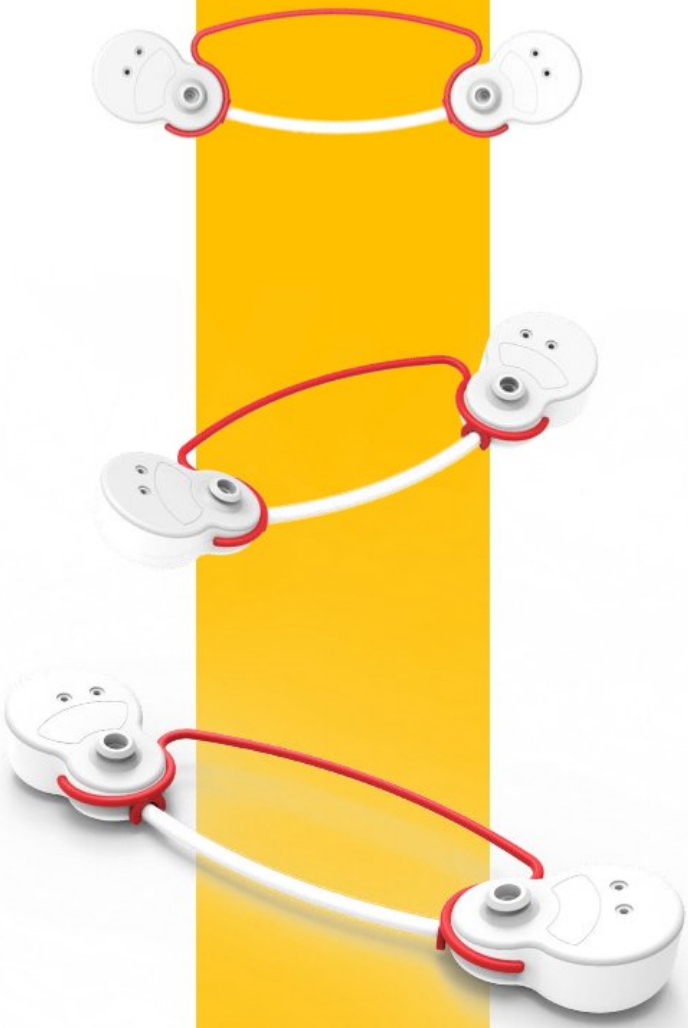
The convex curvature with the confined ends made it look really like a happy face & bouncy enough, but again the toys cannot be put through the bar here.

Then I tried varying the bar cross section from round to flat and flat to round between its end with bigger radius of back curvature.

