I. TITLE OF THE STUDY:A clinical evaluation of effectiveness parameters with gait analysis using MASC-KAFO: a comparative preliminary study of MASC-KAFO & the conventional KAFO with Drop-Lock

Principal Investigator: Dr. Uttara Deshmukh
Co-Principal Investigator: Dr. Rajani Mullerpattan.

II. INTRODUCTION

The Mechanically Actuated Stance Controlled Knee Ankle Foot Orthotic MASC-KAFO is developed at BETiC, IIT Bombay. This is an orthotics for supporting lower limb of patients with reduced muscle power and compromised stability for daily activities.

It is an assistive device and focuses on providing a better alternative to the existing orthotic calipers by automatic locking and unlocking of the knee joint according to the stance and swing phase of the user to provide lower limb stability.

Patient population with plus two power in lower limb as per Manual Muscle test (MMT) of any age group and gender can use this device.

Salient features of MASC-KAFO:

- Knee flexion up to 135°
- Cross Leg
- Avoids hyper extension
- Light weight (less than 2 kg)
- Less energy consumption
- Locking and unlocking without manual intervention
- Force Assist on Knee
- Comfortable fitment

III. BACKGROUND

The invention for which the clinical study has being proposed is related to health-care assistive devices and focuses on providing a better alternative to the existing Orthotic calipers in the market. An orthosis is an "externally applied devices used to modify the structural and functional characteristics of the neuromuscular and skeletal system."Orthotic calipers are required by patients having weak legs, such as those caused by disease (such as Polio) and trauma (mainly road and industrial accidents).

A conventional Knee-Ankle-Foot Orthosis (KAFO) locks the knee during both the stance (load-bearing) and the swing (ground clearing) phase of walking which results in unnatural and tiring gait. Most of the existing devices are bulky, expensive and do not meet the needs (squatting, cross-legged sitting and ease of maintenance) of people in India. Moreover, their availability is limited to the western countries.

The challenge was to design an affordable, compact and functionally superior KAFO to meet the needs of users in developing countries.According to the “Current Status of

Employment of Disabled People in Indian Industries" by Javed Abidi from Disability Information Resources (DINF),over 70% of the employed disabled people have locomotor disability. The product for which the study is being carried out will provide such people locomotion freedom and thereby become better employable.

IV. The Pain Problem /Need Addressed by the Investigational Device:

There is a need for corrective and assistive device for the patients who face difficulties in locomotion, including the elderly and people with multiple sclerosis, muscular dystrophy, polio, post-polio, incomplete spinal injury, unilateral leg paralysis or paresis, trauma, congenital defects, or isolated quadriceps weakness.

The conventional knee ankle foot orthosis KAFO or calipers available in the market and usually provided by NGOs require locking the knee joint in fully extended position during both stance and swing phases, to enable stability during walking. This induces abnormal gait events such as circumduction, hip hiking, and vaulting during gait. These lead to excessive energy consumption and thereby premature exhaustion, as well as pain, limited mobility and decreased range of motion in lower limb joint. Due to these factors, there is a high rate of rejection 60-100 among patients using conventional KAFO.

V. Investigational Device-A solution:

A mechanically activated stance-controlled knee ankle foot orthosis has been designed to provide improved gait for people with knee-extensor weakness. This MASC-KAFO inhibits knee flexion at any knee angle while allowing knee extension locking during weight bearing. During swing or other non- weight bearing activities, the device allows free knee motion. The device has unique mechanism for automatic locking and unlocking at desirable angles which will allow the patient to walk conveniently, cycle easily and climb stairs.

The production model is developed and mechanically tested, and the clinical study has to be performed to bring the product into the market as early as possible.

VI. Market Competition/Study for the Investigational Device:

Over 13 million in India people suffer from various locomotor disabilities, of which 4 million have been afflicted by polio. The present KAFOs provide stability during walking by locking the knee joint in a fully extended position during both stance and swing phases. This results in excessive energy consumption and induces abnormal gait events such as circumduction, hip hiking, and vaulting during gait. Walking with conventional KAFOs can also lead to premature exhaustion during ambulation, as well as limited mobility, pain, and a decreased range of motion (ROM) in lower limb joints. It has been reported that using a conventional KAFO reduces gait efficiency by 24%, increases vertical displacement of the center of mass (COM) by up to 65%, and also increases energy expenditure.

Due to the above factors, the rejection rate of using KAFOs in patients with muscular weakness of the lower limb due to conditions such as poliomyelitis, post-polio syndrome, CVA, CP, SCI, and MS have been reported as being between 60% and 100%.

There are existing solutions in the market that serve a similar purpose but do not cover all the requirements of the user such as providing a supporting force to straighten the leg and locking and any desired angle.

For Example:

1. Stance control knee brace (FreeWalk): This does not have an arrangement to exert a pull on the thighs to straighten the leg. It cannot lock at any angle, required by the patients.



Left- FreeWalk, Middle- EMAG, Right- Jaipur Calipers

2. E-MAG Active electronically controlled knee joint system: Unlike traditional braces, this doesn't require a person to lock and unlock it while walking. The enclosed knee joint is secured by an electromagnetic lock. The lock is controlled and its function monitored by a microprocessor controlled electronic system. However, the presence of electronics may make the device difficult to maintain.

3. Jaipur foot drop lock calipers: Thisis provided by various NGOs to the needy patients at affordable cost. The main drawback is in terms of operation, since it remains locked all the time unless unlocked by the user. This results in an inefficient and tiring gait.

However , MASC-KAFO is a unique solution that addresses the basic need for locking and unlocking of the mechanism according to the stance of the user. It includes force transmitters which provide an extra boost to straighten the leg as the person walks. The solution –Orthotic brace is light weight, comfortable and intuitive to operate. The core mechanism consists of a pawl and ratchet mechanism that locks on heel strike and unlocks when heel is not in contact with ground.

There are four competitors in the market providing stance-controlled knee foot ankle orthoses, but they have certain limitations in terms of functionality, maintainability and affordability they cost more than Rs. 1 lakh

Nearest competitors:

1. Ottobock
2. Walnut Medical

3. Becker Orthopaedic
4. Boston Orthotics and Prosthetics

Competitive Landscape

Parameter	Ottobock E-MAG Active	Ottobock FreeWalk	Backar KAFO	Calipers (Drop Lock)	MASC KAFO (Proposed)
Product					
Actuation Mode	Electromagnetic	Stance controlled	Stance controlled	Manual drop lock	Stance controlled
Force Assist	Present	Absent	Absent	Absent	Present
Patient Weight (Kg)	85	80-120	90	90	120
Gait	Natural	Natural	Natural	Unnatural	Natural
Efficiency (ease of use)	High	Medium	Medium	Low	High
Maintenance	Difficult	Medium	Medium	Easy	Easy
Price (₹)	4,50,000	3,00,000	69,500	20,000	20,000

VII. REVIEW OF LITERATURE

Knee–ankle–foot orthoses (KAFOs) are lower extremity devices which extend over the knee, ankle, and foot. KAFOs are prescribed for people with lower limb muscle weakness; particularly in quadriceps muscles.1–3 KAFOs are prescribed for varying muscular weakness of the lower limb including poliomyelitis, post-polio syndrome, cerebrovascular accident (CVA), cerebral palsy (CP), spinal cord injury (SCI), and multiple sclerosis (MS) to provide stability of the lower limb during locomotion.2 Lower limb weakness, especially knee extensor weakness, is a condition that alters normal gait patterns,4 and this condition may result in decreased stability during daily tasks.

Conventional KAFOs provide stability during walking by locking the knee joint in a fully extended position during both stance and swing phases. This requires excessive energy consumption and induces abnormal gait events such as circumduction, hip hiking, and vaulting during gait.6,7 Walking with conventional KAFOs can also lead to premature exhaustion during ambulation, as well as limited mobility, pain, and a decreased range of motion (ROM) in lower limb joints.

It has been reported that using a conventional KAFO reduces gait efficiency by 24%, increases vertical displacement of the center of mass (COM) by up to 65%, and also increases energy expenditure.9 Due to these factors, the rejection rate of using KAFOs in patients with muscular weakness of the lower limb due to conditions such as P a g e 6 |

76 poliomyelitis, post-polio syndrome, CVA, CP, SCI, and MS has been reported as being between 60% and 100%

Stance control KAFOs (SCKAFOs) are a new generation of KAFO which have been developed to prevent knee flexion during stance phase and permit free knee motion during swing phase of gait.10 Mechanical SCKAFOs are usually activated by ankle ROM mechanisms or limb inclination. The UTX, stance control orthosis (SCO) knee joint, swing phase lock (SPL), Horton, Otto Bock Free Walk, and the Otto Bock Sensor Walk are all examples of SCKAFOs.8,11 Using a SCKAFO produces an increased acceptance rate for wearing orthoses by patients with poliomyelitis, CP, CVA, and leg muscle weakness because of the ability to control knee flexion in stance and the provision of free knee flexion during swing phase of gait.3,8,12 Studies have demonstrated that velocity, cadence, stride length, and step length can increase when walking with a SCKAFO versus a locked knee KAFO.2,3,8,12 Irby et al.11 reported that KAFO users showed improvements in velocity, cadence, and stride length after 6months of walking with the dynamic knee brace system (DKBS). SCKAFOs improve gait by encouraging more normal gait patterns, improving mobility, reducing the energy cost of walking, and reducing compensatory strategies that may lead to chronic pain and loss of motion.2,12–14 . Unfortunately, current commercial SCKAFOs are very expensive and in some cases are not effective in improving kinematic variables and energy expenditure.

MASC-KAFO is a projected affordable substitute to the conventional KAFO with the Droplock .Thus ,this research aims to study the effects on walking parameters, ROM of Knee joint and Energy consumption while using the MASC-KAFO in comparison to a conventional KAFO.

VIII. OBJECTIVES OF THE STUDY

a. Primary objective
To Perform a Comparative Pilot Study of MASC-KAFO and the Conventional KAFO with Drop Lock.

b. Secondary objective(s):
To perform the gait evaluation of the two KAFO namely the MASC-KAFO and the Conventional KAFO with Drop Lock.

IX. TYPE OF STUDY

The Clinical Study will be an uncontrolled comparative prospective preliminary Study.

X. METHODOLOGY

i. Duration of the Study: 3 Months.

ii. Study Site: MGM Hospital

iii. Total Number of Subjects: 15

iv. Details about the Study:

The Clinical study will be an uncontrolled comparative prospective Study. This study shall be performed with 15 patients with any locomotory disorder with plus two power in lower limb as per Manual Muscle test (MMT).

The patients shall be given the MASC-KAFO to use for a period of 3 months. The effectiveness of MASC-KAFO will be measured using a feedback questionnaire and gait Analysis.

Gait analysis to be performed on 10 randomly selected patients.

The first month shall be the acclimatization phase, wherein the volunteer has to follow the training instructions.

v. Study design:

Step 1: Screening of subjects as per inclusion & exclusion criteria
Step 2: Evaluating the included subjects in the Study including gait analysis
Step 3: Measurement for the MASC-KAFO
Step 4: Subjects shall receive the MASC-KAFO after proper fine tuning and trials
Step 5: Training on how to use the MASC-KAFO
Step 6: Mid-term Evaluation
Step 7: Evaluation of the subjects 'post completion of the study including gait analysis
Step8: Reporting
Note: observation for any adverse effects shall be practiced in the entire course of study.

vi. Subject selection:

a. General characteristics of the proposed subject population(s).

- All adults both male and female included for study should have a locomotory disability with plus two power in lower limb as per Manual Muscle test (MMT)
- Adults must be above 18 years and less than 50 years old.

b. Inclusion criteria.

- Adults both male and female above 18 years and below 50 years of age.
- Should have a locomotory disorder with plus two power in lower limb as per Manual Muscle test (MMT)
- Should be ambulatory with assistance or gait aids.
- Self-consent to be the part of the Study
- should be able to speak, read and understand at least one of the following languages - Hindi, Marathi or English
- Living in Mumbai/ Navi Mumbai till the course of study is completed.

c. Exclusion criteria.

- Adults above 50 years of age
- Pregnant or lactating females/women.

- Having a locomotory disorder with less than two power in lower limb as per Manual Muscle test (MMT)
- Cognitive impairment
- Progressive medical issues that would impact mobility (e.g., Parkinson's disease, cerebellar atrophy, etc.)

vii. Screening procedures

- An authenticated proof of locomotory disorder eg Disability Certificate
- Medical history to verify any history of fracture in spine or lower extremity.
- Proof for Date of birth to confirm the age at the time of recruitment.
- Signed informed consent form to verify that they are aware of the product, procedures & risk involved.

viii. Study Treatment

- The Subjects will be provided with MASC-KAFO's after proper measurements and fittings.
- They will be provided with proper training on using the MASC-KAFO
- They will be given a total of 60 days to use the MASC- KAFO

ix. Study Procedure

- In the first visit i.e. Week 0, the lower limb measurements of the subjects will be taken for preparing the Orthotic Brace.

Also details about their general health will be recorded.

Subjects shall fill up the Product Evaluation and Effectiveness questionnaires in relation to their existing Orthosis.

- At the next visit i.e., Week 1 which will be one week later or at maximum 10 days, the New Orthotic Brace-MASC-KAFO will be fitted and they will be trained to use it and will be required to take 3D Gait Analysis of the new Orthotic Brace-MASC-KAFO and existing Orthotic Brace.
- At the next visit i.e. Week 4, After three weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0
- At the next visit i.e. Week 6, After five weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0 along with 2D Gait Analysis
- At the next visit i.e. Week 8, After seven weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0
- At the next visit i.e. Week 12, After eleven weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0 along with 3 D Gait analysis.

x. Study outcome evaluations

The pretest (while using the drop-lock calliper)-post-test (Using the MASC-KAFO-V3) assessments of the subjects will be done using gait analysis by the P& O expert and the physiotherapist expert such
-Gait parameters such as length of walking , Hyper Extension etc
-R.O.M. of the Knee Joint.
-Enegry Consumption during the walk
It will give scientific data to evaluate the results.

Assessment & Reassessment protocol/Methods to be used:

- Feedback Questionnaire

Gait Analysis: 3-D Gait analysis at MGM CHMS will be conducted using Vicon motion capture system and AMTI (Advance Medical Technology, Watertown, MA) force plates. MGM CHMS motion analysis system is a robust gold standard equipment which includes- 12 [Bonita] 240 fps optical cameras (VICON, UK), 2 VGA video camera and three force platforms (AMTI, USA).
3D gait analysis procedure will be explained to the patient and a signed informed consent will be obtained prior to commencement of the analysis.

Patient preparation:

The patient will be asked to change into appropriate testing attire as well as wax and sterilize the areas on the upper and lower extremities where retro-reflective markers and EMG sensors will be placed to enable gait and muscle analysis. Anthropometric data of the patient will be collected and entered into Nexus after calibration of the system. Sterilized 39 retro-reflective markers will be placed using a double sticking tape on the bony prominences according to a Vicon plug-in gait model. EMG sensors will be placed on the anti-gravity muscles.

Data capture:

Patient will be instructed to walk with Conventional Knee-Ankle-Foot Orthosis (KAFO) and mechanically activated stance-controlled knee ankle foot orthosis at a self-selected speed along a 10-m walkway. A minimum of 3 trials will be recorded, with each foot striking a force plate without any overlapping step on same force plate. Kinetics and kinematics data of lower extremity will be analyzed.
After gait trails are recorded, maximum voluntary contraction of each anti-gravity muscle will be recorded. Post-trial, markers and sensors will be removed gently.

xi. Expected Outcomes

- Reduced Hyper Extension; Close to Natural Gait as compared to Drop Lock Calipers
- Knee Flexion Up to 135 degrees

- Less Energy consumption during walking as compared to conventional drop-lock callipers.
- Better walking in terms of distance covered.
- Improvement in Activities of daily living

xii. Outcome data and data analysis:

After completion of 3 months, the set period of study, outcome data obtained from all the questionnaires and report, from both subject & investigator will be analyzed statistically using mean & variance parameters. Results procured after three months from pre & post analysis will be studied.

xiii. Anticipated Risks:

- Pain
- Rashes
- Any other unexpected adverse effect.

xiv. Serious adverse effect management and reporting:

- The recording of Adverse Events is an important aspect of Study documentation. It is the Investigator's responsibility to document all Adverse Events according to the detailed guidelines of the Protocol. The Investigator agrees to answer any questions of Sponsor's medical monitor concerning any Adverse Events.

- The Investigator must immediately report all Serious Adverse Events ("SAE") (as defined in the Protocol) (within 24 hours of occurrence of SAE) to the Sponsor or its designee by fax and/or other electronic means and Ethics Committee which occur within twenty-four (24) hours of the occurrence. since informed consent is signed, during the course of the Study and up to the date of the subject´s last visit.

- In case of an injury occurring to the subject during the Study, free medical management shall be given as long as required or till such time it is established that the injury is not related to the Study, whichever is earlier.

- In the event of a Study related injury or death, the Sponsor shall provide financial compensation for the injury or death.

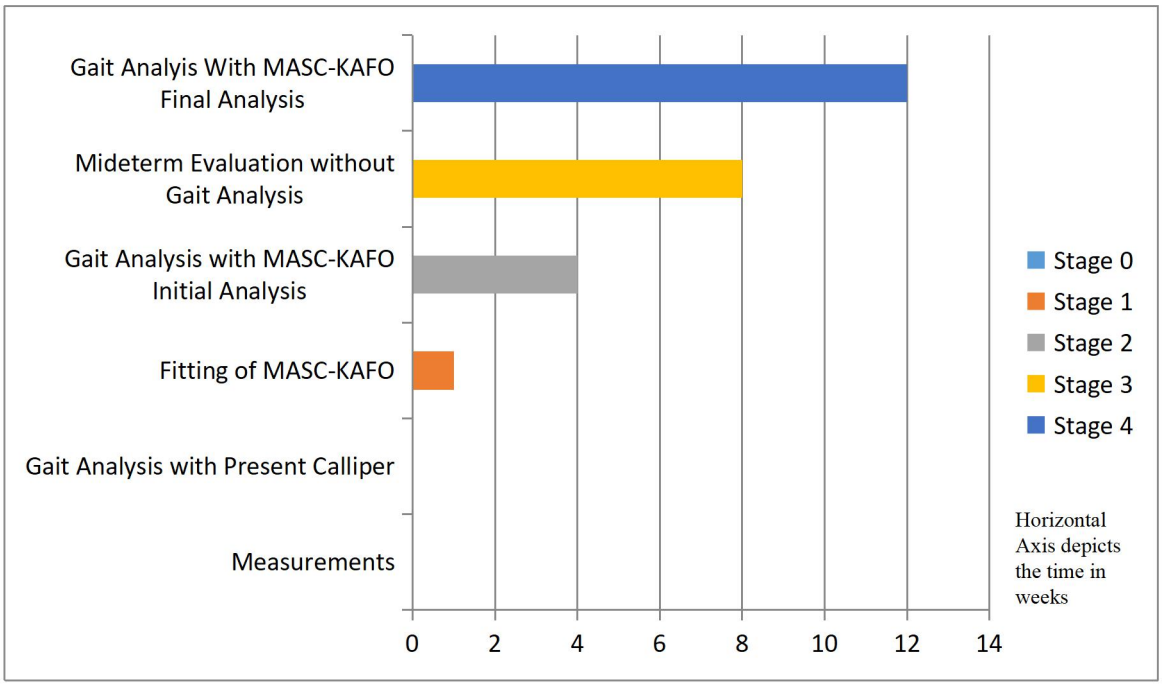
- Sponsor shall be held harmless from or not responsible for , any loss, damage, liability, claim, cost (including reasonable attorney fees) or demand arising from any injuries or damages resulting from negligence, failure to adhere to the Protocol, failure to comply with Applicable Laws, failure to obtain informed consent, unauthorized warranties made by, breach of this clinical study protocol or willful misconduct or omission of Site or any Site Personnel in performing their obligations under the clinical study Agreement.

- Sponsor will promptly inform both the investigator and the institutional ethics committee of any finding that could affect the safety of subjects or their willingness to continue participation in the Study, influence the

conduct of the Study, or alter Site's IRB/EC approval to continue the Study. Investigator shall promptly, in accordance with Applicable Laws, advise Sponsor of any Adverse Event occurring during the conduct of the Study that he/she becomes aware of. In the event of the occurrence of any serious Adverse Event,

- The Investigator shall forward a due analysis report to Ethics Committee and the sponsor within fourteen (14) days of occurrence of SAE including all initial information and follow-up information until stabilization/ resolution of the SAE.

XI. Total duration with GANTT Chart



XII. . BUDGET FOR THE PROJECT:

Sr.No	Nature of Expense	Amount of Expense per visit	Number of Subjects	Total visits/tests per patient during entire study	Total Expense
1	Travel Allowance for patients	200	15	8	24000
2	Gait Analysis	3333.33	10	3	100000
3	MGM Committee Fees	5000			5000
4	MASC KAFO Consultation fee to P&O and Tools & equipment	3000	15	1	45000
5	**Miscellaneous**				**20000**
	TOTAL				**194000**

XIII. REFERENCE

a. U.S. Patent - US2519226A: Filing date:–1948-01-12: Publication date :– 1950-08-15: Title:– Hydraulic knee joint for artificial legs or leg braces Inventor(s): Jr Thomas H Coe
b. U.S. Patent - US2573866A: Filing date:–1948-05-14: Publication date :– 1951-11-06: Title:– Leg brace: Inventor(s) John H Murphy
c. U.S. Patent - US2632440A : Filing date:– 1947-12-17: Publication date :– 1953-03-24: Title:– Leg brace joint and lock Inventor(s) John M Hauser, Snow Burke Mcarthur
d. U.S. Patent - US20130245524A1 : Filing date:– 2013-03-15: Publication date :– 2013-09-19: Title:– Knee ankle foot orthosis Inventor(s) Jonathon S. Schofield
e. U.S. Patent - US20100125229A1: Filing date:– 2010-05-20:: Title Controllable Joint Brace Inventor(s) Katherine RudolphJian-Qiao Sun
f. U.S. Patent -US7410472B2: Filing date:–2017-12-07:: Actuator-equipped knee ankle foot orthosis Rei Takahashi Yuichi Sawada Yoshiyuki Higashi HonkyoTooruMasayamaNoriakiIchibashi Toshikazu Ohata Kawaguchi.
g. U.S. Patent -US7410472B2: Filing date:– 2006-09-14 Publication date :– 2008-08-12:: Title Articulating joint Inventor(s) TerrisYakimovichEdwardLemaireJonathanKofman
h. U.S. Patent -US20160175134A1: Filing date:– 2016-06-23 Title Weight Acceptance Control Orthosis Inventor(s) Kamran ShamaeiGhahfarokhiAaron Michael Dollar
i. U.S. Patent -US6500138B1: Filing date:– 2000-04-07 Publication date :– 2002-12-31:: Title Electromechanical joint control device with wrap spring clutch Inventor(s) Steven E. IrbyKenton R. Kaufman
j. U.S. Patent -US4632096A: Filing date:–1985-08-12 Publication date :– 1986-12-30:: Title Automatically releasing knee brace Inventor(s) Adam I. Harris
k. U.S. Patent -US20110071452A1: Filing date:–2011-03-24Publication date :– 2015-05-05:: Title Knee orthosis, and method for controlling a knee orthosis Inventor(s) Roland Auberger
l. U.S. Patent - US9433255B2: Filing date:– 2014-04-24Publication date :– 2016-09-06:: Title Stance-controlled articulated ankle-foot orthosis Inventor(s) Hsin-Chen Daniel FanchiangMark Daniel GeilToshikiNashimoto.
m. U.S. Patent - US20100125229A1: Filing date:– 2010-05-20 Title Controllable Joint Brace Inventor(s) Katherine RudolphJian-Qiao Sun
n. U.S. Patent - WO2017208851 (A1): Filing date:–2017-12-07:: Title Actuator-equipped knee ankle foot orthosis Inventor(s) Rei Takahashi Yuichi Sawada Yoshiyuki Higashi HonkyoTooruMasayamaNoriakiIchibashi Toshikazu Ohata Kawaguchi
o. (*Design, Construction and Evaluation of an Electromechanical Stance-Control Knee-Ankle-Foot-Orthosis TerrisYakimovich, Jonathan Kofman, Edward Lemaire, Proceedings of the 2005 IEEE, Engineering in Medicine and Biology 27th Annual Conference, Shanghai, China, September 1-4, 2005)*