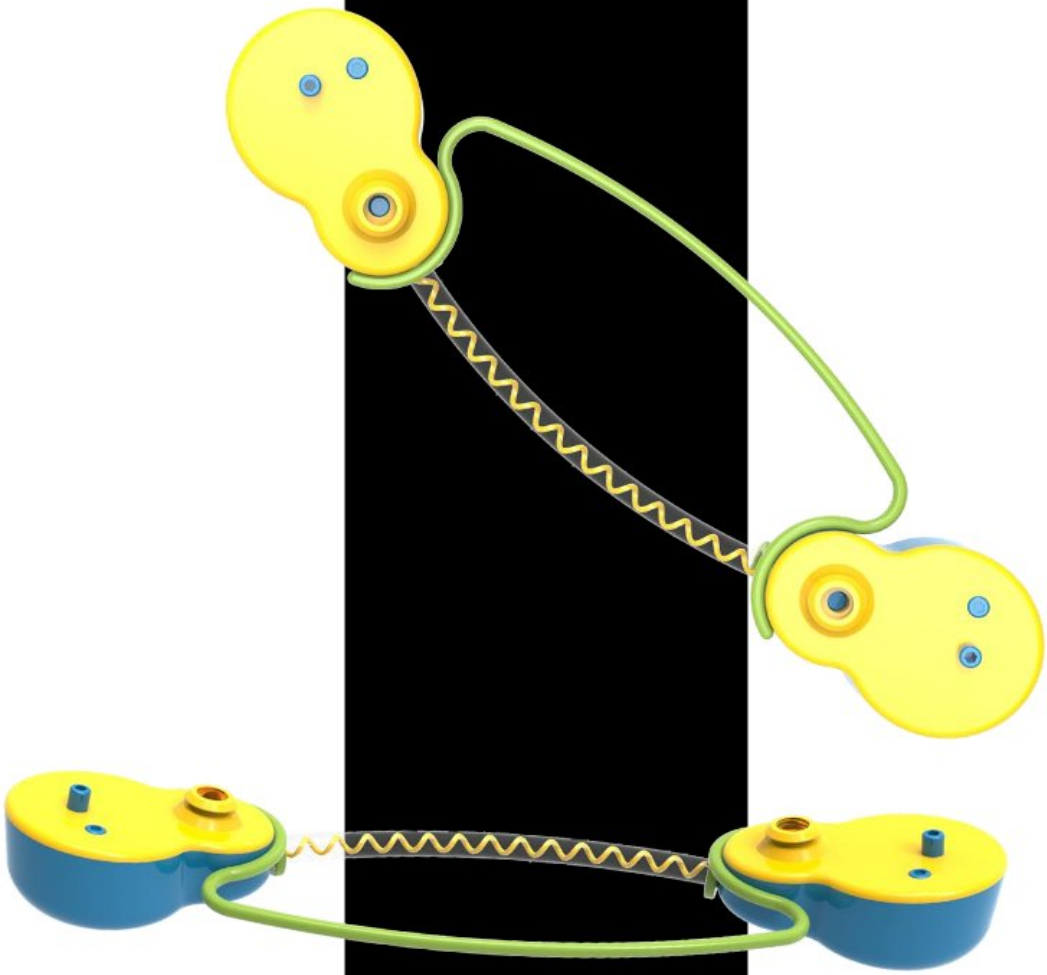
But it looked very unreliable and fragile. It lost that visual bouncy-ness.

Finally I made the cross-section all round uniformly throughout the bar and now it looked playful, simple and makes a static statement with the brace.

The bar now has open ends that facilitates the mounting of hollow toys over it and also retains the bouncy nature due to convex curvature and circular ends.



- The Space-bar can be attached and detached with a snap on the brace.
- Making it easy to attach and detach.
- Considering the resistance to steam sterilization, high flexural strength, high fatigue strength and low surface bonding properties of polypropylene [PP] plastic, the Space-bar can produced in PP by injection molding process.