XV. ANNEXURES:

Sr. No.	Study Documents
Annexure A	Case Study cum Evaluation Form in English
Annexure B	Informed Consent Form (ICF) in English
Annexure C	Informed Consent Form (ICF) in Hindi
Annexure D	Informed Consent Form (ICF) in Marathi
Annexure E	Product Evaluation & Effectiveness Questionnaire/Feedback Questionnaire (PEEQ)in English and Hindi
Annexure F	Product Evaluation Questionnaire/Feedback Questionnaire (PEEQ)in Marathi
Annexure G	Copy of safety Report: Mechanical Load testing
Annexure H	Copy of Safety Analysis: Ansys Report
Annexure I	Copy of Patent Licensing agreement between IITB and Aumeesh Tech
Annexure J	Proof of Birac BIG Grant approval

Annexure A

Case Study cum Evaluation Form

Date:

Patient No.: Study No.: 01

Prerequisite Questions:

1. Is the patient using any Lower limb Orthosis presently? If yes since how long?

☐Yes,.Months and___Years

☐No

2. If yes, what type of Lower Limb Orthosis is the patient using?

   a) Drop-Lock Caliper

   b)Dynamic Caliper Please Specify which_____

3. If the above answer is a) Drop Lock Caliper then is the user willing to use the MASC-KAFO described in the Consent form?

☐Yes

☐ No

4. Since how long ago does he/she has this lower limb disability?

   ____Months and___Years

5. What is the Weight of the Patient?

   ____Kilograms

6. What is the Age of the Patient?

   ____Months and___Years

7. What is the Gender of the Patient?

☐Male

☐ Female

☐ Other

Notes for the Investigator:

1. If the **answer was for question 2 is a) Drop-Lock Caliper** and **if the user is willing to use MASC-_KAFO test** please perform the Muscle Strength Test using Oxford Scale?

   Core Muscle Strength:

2. What is the Diagnosis of Disability?

Details filled by Name:	Verified by Principal Investigator: Yes/No
Signature& Stamp: Date:	Signature& Stamp: Date:

Date:	Patient No./ID No.:
	Week No. 1
A. Conventional Caliper and MASC-KAFO	
Elements to be Checked	Remark (Yes/No) If Yes, the Quantify
1. Knee Flexion : 2. Squatting: 3.ROM of Knee Joint: 4. Gait Parameters: 5. Comfort: (on the Scale of 1 to 10) 1 being least comfortable 5 being satisfactory 10 being very comfortable	
B. 3D-Gait Analysis Using MASC-KAFO and Conventional Caliper	Yes/ No If Yes Report to be attached
Details filled by Name:	Verified by Principal Investigator: Yes/No
Signature& Stamp: Date:	Signature& Stamp: Date:

Date:	Patient No./ID No.:
	Week No. 4
A. MASC-KAFO	
Elements to be Checked	Remark (Yes/No) If Yes, the Quantify
1. Knee Flexion : 2. Squatting: 3.ROM of Knee Joint: 4. Gait Parameters: 5. Comfort: (on the Scale of 1 to 10) 1 being least comfortable 5 being satisfactory 10 being very comfortable	
Details filled by Name:	Verified by Principal Investigator: Yes/No
Signature& Stamp: Date:	Signature& Stamp: Date:

Date:	Patient No./ID No.:
	Week No. 6
A. MASC-KAFO	
Elements to be Checked	Remark (Yes/No) If Yes, the Quantify
1. Knee Flexion : 2. Squatting: 3.ROM of Knee Joint: 4. Gait Parameters: 5. Comfort: (on the Scale of 1 to 10) 1 being least comfortable 5 being satisfactory 10 being very comfortable	
B. 2D-Gait Analysis Using MASC-KAFO and Conventional Caliper	Yes/ No If Yes Report to be attached
Details filled by Name:	Verified by Principal Investigator: Yes/No
Signature& Stamp: Date:	Signature& Stamp: Date:

Date:	Patient No./ID No.:
	Week No. 8
A. MASC-KAFO	
Elements to be Checked	Remark (Yes/No) If Yes, the Quantify
1. Knee Flexion : 2. Squatting: 3.ROM of Knee Joint: 4. Gait Parameters: 5. Comfort: (on the Scale of 1 to 10) 1 being least comfortable 5 being satisfactory 10 being very comfortable	
Details filled by Name:	Verified by Principal Investigator: Yes/No
Signature& Stamp: Date:	Signature& Stamp: Date:

Date:	Patient No./ID No.:
	Week No. 12
A. MASC-KAFO	
Elements to be Checked	Remark (Yes/No) If Yes, the Quantify
1. Knee Flexion : 2. Squatting: 3.ROM of Knee Joint: 4. Gait Parameters: 5. Comfort: (on the Scale of 1 to 10) 1 being least comfortable 5 being satisfactory 10 being very comfortable	
B. 3D-Gait Analysis Using MASC-KAFO and Conventional Caliper	Yes/ No If Yes Report to be attached
Details filled by Name:	Verified by Principal Investigator: Yes/No
Signature& Stamp: Date:	Signature& Stamp: Date:

Annexure B

Informed Consent Form (ICF) in English

[YOUR INSTITUTIONAL LETTERHEAD]

Product Name: Date:

Patients No.: Trial No.:

Informed Consent form for Clinical Evaluation of Effectiveness parameters with Gait Analysis Using MASC-KAFO: A Comparative pilot study of MASC-KAFO & the conventional Drop-Lock Caliper dated 27April 2022.

This Informed Consent Form is for men and women of age group 18 to 50 years suffering from a Disability of Lower Limb with reduced muscle power {plus two power in lower limb as per Manual Muscle test (MMT)}and compromised stability for daily activities.

You may provide the following information either as a running paragraph or under headings as shown below.

Name of Principal Investigator: Dr. Uttara Upendra Deshmukh (P&O)

Name of Organization: MGM Institute's University Department of Prosthetics and Orthotics.

Name of Sponsor: *Aumeesh Tech Private Limited.*

Name of Proposal and version: - *Clinical Evaluation of Effectiveness parameters with Gait Analysis Using MASC-KAFO: A Comparative pilot study of MASC-KAFO & the conventional Drop-Lock Caliper Version dated 27 April 2022*

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

- **You will be given a copy of the full Informed Consent Form**

PART I: Information Sheet

Introduction

*I am **Dr. Uttara Upendra Deshmukh (P&O)** working with/for the Department of Prosthetics and Orthotics at MGM Hospital. We are doing some research on Rehabilitation of people with lower limb disability which is rising in India. I am going to give you information and invite you to be a part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.*

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

The conventional KAFOs provide stability by locking the knee joint in a fully extended position during both stance and swing phases. This results in excessive energy consumption and induces abnormal gait events such as circumduction, hip hiking, and vaulting during gait. Walking with conventional KAFOs can also lead to premature exhaustion during ambulation, as well as limited mobility, pain, and a decreased range of motion (ROM) in lower limb joints. It has been reported that using a conventional KAFO reduces gait efficiency by 24%, increases vertical displacement of the center of mass (COM) by up to 65%, and also increases energy expenditure.

The MASC-KAFO is an assistive device and focuses on providing a better alternative to the existing orthotic calipers. The research is a comparative trail between the MASC-KAFO and the Conventional Drop-Lock Caliper.

Type of Research Intervention

For this research we will not be performing any surgery or giving you any injections or medications. We will first take the measurements of your lower limb and create an Orthotic brace for you so that you will be able to use it. You will have to perform all your day to day tasks and fill out questionnaires at intervals of 4 weeks, 8 weeks, and 12 weeks to evaluate the impact of the device on your life.

Participant selection

We are inviting all adults with the below criteria to participate in the clinical evaluation of the Orthotic device "MASC-KAFO":

1. *Adults above 18 years and below 50 years of age.*
2. *Should have a locomotor disorder with less than plus two power in lower limb as per Manual Muscle test (MMT)*
3. *Should be ambulatory with assistance or gait aids.*
4. *Self-consent to be the part of the Study*
5. *should be able to speak, read and understand at least one of the following languages - Hindi, Marathi or English*
6. *Living in Mumbai till the course of study is completed.*

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this clinic/hospital for rehabilitation of locomotor disability and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

A. Unfamiliar Procedures

In case of any phantom limb pain or rashes or ulceration counter-measures like off the shelf medication or therapy will be administered.

B. Description of the Process

During the research you make four visits to the clinic.

- *In the first visit i.e. Week 0, the lower limb measurements of the subjects will be taken for preparing the Orthotic Brace. Also details about their general health will be recorded. Subjects shall fill up the Product Evaluation and Effectiveness questionnaires in relation to their existing Orthosis.*
- *At the next visit i.e., Week 1 which will be one week later or at maximum 10 days, the New Orthotic Brace-MASC-KAFO will be fitted and they will be trained to use it and will be required to take 3D Gait Analysis of the new Orthotic Brace-MASC-KAFO and existing Orthotic Brace.*
- *At the next visit i.e. Week 4, After three weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0*
- *At the next visit i.e. Week 6, After five weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0 along with 2D Gait Analysis*
- *At the next visit i.e. Week 8, After seven weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0*
- *At the next visit i.e. Week 12, After eleven weeks of fitment, they will come back to the clinic to repeat all the tests performed in week 0 along with 3 D Gait analysis.*

Duration

The research takes place over 90 days / or 12 weeks in total. During that time, it will be necessary for you to come to the hospital facility 4 to 6 days, for 2 to 3 (number of) hours each day. We would

like to meet with you at intervals 1 week, 4 weeks, 8 weeks, and 12 weeks after your Lower Limb Orthotic Brace fitment (MASC-KAFO)).

In total, you will be asked to come 4 times to the clinic in 3 months. At the end of 3 months, the research will be finished.

Side Effects

As already mentioned, this device can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the socket is fitted on your Limb. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions if any. Or we may stop the study. If this is necessary, we will discuss it together with you and you will always be consulted before we move to the next step.

Risks

By participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your lower limb may experience pain know as phantom limb pain or swelling or ulceration of the limb.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with necessary treatment.

Benefits

If you participate in this research, you will have the following benefits:

*<u>After the end of study</u>, if you would like to continue using the device you would be able to purchase from us **<u>free of Cost.</u>***

Reimbursements

We will give you Rs.200 to pay for your travel to the clinic/parking. You will not be given any other money or gifts to take part in this research.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except research sponsors, your clinician, etc.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these

meetings, we will publish the results in order that other interested people may learn from our research

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected. At the time of withdrawal, you need to return back the material, device or anything given by research team

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name: **Dr. Uttara Upendra Deshmukh (P&O)**

Title: Department of Prosthetics and Orthotics

Institution: MGM Institute's University

This proposal has been reviewed and approved by ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS of MGM INSTITUTE OF HEALTH SCIENCES which is a committee whose task it is to make sure that research participants are protected from harm.

If you wish to find about more about the IRB, contact Dept. of Prosthetic and Orthotic MGM Hospital.

It has also been reviewed by the Management of Aumeesh Tech Private Limited, which is sponsoring and supporting the study.

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. **The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the procedures listed in ICF will be done.

Confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

Annexure C

Informed Consent Form (ICF) in Hindi

[आपका संस्थागत लेटरहेड]

प्रोडक्टकानाम:	दिनांक:
मरीजोंकीसंख्या :	परीक्षणसंख्या :

MASC-KAFO केलिएसूचितसहमतिप्रपत्र:MASC-KAFO का उपयोग करते हुए चाल विश्लेषण के साथ प्रभावशीलता मापदंडों का नैदानिक मूल्यांकन: MASC-KAFO और पारंपरिक ड्रॉप-लॉक कैलिपर दिनांक 27 अप्रैल 2022 का एक तुलनात्मक पायलट अध्ययन।

यह सूचित सहमति प्रपत्र 18 से 50 वर्ष के आयु वर्ग के पुरुषों और महिलाओं के लिए है जो कम मांसपेशियों की शक्ति के साथ निचले अंग की विकलांगता से पीड़ित हैं (मैनुअल मांसपेशी परीक्षण (एमएमटी) के अनुसार निचले अंग में दो शक्ति से अधिक है और दैनिक गतिविधियों के लिए समझौता स्थिरता है।

आप निम्न जानकारी या तो चल रहे अनुच्छेद के रूप में या नीचे दिखाए गए शीर्षकों के तहत प्रदान कर सकते हैं.

प्रधान अन्वेषक का नाम: डॉ. उत्तरा उपेन्द्र देशमुख (P&O)

संगठन का नाम: MGM Institute's University Department of Prosthetics and Orthotics

प्रायोजक का नाम: *Aumeesh Tech Private Limited*

प्रस्ताव और संस्करण का नाम: *- MASC-KAFO का उपयोग करके चाल विश्लेषण के साथ प्रभावशीलता मापदंडों का नैदानिक मूल्यांकन: MASC-KAFO का एक तुलनात्मक पायलट अध्ययन और पारंपरिक ड्रॉप-लॉक कैलिपर संस्करण दिनांक 27अप्रैल 2022*

इस सूचित सहमति प्रपत्र के दो भाग हैं:

- **सूचना पत्रक (आपके साथ अनुसंधान के बारे में जानकारी साझा करने के लिए)**
- **सहमति का प्रमाण पत्र (हस्ताक्षर के लिए यदि आप भाग लेने के लिए सहमत हैं)**
- **आपको पूर्ण सूचित सहमति फॉर्म की एक प्रति दी जाएगी**

भाग I: सूचना पत्रक

परिचय

*मैं**डॉ उत्तरा उपेन्द्र देशमुख (पी एंड ओ)** एमजीएम अस्पताल में प्रोस्थेटिक्स और ऑर्थोटिक्स विभाग के साथ/उसके लिए काम कर रहा हूं। हम निचले अंग विकलांगता वाले लोगों के पुनर्वास पर कुछ शोध कर रहे हैं जो भारत में बढ़ रहा है। मैं आपको जानकारी देने जा रहा हूं और आपको इस शोध का हिस्सा बनने के लिए आमंत्रित करने जा रहा हूं। आपको आज यह तय करने की ज़रूरत नहीं है कि आप शोध में भाग लेंगे या नहीं। इससे पहले कि आप तय करें, आप किसी से भी बात कर सकते हैं जिसे आप अनुसंधान के बारे में सहज महसूस करते हैं।*

कुछ ऐसे शब्द हो सकते हैं जिन्हें आप समझ नहीं पाते हैं। कृपया मुझे रोकने के लिए कहें क्योंकि हम जानकारी के माध्यम से जाते हैं और मुझे समझाने में समय लगेगा। यदि आपके पास बाद में प्रश्न हैं, तो आप उनसे मुझसे, अध्ययन डॉक्टर या कर्मचारियों से पूछ सकते हैं।

अनुसंधान का उद्देश्य

पारंपरिक KAFOs रुख और स्विंग दोनों चरणों के दौरान एक पूरी तरह से विस्तारित स्थिति में घुटने के जोड़ को लॉक करके स्थिरता प्रदान करते हैं। इसके परिणामस्वरूप अत्यधिक ऊर्जा की खपत होती है और असामान्य चाल की घटनाओं जैसे कि परिक्रमण, हिप हाइकिंग और चाल के दौरान वॉल्टिंग को प्रेरित करता है। पारंपरिक केएएफओ के साथ चलना भी एम्बुलेशन के दौरान समय से पहले थकावट का कारण बन सकता है, साथ ही सीमित गतिशीलता, दर्द, और निचले अंग जोड़ों में गति की कम सीमा (रॉम) भी हो सकती है। यह बताया गया है कि पारंपरिक KAFO का उपयोग करने से चाल

दक्षता 24% तक कम हो जाती है, द्रव्यमान के केंद्र (COM) के ऊर्ध्वाधर विस्थापन को 65% तक बढ़ाता है, और ऊर्जा व्यय भी बढ़ जाता है।

MASC-KAFO एक सहायक उपकरण है और मौजूदा ऑर्थोटिक कैलिपर्स के लिए एक बेहतर विकल्प प्रदान करने पर केंद्रित है। अनुसंधान MASC-KAFO और पारंपरिक ड्रॉप-लॉक कैलिपर के बीच एक तुलनात्मक निशान है।

अनुसंधान हस्तक्षेप के प्रकार

इस शोध के लिए हम कोई सर्जरी नहीं करेंगे या आपको कोई इंजेक्शन या दवाएं नहीं देंगे। हम पहले आपके निचले अंग के माप लेंगे और आपके लिए एक ऑर्थोटिक ब्रेस बनाएंगे ताकि आप इसका उपयोग कर सकें। आपको अपने जीवन पर डिवाइस के प्रभाव का मूल्यांकन करने के लिए अपने सभी दिन-प्रतिदिन के कार्यों को करना होगा और 4 सप्ताह, 8 सप्ताह और 12 सप्ताह के अंतराल पर प्रश्नावली भरनी होगी।

प्रतिभागी चयन

हम ऑर्थोटिक डिवाइस "MASC-KAFO" के नैदानिक मूल्यांकन में भाग लेने के लिए नीचे दिए गए मानदंडों के साथ सभी वयस्कों को आमंत्रित कर रहे हैं:

1. *18 वर्ष से अधिक और 50 वर्ष से कम आयु के वयस्क।*
2. *मैनुअलमांसपेशीपरीक्षण (एमएमटी) केअनुसारनिचलेअंगमेंप्लसदोशक्तिकेसाथएकलोकोमोटरविकारहोनाचाहिए*
3. *सहायतायाचालएड्सकेसाथ ambulatory होनाचाहिए.*
4. *अध्ययन का हिस्सा बनने के लिए आत्म-सहमति*
5. *निम्नलिखित भाषाओं में से कम से कम एक को बोलने, पढ़ने और समझने में सक्षम होना चाहिए - हिंदी, मराठी या अंग्रेजी*
6. *पढ़ाई का कोर्स पूरा होने तक मुंबई में रहना।*

स्वैच्छिक सहभागिता

इस शोध में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यह आपकी पसंद है कि भाग लेना है या नहीं। चाहे आप भाग लेना चुनते हैं या नहीं, इस क्लिनिक में आपको प्राप्त होने वाली सभी सेवाएं जारी रहेंगी और कुछ भी नहीं बदलेगा। यदि आप इस शोध परियोजना में भाग नहीं लेना चुनते हैं, तो आप उस उपचार की पेशकश करेंगे जो नियमित रूप से लोकोमोटर विकलांगता के पुनर्वास के लिए इस क्लिनिक / अस्पताल में पेश किया जाता है और हम आपको बाद में इसके बारे में अधिक

बताएंगे। आप बाद में अपना मन बदल सकते हैं और भाग लेना बंद कर सकते हैं, भले ही आप पहले सहमत हों।.

प्रक्रियाओं और प्रोटोकॉल

A. अपरिचित प्रक्रियाएं

किसी भी प्रेत अंग दर्द या चकत्ते या अल्सर के मामले में शेल्फ दवा या चिकित्सा जैसे काउंटर-उपायों को प्रशासित किया जाएगा।

B. प्रक्रिया का विवरण

शोध के दौरान आप क्लिनिक में चार दौरे करते हैं।

पहली मुलाकात यानि सप्ताह 0 में, ऑर्थोटिक ब्रेस तैयार करने के लिए विषयों के निचले अंगों का माप लिया जाएगा। साथ ही उनके सामान्य स्वास्थ्य की जानकारी भी दर्ज की जाएगी। विषय अपने मौजूदा ऑर्थोसिस के संबंध में उत्पाद मूल्यांकन और प्रभावशीलता प्रश्नावली को भरेंगे।

अगले मुलाक़ात यानी सप्ताह 1 में, जो एक सप्ताह बाद या अधिकतम 10 दिनों में होगा, नया ऑर्थोटिक ब्रेस-एमएएससी-केएएफओ लगाया जाएगा और उन्हें इसका इस्तेमाल करने के लिए प्रशिक्षित किया जाएगा और उन्हें 3डी गैट एनालिसिस लेना होगा। नया ऑर्थोटिक ब्रेस-एमएएससी-केएएफओ और मौजूदा ऑर्थोटिक ब्रेस।

अगले मुलाक़ात यानी सप्ताह 4 में, फिट होने के तीन सप्ताह के बाद, वे सप्ताह 0 में किए गए सभी परीक्षणों को दोहराने के लिए क्लिनिक वापस आएंगे।

अगले दौरे पर यानी सप्ताह 6 में, फिट होने के पांच सप्ताह के बाद, वे क्लिनिक में वापस आएंगे और सप्ताह 0 में किए गए सभी परीक्षणों को 2 डी गैट विश्लेषण के साथ दोहराएंगे।

अगले मुलाक़ात यानि आठवें सप्ताह में, सात सप्ताह के फिट होने के बाद, वे सप्ताह 0 में किए गए सभी परीक्षणों को दोहराने के लिए क्लिनिक वापस आएंगे।

अगले मुलाक़ात यानी सप्ताह 12 में, ग्यारह सप्ताह के फिट होने के बाद, वे 3 डी गैट विश्लेषण के साथ सप्ताह 0 में किए गए सभी परीक्षणों को दोहराने के लिए क्लिनिक वापस आएंगे।

अवधि

अनुसंधान कुल मिलाकर 90 दिनों / या 12 सप्ताह में होता है। उस समय के दौरान, आपके लिए अस्पताल की सुविधा में 4 से 6 दिनों के लिए, प्रत्येक दिन 2 से 3 (की संख्या) घंटे के लिए आना