The Orthosis

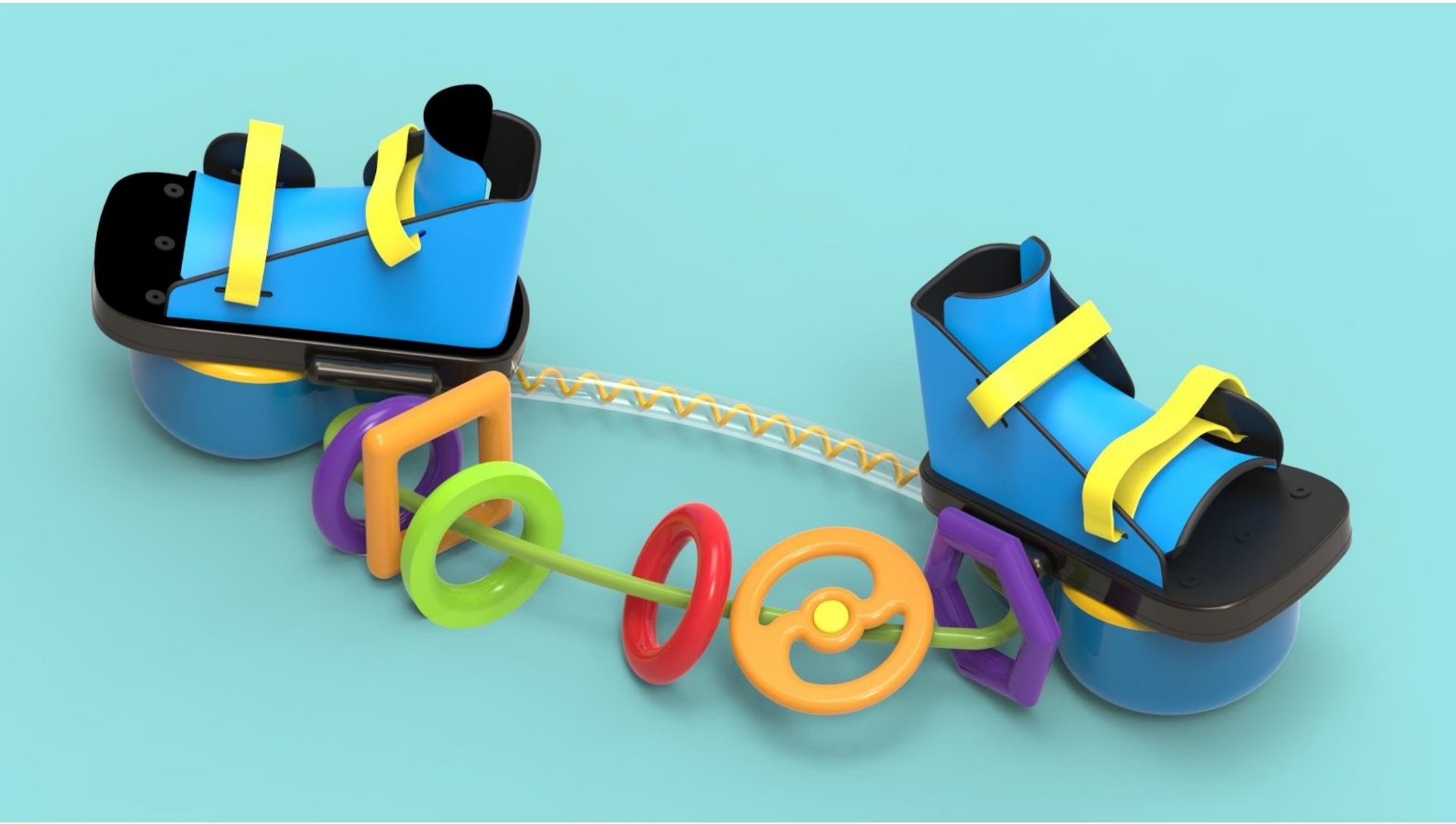
The orthosis would be given to a patient as per the prescribed Brace Size and the Footwear fit. So, it would have a pair of Shoe, a Brace and the Space-Bar.

Toys for *Space-bar*

The major considerations for designing the toys for the bar are –

- *Child's most challenging period of adapting to brace, especially, the duration of 23 hours of bracing schedule.*
- *Child's visual development.*
- *Child's physical growth, and motor skills development.*
- *Situations the child will be subjected*
- *Portability*
- *Variety by information*
- *Ease of cleaning*