आवश्यक होगा। हम आपके लोअर लिंब ऑर्थोटिक ब्रेस फिटमेंट (MASC-KAFO)) के बाद 1 सप्ताह, 4 सप्ताह, 8 सप्ताह और 12 सप्ताह के अंतराल पर आपके साथ मिलना चाहते हैं।

कुल मिलाकर, आपको 3 महीने में क्लिनिक में 4 बार आने के लिए कहा जाएगा। 3 महीने के अंत में, अनुसंधान समाप्त हो जाएगा।

दुष्प्रभाव

जैसा कि पहले ही उल्लेख किया गया है, इस डिवाइस के कुछ अवांछित प्रभाव हो सकते हैं। यह आपको थका सकता है और यह उस जगह के आसपास कुछ अस्थायी सूजन पैदा कर सकता है जहां सॉकेट आपके अंग पर फिट होता है। यह संभव है कि यह कुछ समस्याओं का कारण भी बन सकता है जिसके बारे में हम नहीं जानते हैं। हालांकि, हम आपको बारीकी से पालन करेंगे और किसी भी अवांछित प्रभाव या किसी भी समस्या का ट्रैक रखेंगे। हम साइड इफेक्ट्स या प्रतिक्रियाओं के लक्षणों को कम करने के लिए कुछ अन्य दवाओं का उपयोग कर सकते हैं यदि कोई हो। या हम अध्ययन को रोक सकते हैं। यदि यह आवश्यक है, तो हम आपके साथ मिलकर इस पर चर्चा करेंगे और अगले चरण में जाने से पहले आपसे हमेशा परामर्श किया जाएगा।

जोखिम

इस शोध में भाग लेने से यह संभव है कि आप अन्यथा होने की तुलना में अधिक जोखिम में होंगे। उदाहरण के लिए, एक जोखिम है कि आपके निचले अंग को दर्द का अनुभव हो सकता है, जिसे प्रेत अंग दर्द या अंग की सूजन या अल्सरेशन के रूप में जाना जाता है।

जबकि ऐसा होने की संभावना बहुत कम है, फिर भी आपको संभावना के बारे में पता होना चाहिए। हम इस घटना के होने की संभावना को कम करने की कोशिश करेंगे, लेकिन अगर कुछ अप्रत्याशित होता है, तो हम आपको आवश्यक उपचार प्रदान करेंगे।

लाभ

यदि आप इस शोध में भाग लेते हैं, तो आपके पास निम्नलिखित लाभ होंगे:

अध्ययन की समाप्ति के बाद, यदि आप डिवाइस का उपयोग जारी रखना चाहते हैं तो आप हमसे मुफ्त में खरीद सकेंगे।

पैसे

हम आपको क्लिनिक / पार्किंग की यात्रा के लिए भुगतान करने के लिए 200 रुपये देंगे। इस शोध में भाग लेने के लिए आपको कोई अन्य धन या उपहार नहीं दिया जाएगा।

गोपनीयता

इस शोध के साथ, आपके समुदाय में सामान्य से बाहर कुछ किया जा रहा है। यह संभव है कि यदि समुदाय के अन्य लोगों को पता है कि आप भाग ले रहे हैं, तो वे आपसे सवाल पूछ सकते हैं। हम अनुसंधान में भाग लेने वालों की पहचान साझा नहीं करेंगे।

इस शोध परियोजना से हम जो जानकारी एकत्र करते हैं, उसे गोपनीय रखा जाएगा। आपके बारे में जो जानकारी शोध के दौरान एकत्र की जाएगी, उसे दूर रखा जाएगा और कोई भी नहीं बल्कि शोधकर्ता इसे देख पाएंगे। आपके बारे में किसी भी जानकारी पर आपके नाम के बजाय एक नंबर होगा। केवल शोधकर्ताओं को पता चल जाएगा कि आपका नंबर क्या है और हम उस जानकारी को लॉक और कुंजी के साथ लॉक कर देंगे। यह अनुसंधान प्रायोजकों, आपके चिकित्सक, आदि को छोड़कर किसी के साथ साझा या दिया नहीं जाएगा।

परिणाम साझा करना

इस शोध को करने से हमें जो ज्ञान मिलता है, उसे जनता के लिए व्यापक रूप से उपलब्ध कराने से पहले सामुदायिक बैठकों के माध्यम से आपके साथ साझा किया जाएगा। गोपनीय जानकारी साझा नहीं की जाएगी। समुदाय में छोटी बैठकें होंगी और इनकी घोषणा की जाएगी। इन बैठकों के बाद, हम परिणामों को प्रकाशित करेंगे ताकि अन्य इच्छुक लोग हमारे शोध से सीख सकें।

इनकार करने या वापस लेने का अधिकार

आपको इस शोध में भाग लेने की ज़रूरत नहीं है यदि आप ऐसा नहीं करना चाहते हैं और भाग लेने से इनकार करने से इस क्लिनिक में आपके उपचार को किसी भी तरह से प्रभावित नहीं किया जाएगा। आपके पास अभी भी सभी लाभ होंगे जो आपके पास अन्यथा इस क्लिनिक में होंगे। आप किसी भी समय अनुसंधान में भाग लेना बंद कर सकते हैं जो आप यहां एक रोगी के रूप में अपने किसी भी अधिकार को खोए बिना चाहते हैं। इस क्लिनिक में आपका इलाज किसी भी तरह से प्रभावित नहीं होगा। आप किसी भी समय अपने द्वारा चुने गए शोध में भाग लेना बंद कर सकते हैं। यह आपकी पसंद है और आपके सभी अधिकारों का अभी भी सम्मान किया जाएगा। वापसी के समय, आपको अनुसंधान टीम द्वारा दी गई सामग्री, डिवाइस या कुछ भी वापस करने की आवश्यकता है।

भाग लेने के लिए विकल्प

यदिआपअनुसंधानमेंभागनहींलेनाचाहतेहैं,
तोआपकोअस्पतालमेंउपलब्धस्थापितमानकउपचारप्रदानकियाजाएगा।

किससे संपर्क करें

यदि आपके पास कोई प्रश्न हैं, तो आप अध्ययन शुरू होने के बाद भी उनसे अभी या बाद में पूछ सकते हैं। यदि आप बाद में प्रश्न पूछना चाहते हैं, तो आप निम्न में से किसी से भी संपर्क कर सकते हैं:

नाम: **डॉ उत्तरा उपेंद्र देशमुख (पी एंड ओ)**

साँचा: Department of Prosthetics and Orthotics

संस्थान: एमजीएम संस्थान के विश्वविद्यालय

इस प्रस्ताव की समीक्षा की गई है और एमजीएम इंस्टीट्यूट ऑफ हेल्थ साइंसेज **केमानवविषयोंपरअनुसंधानकेलिएनैतिकतासमिति** द्वारा अनुमोदित किया गया **है जो एक समिति है जिसका कार्य यह सुनिश्चित करना है कि अनुसंधान प्रतिभागियों को नुकसान से बचाया जाए।**

यदि आप आईआरबी के बारे में अधिक जानना चाहते हैं, तो प्रोस्थेटिक और ऑर्थोटिक एमजीएम अस्पताल विभाग से संपर्क करें।

इसकी समीक्षा औमीश टेक प्राइवेट लिमिटेड के प्रबंधन द्वारा भी की गई है, जो अध्ययन को प्रायोजित और समर्थन कर रहा है।

भाग II: सहमति का प्रमाण पत्र

इस अनुभाग को पहले व्यक्ति में लिखा जाना चाहिए और नीचे बोल्ड में एक के समान एक बयान होना चाहिए। यदि प्रतिभागी अनपढ़ है लेकिन मौखिक सहमति देता है, तो एक गवाह को हस्ताक्षर करना चाहिए। एक शोधकर्ता या सूचित सहमति पर जाने वाले व्यक्ति को प्रत्येक सहमति पर हस्ताक्षर करना होगा। **सहमति के प्रमाण पत्र को उन बयानों से बचना चाहिए जिनके पास "मैं समझता हूं ..." वाक्यांश। समझ को शायद सूचना पत्रक के पढ़ने के दौरान लक्षित प्रश्नों के माध्यम से बेहतर परीक्षण किया जाना चाहिए (प्रश्नों के कुछ उदाहरण ऊपर दिए गए हैं), या सूचना पत्रक के पढ़ने के अंत में पूछे जाने वाले प्रश्नों के माध्यम से, यदि संभावित प्रतिभागी सूचना पत्रक पढ़ रहा है तो उसे /**

मैंने पूर्वगामी जानकारी पढ़ी है, या इसे मुझे पढ़ा गया है। मुझे इसके बारे में सवाल पूछने का अवसर मिला है और मैंने जो भी प्रश्न पूछे हैं, उनका उत्तर मेरी संतुष्टि के लिए दिया गया है। मैं स्वेच्छा से इस शोध में एक प्रतिभागी के रूप में भाग लेने के लिए सहमत हूं।

प्रतिभागी का नाम_____

प्रतिभागी _____

दिनांक_____

दिन/महीना/वर्ष

यदि अनपढ़

एक साक्षर गवाह को हस्ताक्षर करना चाहिए (यदि संभव हो, तो इस व्यक्ति को प्रतिभागी द्वारा चुना जाना चाहिए और अनुसंधान टीम से कोई संबंध नहीं होना चाहिए)। जो प्रतिभागी अनपढ़ हैं, उन्हें अपने अंगूठे के निशान को भी शामिल करना चाहिए।

मैंने संभावित प्रतिभागी को सहमति फॉर्म का सटीक पढ़ने का गवाह बनाया है, और व्यक्ति को प्रश्न पूछने का अवसर मिला है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से सहमति दी है।

गवाह का नाम _____और प्रतिभागीकेअंगूठेकानिशान

गवाह _____

दिनांक _____

दिन/महीना/वर्ष

सहमति लेने वाले शोधकर्ता/ व्यक्ति द्वारा बयान

मैंने संभावित प्रतिभागी को सूचना पत्रक को सटीक रूप से पढ़ा है, और मेरी क्षमता का सबसे अच्छा यह सुनिश्चित करने के लिए कि प्रतिभागी समझता है कि आईसीएफ में सूचीबद्ध प्रक्रियाएं पूरी हो जाएंगी।

पुष्टि करें कि प्रतिभागी को अध्ययन के बारे में प्रश्न पूछने का अवसर दिया गया था, और प्रतिभागी द्वारा पूछे गए सभी प्रश्नों का सही उत्तर दिया गया है और मेरी क्षमता का सबसे अच्छा उत्तर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति को सहमति देने के लिए मजबूर नहीं किया गया है, और सहमति स्वतंत्र रूप से और स्वेच्छा से दी गई है।

इस आईसीएफ की एक प्रति प्रतिभागी को प्रदान की गई है।

सहमतिलेनेवालेअनुसंधानकर्ता/व्यक्तिकानाम_____

शोधकर्ता/सहमतिलेनेवालेव्यक्तिकेहस्ताक्षर_____

दिनांक _____

दिन/महीना/वर्ष

Annexure D

Informed Consent Form (ICF) in Marathi

[संस्थेच्या P&O चे लेटरहेड]

प्रोडक्ट चे नाव: दिनांक :

रूग्णाचा नंबर : ट्रायल नंबर:

MASC-KAFO वापरून चालण्याच्या विश्लेषणासह परिणामकारकता पॅरामीटर्सच्या क्लिनिकल मूल्यमापनासाठी सूचित संमती फॉर्म: दिनांक 25 अप्रैल, 2022 पासून MASC-KAFO आणि परंपरागत ड्रॉप-लॉक कॅलिपरचा चा तुलनात्मक पायलट अभ्यास करण्यात आला आहे.

हा माहितीपूर्ण संमती फॉर्म 18 ते 50 वर्षे वयोगटातील पुरुष आणि स्त्रियांसाठी आहे, ज्यामध्ये स्नायूंची शक्ती कमी झाली आहे {हातपाय स्नायूंची चाचणी (एमएमटी) नुसार खालच्या अंगात ज्यांची दोन किंवा अधिक शक्ती आहे} आणि दैनंदिन हालचालींवर तोडगा काढलेला एक महत्त्वाचा पर्याय.

तुम्ही खालील माहिती एकतर चालू परिच्छेद म्हणून किंवा खाली दाखवल्याप्रमाणे शीर्षकाखाली देऊ शकता.

मुख्य अन्वेषकाचे नाव: डॉ. उत्तरा उपेंद्र देशमुख (पी आणि ओ)

संस्थेचे नाव: एमजीएम इन्स्टिट्युट युनिवर्सिटी डिपार्टमेंट ऑफ प्रोस्थेटिक्स आणि ऑर्थोटिक्स विभाग.

प्रायोजकाचे नाव: Aumeesh Tech Private Limited.

प्रस्तावाचे नाव आणि आवृत्ती: - MASC-KAFO वापरून चालण्याच्या विश्लेषणासह परिणामकारकता पॅरामीटर्सच्या क्लिनिकल मूल्यमापनासाठी सूचित संमती फॉर्म: दिनांक 27 अप्रैल, 2022 पासून MASC-KAFO आणि परंपरागत ड्रॉप-लॉक कॅलिपरचा चा तुलनात्मक पायलट अभ्यास करण्यात आला आहे.

या माहितीपूर्ण संमती फॉर्मचे दोन भाग आहेत:

- **माहिती पत्रक (संशोधनाची माहिती तुमच्यासोबत शेअर करण्यासाठी)**
- **संमतीचे प्रमाणपत्र (तुम्ही भाग घेण्यास सहमत असाल तर स्वाक्षरीसाठी)**
- **तुम्हाला संपूर्ण माहितीपूर्ण संमती फॉर्मची एक प्रत दिली जाईल**

भाग I: माहिती पत्रक

परिचय

मी डॉ. उत्तरा उपेंद्र देशमुख (P&O) MGM हॉस्पिटलमधील प्रोस्थेटिक्स आणि ऑर्थोटिक्स विभागासोबत/साठी काम करीत आहे. आम्ही कमी अंगाचे अपंगत्व असलेल्या लोकांच्या पुनर्वसनावर काही संशोधन करत आहोत, जे भारतात वाढत आहे. मी तुम्हाला माहिती देणार आहे आणि तुम्हाला या संशोधनाचा भाग होण्यासाठी आमंत्रित करणार आहे. तुम्ही संशोधनात सहभागी व्हाल की नाही हे आज ठरवायचे नाही. तुम्ही ठरविण्यापूर्वी, तुम्ही संशोधनाविषयी तुम्हाला सोयीस्कर वाटणाऱ्या कोणाशीही बोलू शकता.

असे काही शब्द असू शकतात जे तुम्हाला समजत नाहीत. कृपया माहिती जाणून घेण्यासाठी मला थांबायला सांगा आणि मला स्पष्ट करण्यासाठी वेळ लागेल. तुम्हाला नंतर प्रश्न असल्यास, तुम्ही त्यांना माझ्याकडून, अभ्यासाच्या डॉक्टरांना किंवा कर्मचाऱ्यांना विचारू शकता

संशोधनाचा उद्देश

पारंपारिक KAFOs स्टेन्स आणि स्विंग या दोन्ही टप्प्यांमध्ये गुडघ्याच्या सांध्याला पूर्णपणे विस्तारित स्थितीत लॉक करून स्थिरता प्रदान करतात. याचा परिणाम जास्त ऊर्जेचा वापर होतो आणि चालण्याच्या दरम्यान असामान्य चालण्याच्या घटना घडतात जसे की परिक्रमा, हिप हायकिंग आणि वॉल्टिंग. पारंपारिक KAFOs सह चालणे देखील अॅम्ब्युलेशन दरम्यान अकाली थकवा, तसेच मर्यादित हालचाल, वेदना आणि खालच्या अंगांच्या सांध्यामध्ये गतीची श्रेणी (ROM) कमी होऊ शकते. असे नोंदवले गेले आहे की पारंपारिक KAFO वापरल्याने चालण्याची कार्यक्षमता 24% कमी होते, वस्तुमान केंद्र (COM) चे अनुलंब विस्थापन 65% पर्यंत वाढते आणि ऊर्जा खर्च देखील वाढतो.

MASC-KAFO हे एक सहाय्यक उपकरण आहे आणि सध्याच्या ऑर्थोटिक कॅलिपरला एक चांगला पर्याय प्रदान करण्यावर लक्ष केंद्रित करते. संशोधन हे MASC-KAFO आणि पारंपरिक ड्रॉप-लॉक कॅलिपर यांच्यातील तुलनात्मक मार्ग आहे.

संशोधन हस्तक्षेपाचा प्रकार

या संशोधनासाठी आम्ही कोणतीही शस्त्रक्रिया करणार नाही किंवा तुम्हाला कोणतेही इंजेक्शन किंवा औषधे देणार नाही. आम्ही प्रथम तुमच्या आधू असलेल्या खालच्या अंगाचे मोजमाप घेऊ आणि तुमच्यासाठी ऑर्थोटिक ब्रेस तयार करू जेणेकरून तुम्ही ते वापरू शकाल. तुम्हाला तुमची सर्व दैनंदिन कामे करावी लागतील आणि 4 आठवडे, 8 आठवडे आणि 12 आठवड्यांच्या अंतराने प्रश्नावली भरून तुमच्या जीवनावर डिव्हाइसचा प्रभाव पडेल.

सहभागी निवड

आम्ही खालील निकषांसह सर्व प्रौढांना ऑर्थोटिक उपकरण "MASC-KAFO"च्या क्लिनिकल मूल्यांकनात सहभागी होण्यासाठी आमंत्रित करत आहोत:

1. 18 वर्षांवरील आणि 50 वर्षांपेक्षा कमी वयाचे प्रौढ.

2. मॅन्युअल मसल टेस्ट (MMT) नुसार खालच्या अंगात प्लस टू पॉवर असलेला लोकोमोटरी डिसऑर्डर असावा.

3. सहाय्य किंवा चाल सहाय्याने रूग्णवाहक असावे.

4. अभ्यासाचा भाग होण्यासाठी स्वत:ची संमती

5. खालीलपैकी किमान एक भाषा बोलता, वाचता आणि समजता आली पाहिजे - हिंदी, मराठी किंवा इंग्रजी

6. अभ्यासक्रम पूर्ण होईपर्यंत मुंबईत राहणे.

ऐच्छिक सहभाग

या संशोधनात तुमचा सहभाग पूर्णपणे ऐच्छिक आहे. भाग घ्यायचा की नाही हा तुमचा निर्णय आहे. तुम्ही सहभागी होण्याचे निवडले किंवा नसले तरीही, तुम्हाला या क्लिनिकमध्ये मिळणाऱ्या सर्व सेवा सुरू राहतील आणि काहीही बदलणार नाही. तुम्ही या संशोधन प्रकल्पात सहभागी न होण्याचे निवडल्यास, तुम्ही या क्लिनिक/रुग्णालयात लोकोमोटरी अपंगत्वाच्या पुनर्वसनासाठी नियमितपणे दिले जाणारे उपचार देऊ कराल आणि आम्ही तुम्हाला त्याबद्दल नंतर अधिक सांगू. तुम्ही तुमचा विचार नंतर बदलू शकता आणि तुम्ही आधी सहमत असलात तरीही सहभागी होणे थांबवू शकता.

प्रक्रिया आणि प्रोटोकॉल

A. अपरिचित प्रक्रिया

अंगदुखी किंवा रॅशेस किंवा अल्सरेशनच्या बाबतीत आॅफ द शेल्फ किंवा फिजिओथेरपी यांसारखे उपाय केले जातील.

B. प्रक्रियेचे वर्णन

संशोधनादरम्यान तुम्ही क्लिनिकला चार वेळा भेट देता.

- पहिल्या भेटीत म्हणजे आठवडा 0, ऑर्थोटिक ब्रेस तयार करण्यासाठी विषयांच्या खालच्या अंगांचे मोजमाप घेतले जाईल. तसेच त्यांच्या सामान्य आरोग्याबाबत तपशील नोंदवला जाईल. विषय त्यांच्या विद्यमान ऑर्थोसिसच्या संबंधात उत्पादन मूल्यमापन आणि परिणामकारकता प्रश्नावली भरतील.
- पुढील भेटीत म्हणजे, आठवडा 1 जो एक आठवड्यानंतर किंवा जास्तीत जास्त 10 दिवसांचा असेल, नवीन ऑर्थोटिक ब्रेस-MASC-KAFO बसवले जाईल आणि त्यांना ते वापरण्यासाठी प्रशिक्षित केले जाईल आणि त्यांना 3D चालणे विश्लेषण करणे आवश्यक असेल. नवीन ऑर्थोटिक ब्रेस-MASC-KAFO आणि विद्यमान ऑर्थोटिक ब्रेस.
- पुढच्या भेटीत म्हणजे आठवडा 4, तीन आठवड्यांच्या फिटमेंटनंतर, ते आठवडा 0 मध्ये केलेल्या सर्व चाचण्या पुन्हा करण्यासाठी क्लिनिकमध्ये परत येतील.
- पुढील भेटीत म्हणजे आठवडा 6, फिटमेंटच्या पाच आठवड्यांनंतर, ते 2D गेट ॲनालिसिससह आठवडा 0 मध्ये केलेल्या सर्व चाचण्यांची पुनरावृत्ती करण्यासाठी क्लिनिकमध्ये परत येतील.
- पुढील भेटीत म्हणजे आठवडा आठवडा, सात आठवड्यांच्या फिटमेंटनंतर, ते आठवडा 0 मध्ये केलेल्या सर्व चाचण्या पुन्हा करण्यासाठी क्लिनिकमध्ये परत येतील.
- पुढील भेटीत म्हणजे आठवडा 12, फिटमेंटच्या अकरा आठवड्यांनंतर, ते 3 डी गेट विश्लेषणासह आठवडा 0 मध्ये केलेल्या सर्व चाचण्या पुन्हा करण्यासाठी क्लिनिकमध्ये परत येतील.

कार्यकाळ

संशोधन एकूण 90 दिवस / 12 आठवड्यांत होणार आहे. या कालावधीत आपल्याला 4 ते 6 दिवस रूग्णालयाच्या सुविधेसाठी प्रत्येक दिवशी 2 ते 3 तास यावे लागेल. आम्ही आपल्याला MASC-KAFO घालून प्रत्येक आठवडयात भेटण्यासाठी बोलावू.

एकूणच 3 ते 4 महिन्यांमध्ये आपल्याला 4 वेळा क्लिनिक मध्ये यायला सांगितले जाईल. तीन महिन्यांच्या आत हे संशोधन पूर्ण होऊन जाईल.

दुष्परिणाम

आधीच नमूद केल्याप्रमाणे, या डिव्हाइसमध्ये काही अवांछित प्रभाव असू शकतात. यामुळे तुम्हाला थकवा येऊ शकतो आणि तुमच्या अंगावर सॉकेट बसवलेल्या जागेभोवती काही काळासाठी सूज येऊ शकते. हे शक्य आहे की यामुळे काही समस्या उद्भवू शकतात ज्यांची आपल्याला माहिती नाही. तथापि, आम्ही तुमचे बारकाईने अनुसरण करू आणि कोणत्याही अवांछित परिणामांचा किंवा कोणत्याही समस्यांचा मागोवा ठेवू. साइड इफेक्ट्स किंवा प्रतिक्रियांची लक्षणे कमी करण्यासाठी आम्ही काही इतर औषधे वापरू शकतो. किंवा आपण अभ्यास थांबवू शकतो. हे आवश्यक असल्यास आम्ही तुमच्याशी एकत्रितपणे चर्चा करू आणि आम्ही पुढील चरणावर जाण्यापूर्वी तुमचा नेहमी सल्ला घेतला जाईल.