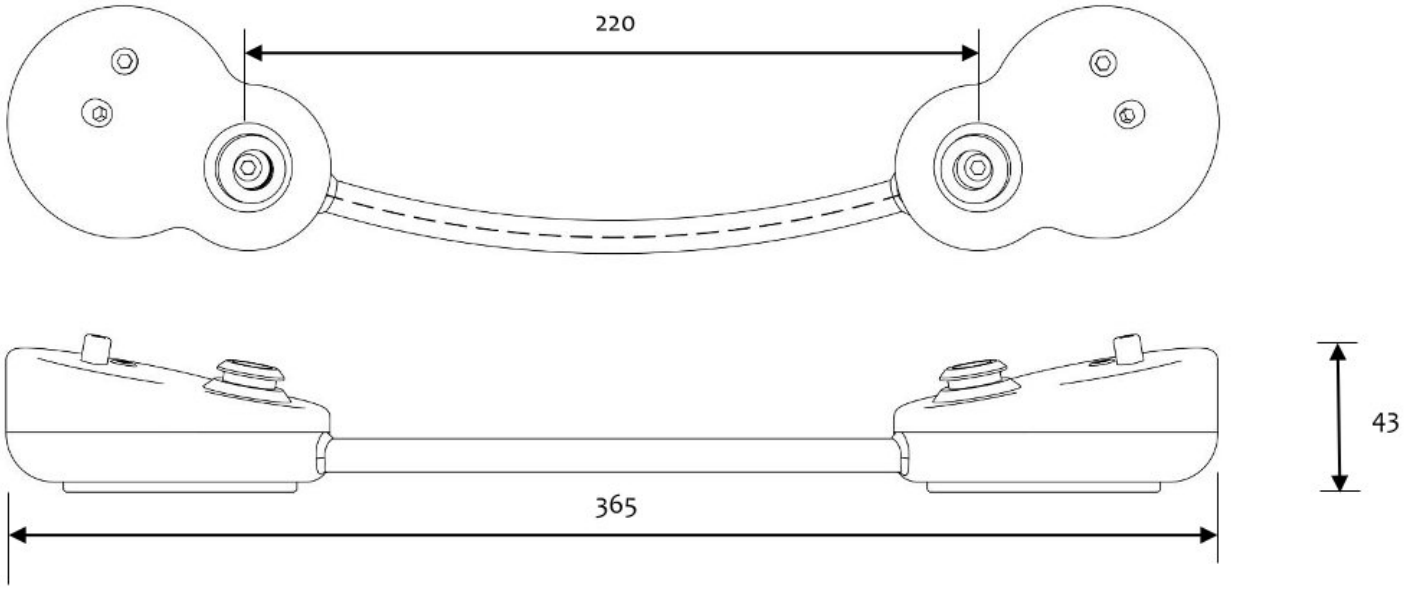
The inspiration for the toys came from Alphabets, Shapes, Numbers, and Motion.



Basic Dimension

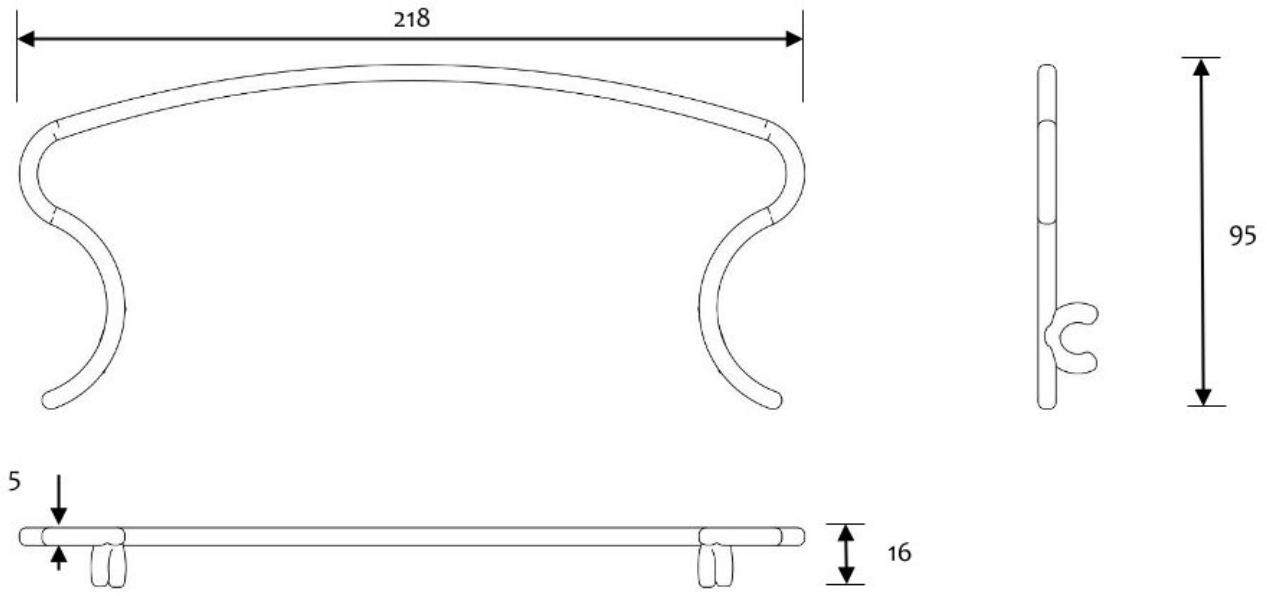
Brace

[All dimension are in mm.]