जोखीम

या संशोधनात भाग घेतल्याने हे शक्य आहे की तुम्हाला त्यापेक्षा जास्त धोका असेल. उदाहरणार्थ, तुमच्या खालच्या अंगाला वेदना जाणवण्याची जोखीम आहे, ज्याला फाँटम लिंब वेदना किंवा सूज किंवा अंगाचा व्रण म्हणून ओळखले जाते.

हे घडण्याची शक्यता खूपच कमी असली तरीही, तुम्हाला त्या शक्यतांची जाणीव असली पाहिजे. आम्ही ही घटना घडण्याची शक्यता कमी करण्याचा प्रयत्न करू, परंतु काही अनपेक्षित घडल्यास, आम्ही तुम्हाला आवश्यक उपचार देऊ.)

फायदे

तुम्ही या संशोधनात भाग घेतल्यास तुम्हाला खालील फायदे होतील:

अभ्यास संपल्यानंतर, तुम्ही डिव्हाइस वापरणे सुरू ठेवू इच्छित असल्यास, तुम्ही आमच्याकडून विनामूल्य खरेदी करू शकाल.

प्रतिपूर्ती

तुमच्या क्लिनिक/पार्किंगच्या प्रवासासाठी आम्ही तुम्हाला रु. 200 देऊ. या संशोधनात भाग घेण्यासाठी तुम्हाला इतर कोणतेही पैसे किंवा भेटवस्तू दिल्या जाणार नाहीत.

गुप्तता

या संशोधनामुळे, तुमच्या समाजात काहीतरी सामान्य केले जात आहे. हे शक्य आहे की समाजातील इतरांना तुम्ही सहभागी होत असल्याची जाणीव असल्यास, ते तुम्हाला प्रश्न विचारतील. संशोधनात सहभागी झालेल्यांची ओळख आम्ही शेअर करणार नाही.

या संशोधन प्रकल्पातून आम्ही जी माहिती गोळा करतो ती गोपनीय ठेवली जाईल. संशोधनादरम्यान संकलित केली जाणारी तुमच्याबद्दलची माहिती टाकली जाईल आणि संशोधकांशिवाय कोणीही ती पाहू शकणार नाही.

तुमच्याबद्दलची कोणतीही माहिती त्यावर तुमच्या नावाऐवजी नंबर असेल. तुमचा नंबर काय आहे हे फक्त संशोधकांनाच कळेल आणि आम्ही ती माहिती गुप्त ठेवू. हे संशोधन प्रायोजक, तुमचा चिकित्सक इत्यादींशिवाय कोणाशीही शेअर केले जाणार नाही किंवा दिले जाणार नाही.

परिणाम सामायिक करणे

हे संशोधन केल्याने आम्हाला जे ज्ञान मिळते ते लोकांसाठी व्यापकपणे उपलब्ध होण्यापूर्वी समुदाय सभांद्वारे तुमच्यासोबत शेअर केले जाईल. गोपनीय माहिती शेअर केली जाणार नाही. समाजाच्या

छोट्या-छोट्या बैठका घेऊन त्या जाहीर केल्या जातील. या बैठकांनंतर, आम्ही निकाल प्रकाशित करू जेणेकरून इतर इच्छुक लोकांना आमच्या संशोधनातून शिकता येईल.

- नाकारण्याचा किंवा मागे घेण्याचा अधिकारतुम्हाला असे करायचे नसेल तर तुम्हाला या संशोधनात भाग घेण्याची गरज नाही आणि सहभागी होण्यास नकार दिल्याने तुमच्या या क्लिनिकमधील उपचारांवर कोणताही परिणाम होणार नाही. तुम्हाला अजूनही या क्लिनिकमध्ये मिळणारे सर्व फायदे असतील. येथे रुग्ण म्हणून तुमचे कोणतेही अधिकार न गमावता तुम्ही कधीही संशोधनात सहभागी होणे थांबवू शकता. या दवाखान्यातील तुमच्या उपचारांवर कोणत्याही प्रकारे परिणाम होणार नाही. तुम्ही निवडलेल्या कोणत्याही वेळी तुम्ही संशोधनात भाग घेणे देखील थांबवू शकता. ही तुमची निवड आहे आणि तरीही तुमच्या सर्व अधिकारांचा आदर केला जाईल. पैसे काढताना, तुम्हाला रिसर्च टीमने दिलेली सामग्री, डिव्हाइस किंवा काहीही परत करणे आवश्यक आहे सहभागी होण्यासाठी पर्याय जर तुम्हाला संशोधनात भाग घ्यायचा नसेल, तर तुम्हाला रूग्णालयात उपलब्ध प्रमाणित मानक उपचार प्रदान केले जातील.

- कोणाशी संपर्क साधावा

  तुम्हाला काही प्रश्न असतील तर तुम्ही ते आता किंवा नंतर विचारू शकता, अभ्यास सुरू झाल्यानंतरही. आपण नंतर प्रश्न विचारू इच्छित असल्यास, आपण खालीलपैकी कोणत्याहीशी संपर्क साधू शकता:

- नाव: डॉ. उत्तरा उपेंद्र देशमुख (P&O)
  शीर्षक: प्रोस्थेटिक्स आणि ऑर्थोटिक्स विभाग
  संस्था: एमजीएम संस्थेचे विद्यापीठ

  या प्रस्तावाचे पुनरावलोकन केले गेले आहे आणि MGM इन्स्टिट्यूट ऑफ हेल्थ सायन्सेसच्या मानवी विषयांवर संशोधनासाठी ethics COMMITTEE द्वारे मंजूरी दिली आहे जी एक समिती आहे ज्याचे कार्य हे सुनिश्चित करणे आहे की संशोधन सहभागींना हानीपासून संरक्षित केले जाईल.
  तुम्हाला IRB बद्दल अधिक जाणून घ्यायचे असल्यास, प्रोस्थेटिक आणि ऑर्थोटिक एमजीएम हॉस्पिटलच्या विभागाशी संपर्क साधा.
  अभ्यासाचे प्रायोजक आणि समर्थन करणाऱ्या Aumeesh Tech Private Limited च्या व्यवस्थापनाने देखील याचे पुनरावलोकन केले आहे.

भाग II: संमतीप्रमाणपत्र

हा विभाग प्रथम व्यक्तीमध्ये लिहिला गेला पाहिजे आणि खाली ठळक अक्षरांसारखे विधान असावे. जर सहभागी निरक्षर असेल परंतु तोंडी संमती देत असेल तर साक्षीदाराने स्वाक्षरी करणे आवश्यक आहे. संशोधक किंवा सूचित संमतीवर जाणाऱ्या व्यक्तीने प्रत्येक संमतीवर स्वाक्षरी करणे आवश्यक आहे. संमती प्रमाणपत्राने "मला समजले आहे..."असलेली विधाने टाळली पाहिजेत.

वाक्ये माहिती पत्रकाच्या वाचनादरम्यान लक्ष्यित प्रश्नांद्वारे (काही प्रश्नांची उदाहरणे वर दिली आहेत) किंवा माहिती पत्रकाच्या वाचनाच्या शेवटी विचारल्या जाणाऱ्या प्रश्नांद्वारे समज अधिक चांगल्या प्रकारे तपासली जावी.

सहभागीचे नाव _____

सहभागीची स्वाक्षरी _____

तारीख _____

दिवस/महिना/वर्ष

अशिक्षित असल्यास
साक्षर साक्षीदाराने स्वाक्षरी करणे आवश्यक आहे (शक्य असल्यास, ही व्यक्ती सहभागीद्वारे निवडली जावी आणि संशोधन कार्यसंघाशी कोणताही संबंध नसावा). जे सहभागी अशिक्षित आहेत त्यांनी त्यांच्या अंगठ्याचा ठसा देखील समाविष्ट करावा.

मी संभाव्य सहभागीला संमती फॉर्मचे अचूक वाचन करताना पाहिले आहे आणि त्या व्यक्तीला प्रश्न विचारण्याची संधी मिळाली आहे. मी पुष्टी करतो की व्यक्तीने मुक्तपणे संमती दिली आहे.

साक्षीचे नाव _____ आणिसहभागी व्यक्तीचा अंगठा

साक्षीदाराची स्वाक्षरी _____

तारीख _____

दिवस/महिना/वर्ष

संशोधक/संमती घेणाऱ्या व्यक्तीचे विधान

मी संभाव्य सहभागीला माहिती पत्रक अचूकपणे वाचून दाखवले आहे आणि माझ्या क्षमतेनुसार ICF मध्ये सूचीबद्ध केलेल्या प्रक्रिया पूर्ण केल्या जातील हे सहभागीला समजेल याची खात्री केली आहे. मी पुष्टी करतो की सहभागीला अभ्यासाविषयी प्रश्न विचारण्याची संधी देण्यात आली होती आणि सहभागीने विचारलेल्या सर्व प्रश्नांची उत्तरे माझ्या क्षमतेनुसार अचूक आणि सर्वोत्तम दिली गेली आहेत. मी पुष्टी करतो की संमती देण्यासाठी व्यक्तीवर जबरदस्ती केली गेली नाही आणि संमती मुक्तपणे आणि स्वेच्छेने दिली गेली आहे.

या ICF ची एक प्रत सहभागींना प्रदान करण्यात आली आहे.

संशोधक/संमती घेणाऱ्या व्यक्तीचे नाव _____

संशोधक/संमती घेणाऱ्या व्यक्तीची स्वाक्षरी _____

तारीख _____

दिवस/महिना/वर्ष

Annexure E

Product Evaluation and Effectiveness Questionnaire in English and Hindi

Product Name: Date:

Patient No.: Study No.:

A. Usefulness/उपयोगिता

1.How useful is your current Orthotic Brace (Drop-lock/ MASC-KAFO)? in day to day life?

1. दिन-प्रदिदिनकेजीवनमेंआपकेवितमानऑर्थोदिकब्रेस (ड्रॉप-लॉक / एमएएससी-केएफओ) दकिनाउपयोगीहै?

0	1	2	3	4	5	6	7	8	9	10

Not Useful उपयोगीनहींबहुिउपयोगी Very Useful

2. How easy was Squatting /to use Indian Toilet using your Current Orthotic Brace (Drop-lock/ MASC-KAFO)?

2. अपनेवितमानऑर्थोदिकब्रेस (ड्रॉप-लॉक / एमएएससी-केएएफओ) काउपयोगकरकेभारीयशौचालयकाउपयोगकरनेकेदलएस्क्वैदिंग / दकिनाआसानर्था?

0	1	2	3	4	5	6	7	8	9	10

Very Difficult बहुिमुश्किलबहुिआसानVery Easy

3. How comfortable is the use of your Current Orthotic Brace (Drop-lock/ MASC-KAFO)?

3.आपकेवितमानऑर्थोदिकब्रेस (ड्रॉप-लॉक / एमएएससी-केएएफओ) कउपयोगदकिनाआरामियकहै?

0	1	2	3	4	5	6	7	8	9	10

Not Comfortable आरामियकनहींबहुिआरामियक Very Comfortable

4. How often were your bothered when your Clothes got torn using a Drop-Lock Caliper?

4. दकिनीबारअपनेपरेशानर्थेजबअपनेकपडेएकड्रॉपलॉककैदलपरकाउपयोगकरफिगया?