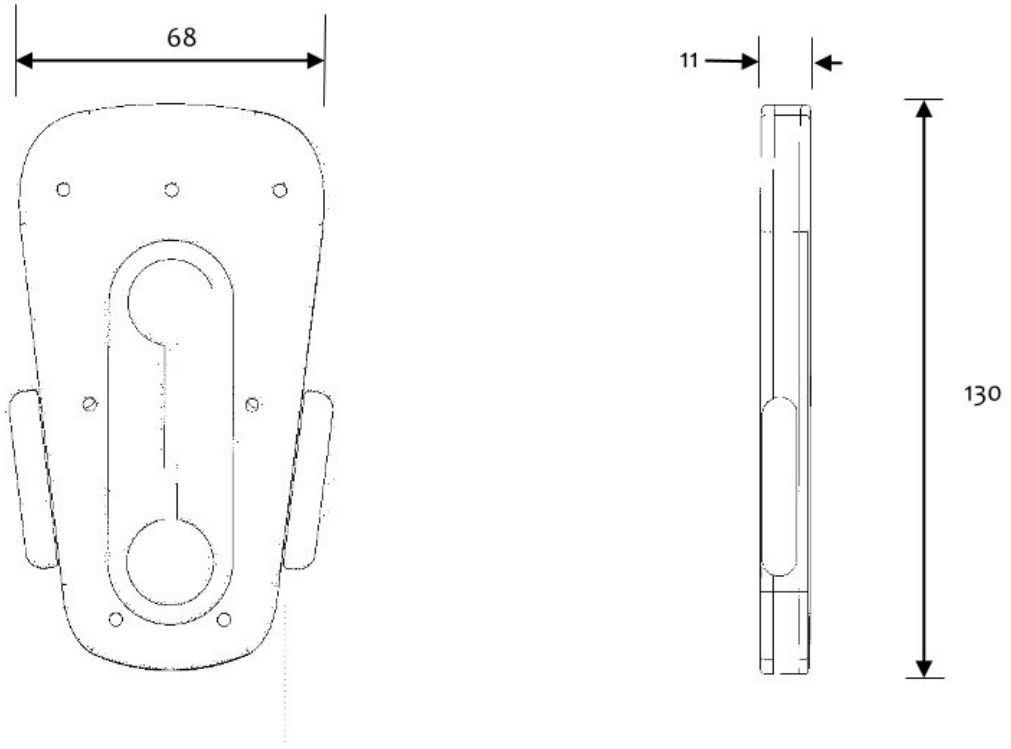
Space Bar

[All dimension are in mm.]



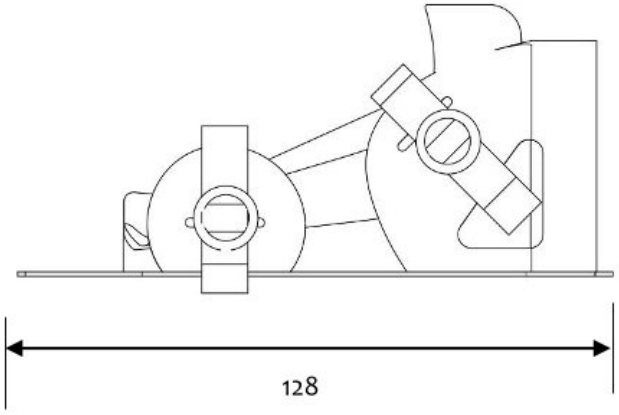
Sole box

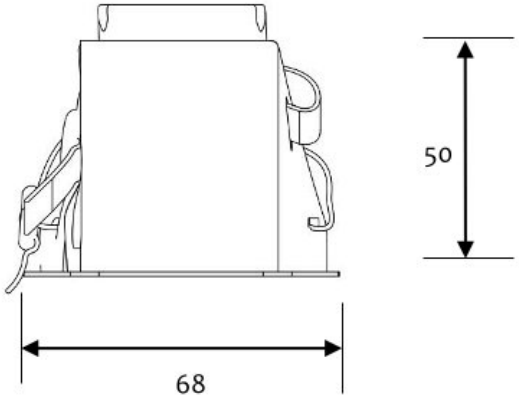
[All dimension are in mm.]

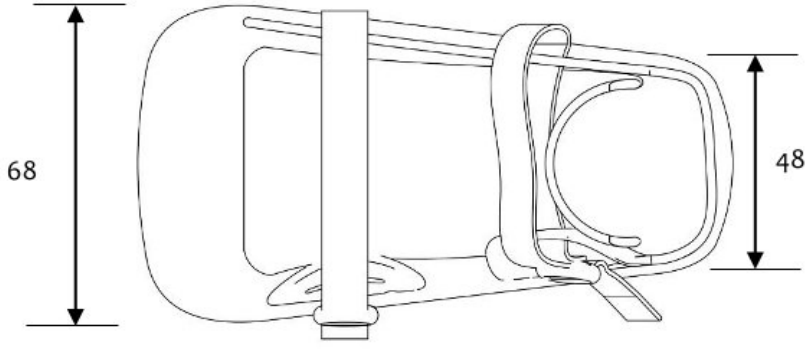


Shoe

[All dimension are in mm.]







Chapter 12

User Testing & Feedback

The user testing was carried out at clubfoot clinic in

B J WADIA Hospital, Parel.

Attempt 1

- The mother of the child was explained the procedure to brace and asked to perform the bracing. As per the desired protocol, she put the shoes first as shown in fig. 12.1 and fig. 12.2 respectively and then the brace.
- Before bracing the shoes, she tried understanding the locking and unlocking of the shoe as shown in fig. 12.3 and fig. 12.4 respectively.
- Initially she tried putting the brace slowly to understand the procedure of locking and unlocking. She repeated the bracing procedure after fully understanding the new bracing procedure as shown in fig. 12.5 and fig. 12.6 respectively.

FIG. 12.1

FIG. 12.2

FIG. 12.3

FIG. 12.4

FIG. 12.5

FIG. 12.6

First round of feedback:

- Accessible unlocking eliminates the turning of feet to unlock as in Stanford brace.
- With lace, child will try to take off the leg out of shoe or sometimes he will try to raise his heel inside. This I did not feel with the belts as visual access is increased.
- The shoe was very quick to put on.
- The locking unlocking was difficult initially, but after I learnt it, it was very easy to lock . However , unlocking is still uneasy. An old person may not be able to open it.

Feedback from
Dr Sourabh Sinha
[Consultant for Clubfoot Project at BETiC]

Feedback:

- As far as functionality is concerned, the brace looks pretty good.
- The provision of brace accessory for the child is a good thought.
- As the shoes are redesigned, we need to validate them by a pilot.
- The duration while the child is wearing the brace for 23 hours, child is not mature enough to unlock the brace, so the locking can be simplified.

Attempt 2

FIG. 12.7

FIG. 12.8

Another user with simpler locking [the with the back locking plate removed] was tested as shown in fig. 12.7 and 12.8 respectively.

Second round of feedback:

- Shoes are very softer and fast to do.
- Lacing is kind of frustrating , often makes us impatient.
- The locking-unlocking procedure is also very simple.
- The brace is more portable as we can detach the shoe.
- It would be good if the brace would be lighter.

Chapter 13

Branding

StepWell Orthosis

FIG.13.1 STEPWELL LOGO

The Inspiration for entitling the Brace as StepWell Brace came from one the User's experience about his treatment of club foot. Describing which he explained that initially when he was on the rugged shoe for the treatment, it was very painful. But gradually when he observed that his pain help helped him step well and better, he felt very happy about the shoes he wore.

The logo is inspired from the form of the product, where the word Step is symbolically resembled by the dots and the word Well is expressed through the foot profile and the curls of connecting wire.

BRANDING

Future Scope

- *The next step of the project will be plastic engineering of the design, to perform simulations to optimise the design, to produce working prototypes and testing them extensively.*
- *Followed by validation for design for its effectiveness of Abduction and User compliance.*
- *The next phase of project should also focus on specifying the shoe sizes, number of sizes and brace size standardisation.*
- *Once the design is validated, the brace and the shoe can be manufactured and distributed by NGOs and Clinics within to the patients.*

Conclusion

- *This project was an* ***inclusive opportunity*** *to understand and learn about one of the* ***confined health care systems, unidentified healthcare needs and conventionally accepted system/solutions in the country****.*

- *It surfaced the* ***significant scope of design intervention in health care for a developing country like India****.*

- *During the course of this Project, the Users and the Clinician has shown keen interest in the problem solving and spoke their hearts out about* ***how they lack or miss upon the precise, affordable and qualitative solutions to deal the untouched entities like clubfoot treatment.***

- *The final prosed design was discussed with Clinicians and the Users, to which, the feedback given was quite positive and motivating.*

- *In this project****, redefining of bracing protocol was attempted*** *and it's actual effectiveness and scope for improvement can be more understood after prototyping and testing of the product.*

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FIGURE 1.1	https://orthoinfo.aaos.org/link/1da43939a3fd4d228f7bccf8af172fde.aspx
FIGURE 1.2	https://emedicine.medscape.com/article/407294-overview
FIGURE 1.3	Https://www.Fyzical.Com/boerne/media/img/351574/clubfoot_intro01.Jpg
FIGURE 1.4	https://clubfootclub.org/wp-content/uploads/2010/06/ponseti-cast-card1.jpg
FIGURE 1.5	https://pro2-bar-s3-cdn-cf1.myportfolio.com/4c4c5b43d9721670b083172df179a66d/2fb8c845370215.582e157e94e1c_car_1x1.jpg?h=bc5f656a6cd4fbcc05678a05f58260f0
FIGURE 1.6	https://pro2-bar-s3-cdn-cf4.myportfolio.com/4c4c5b43d9721670b083172df179a66d/fc45bf95-76e3-4a16-a36e-807e6125e169_rw_1200.jpg?h=55e0d49dfd2886d921b0b8e8ce63bddb
FIGURE 1.7	https://0515f2af61d5e3d37aec-a1d11e7882f6a6aa49a62729309b6434.ssl.cf2.rackcdn.com/2016/06/sewing-machine-web-600x400.jpg
FIGURE 1.8	https://145gjhchid5e3d37aadhgsajchbsa-1d11e788j8565a49a62729309585.sl.cf2s.rackcdn.com/2016/06/club-foot-web-600x400.jpg
FIGURE 1.9	https://www.jbjs.org/elensreader.php?id=30383&rsuite_id=1705134&type=jpeg&name=JBJS.17.01049f3b&subtype=
FIGURE 1.10	https://media.springernature.com/lw785/springer-static/image/art%3A10.1007%2Fs00264-018-3873-3/MediaObjects/264_2018_3873_Fig1_HTML.gif
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FIGURE 9.2	http://lfaclinic.co.uk/wp-content/uploads/2014/11/Slide12-300x179.jpg
FIGURE 4.3	https://www.clubfootsolutions.org/wp-content/uploads/2016/12/brace_side_300x300.jpg
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FIGURE 4.9	https://markellshoe.com/img/1934d.png
FIGURE 4.10	https://www.dobbsbrace.com/images/dcb-cover.jpg
FIGURE 4.11	https://markellshoe.com/img/denis-brown-bar.jpg
FIGURE 4.12	https://markellshoe.com/img/denis-brown.jpg
FIGURE 5.36	https://image.slidesharecdn.com/12-150417055625-conversion-gate01/95/transfemoral-static-alignment-4-638.jpg?cb=1429250744 dated 19/02/2019