0	1	2	3	4	5	6	7	8	9	10

All the time हरसमयकभीनही ever

5. How was your ability to footwear affected when using your Current Orthotic Brace (Drop-lock/ MASC-KAFO)?

5 आपके वर्तमान ऑर्थोटिक ब्रेस (ड्रॉप-लॉक/एमएएससी-केएएफओ) का उपयोग करते समय जूते पहनने की

आपकी क्षमता कैसे प्रभावित हुई?

0	1	2	3	4	5	6	7	8	9	10

Very Difficult बहुिमुश्किलबहुिआसानVery Easy

A. Sensations/संवेदनाएँ

1.Did the MASC- KAFO fit easily? If no describe the issue, if yes rate the comfort level?

_____

1.क्याMASC- KAFO आसानीसेदफिर्था? यदिनहींइसमुद्देकावर्तनकरें, अगरहाँआरामकेस्तरिर?

_____ Yes No _____

हाँ नहीं__

0	1	2	3	4	5	6	7	8	9	10

Not Comfortable आरामिायकनहींबहुिआरामिायक Very Comfortable

1.Rate your experience for the following when using the MASC-KAFO,

1.MASC-KAFO काउपयोगकरिसमयदनम्नकेदलएअपनेअनुभवकोरेिकरें,

a)Pain in the Lower Limb on which the Orthotic Brace is fitted

a) दनचलेअींगमेंिितदजसपरऑर्थोदिकब्रेसदफिदकयाजाि ाहै

0	1	2	3	4	5	6	7	8	9	10

Very Painful बहुिि ितनाककोईिितनहीं No Pain

b) Swelling in the Lower Limb on which the Orthotic Brace is fitted

b) दनचलेअींगमेंसूजनदजसपरऑर्थोदिकब्रेसदफिदकयाजाि ाहै

0	1	2	3	4	5	6	7	8	9	10

Heavy Swelling भारीसूजनकोईसूजननहीींNo Swelling

c) Rashes/Blisters in the Lower Limb on which the Orthotic Brace is fitted

c)दनचलेअींगमेंसूजनदजसपरऑर्थोदिकब्रेसदफिदकयाजाि ाहै

0	1	2	3	4	5	6	7	8	9	10

Heavy Rash भारीि ानेकोई़ीनेनहीींNo Rash

2. Rate how much effort was required to operate the MASC-KAFO?

3. ि रदकिनाप्रयासMASC-KAFO सींचादलिकरनेकेदलएआवश्यकर्था?

0	1	2	3	4	5	6	7	8	9	10

Very Difficult बहुि मुश्किल बहुि आसान Very Easy

C. Dexterity/ गनपुणता

1.Rate your ability to Walk using the MASC-KAFO?

1. MASC-KAFO काउपयोगकरचलनेकीअपनीक्षमाि र?

0	1	2	3	4	5	6	7	8	9	10

Very Difficult बहुि मुश्किल बहुि आसान Very Easy

2. Rate How useful you found the automated locking and Unlocking of MASC-KAFO when you used it?

2. ि रकैसेउपयोगीआपस्वचादलिि ालाऔरMASC-KAFO
केअनलॉदकींगपायाजबआपइसेइस्तेमालदकया?

0	1	2	3	4	5	6	7	8	9	10

Not Useful उपयोगीनहीींबहुि उपयोगीVery Useful

3. The distance of walking did it increase while using MASC-KAFO?

3.चलनेकीिूरी, यहMASC-KAFO काउपयोगकरिसमयवृश्किहुई?

0	1	2	3	4	5	6	7	8	9	10

Increased बढीहुई कमीहुईDecreased

D. Daily Activities /दैगनकिगतगवगियाँ

1.How regular was the occurrence of slipping and fall while performing day to day activities with MASC-KAFO?

1. कैसेदनयदमिरूपसेदफसलनेऔरदगरनेकीघिनार्थी, जबदकMASC-KAFO केसार्थदिन-प्रदिदिनकीगदिदवदियोंकाप्रिशतन?

0	1	2	3	4	5	6	7	8	9	10

All the time हरसमय कभीनहीं Never

2.No of instances when MASC-KAFO became loose or gave any issue while performing day to day activities?

2. ठिहरर्ोींकीकोईजबMASC-KAFO ढीलाहोगयायादिन-प्रदिदिनकीगदिदवदियोंकाप्रिशतनकरिसमयकोईमुद्दादिया?

0	1	2	3	4	5	6	7	8	9	10

All the time हरसमय कभीनह Never

E. Important aspects of MASC-KAFO /MASC-KAFO केमहत्वपूणणपहलू

1.How comfortable are you to balance with the weight of the MASC-KAFO?

1.आपMASC-KAFO केवजनकेसार्थसींिुलनकरनेकेदलएदकिनेआरामियकहैं?

0	1	2	3	4	5	6	7	8	9	10

Not Comfortable आरामियकनहींबहुिआरामियक 'ery Com

2. How useful is the look of Orthotic Brace to you?

2.आपकेदलएऑर्थोदिकब्रेसकारूपदकिनाउपयोगीहै?

0	1	2	3	4	5	6	7	8	9	10

Not Useful उपयोगीनहीीं बहुिउपयोगी Very Useful

3.Satisfied with the training provided to use \

3. उपयोगकरनेकेदलएप्रिानदकएगएप्रदशक्षसेसींिुष्ट?

0	1	2	3	4	5	6	7	9	10

Extremely Satisfied अत्यींिसींिुष्टExtremely dissatisfied अत्यींिअसींिुष्ट

4. Rate if you are satisfied with the weight of the Device

4.ियदिआपदड्वाइसकेवजनसेसींिुष्टहैं

0	1	2	3	4	5	6	7	8	9	10

Extremely Satisfied अत्यींिसींिुष्टExtremely dissatisfied अत्यींिअसींिुष्ट

Annexure F

Product Evaluation and Effectiveness Questionnaire in Marathi

उत्पादन मूल्यमापन आणि परिणामकारकता प्रश्नावली

उत्पादनाचे नाव: तारीख:

रुग्ण क्रमांक: माग क्रमांक:

A. उपयुक्तता

1. तुमचा सध्याचा ऑर्थोटिक ब्रेस (ड्रॉप-लॉक/ MASC-KAFO) दैनंदिन जीवनात किती उपयुक्त आहे?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

उपयुक्त नाही खूप उपयुक्त

2. तुमचे सध्याचे ऑर्थोटिक ब्रेस (ड्रॉप-लॉक/ MASC-KAFO) वापरून स्क्वॅटिंग/भारतीय शौचालय वापरणे किती सोपे होते?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

खूप अवघड खूप सोपे

3. तुमचा सध्याचा ऑर्थोटिक ब्रेस (ड्रॉप-लॉक/ MASC-KAFO) वापरणे कितपत आरामदायक आहे?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

आरामदायक नाही खूप आरामदायक

4. ड्रॉप-लॉक कॅलिपर वापरून तुमचे कपडे फाटले तेव्हा तुम्हाला किती वेळा त्रास झाला?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

सर्व वेळ कधीही नाही

5. तुमचा सध्याचा ऑर्थोटिक ब्रेस (ड्रॉप-लॉक/ MASC-KAFO) वापरताना तुमच्या पादत्राणांच्या क्षमतेवर कसा परिणाम झाला?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

खूप अवघड खूप सोपे

B. संवेदना

1. MASC- KAFO सहज बसते का? जर नाही तर समस्येचे वर्णन करा, होय तर कम्फर्ट लेव्हल रेट करा?

_____

होय नाही _____

0	1	2	3	4	5	6	7	8	9	10

आरामदायक नाही खूप आरामदायक

2. MASC-KAFO वापरताना तुमच्या अनुभवाला खालील गोष्टींसाठी रेट करा,

अ) खालच्या अंगात वेदना ज्यावर ऑर्थोटिक ब्रेस बसवले आहे

0	1	2	3	4	5	6	7	8	9	10

खूप वेदनादायक नाही वेदना

b) खालच्या अंगाला सूज येणे ज्यावर ऑर्थोटिक ब्रेस बसवले आहे

0	1	2	3	4	5	6	7	8	9	10

जड सूज नाही सूज

c) खालच्या अंगात पुरळ/फोडे ज्यावर ऑर्थोटिक ब्रेस बसवले आहे

0	1	2	3	4	5	6	7	8	9	10

जड पुरळ नाही पुरळ

3. MASC-KAFO चालवण्यासाठी किती प्रयत्न करावे लागले ते रेट करा?

0	1	2	3	4	5	6	7	8	9	10

खूप अवघड खूप सोपे

C. निपुणता

1. MASC-KAFO वापरून चालण्याची तुमची क्षमता रेट करा?

0	1	2	3	4	5	6	7	8	9	10

खूप अवघड खूप सोपे

2. MASC-KAFO चा वापर करताना तुम्हाला स्वयंचलित लॉकिंग आणि अनलॉकिंग किती उपयुक्त वाटले?

0	1	2	3	4	5	6	7	8	9	10

उपयुक्त नाही खूप उपयुक्त

3. MASC-KAFO वापरताना चालण्याचे अंतर वाढले का?

0	1	2	3	4	5	6	7	8	9	10

वाढलेली घट

D. दैनंदिन उपक्रम

1. MASC-KAFO सह दैनंदिन क्रियाकलाप करत असताना घसरणे आणि पडणे किती नियमित होते?

0	1	2	3	4	5	6	7	8	9	10

सर्व वेळ कधीही नाही

2. दैनंदिन क्रियाकलाप करताना MASC-KAFO सैल झाल्याची किंवा कोणतीही समस्या आल्याची उदाहरणे नाहीत?

0	1	2	3	4	5	6	7	8	9	10

सर्व वेळ कधीही नाह

E. MASC-KAFO चे महत्त्वाचे पैलू

1. MASC-KAFO च्या वजनाशी समतोल राखणे तुम्हाला किती सोयीचे आहे?

0	1	2	3	4	5	6	7	8	9	10

आरामदायक नाही खूप आरामदायक

2. ऑर्थोटिक ब्रेसचा लुक तुमच्यासाठी किती उपयुक्त आहे?

0	1	2	3	4	5	6	7	8	9	10

उपयुक्त नाही खूप उपयुक्त

3. वापरण्यासाठी दिलेल्या प्रशिक्षणाबाबत समाधानी आहात?

0	1	2	3	4	5	6	7	8	9	10

अत्यंत असंतुष्ट अत्यंत समाधानी

4. तुम्ही डिव्हाइसच्या वजनावर समाधानी असल्यास रेट करा

0	1	2	3	4	5	6	7	8	9	10

अत्यंत असंतुष्ट अत्यंत समाधानी

Annexure G

Copy of safety Report: Mechanical Load testing

GLOBAL LAB
A World of Quality Material Testing

Format No: 01 / 09 Rev. No.- 01

TEST REPORT

TEST REPORT ISSUED BY : LOCATION-01: VASAI LAB (TEST)	: SAMPLE TESTED BY / AT :LOCATION-01: VASAI LAB (TEST)
TEST REPORT NO.	: VST-17539-TR-450760
TEST REPORT DATE	: 28/12/2021
NAME OF CUSTOMER :	PROJECT / SITE ADDRESS :
M/s. Aummesh Tech Pvt Ltd., Gala No. 01, Hanuman Road, Opp IIT Market gate, Pawai. Mumbai	Aummesh Tech Pvt Ltd., Gala No. 01, Hanuman Road, Opp IIT Market gate, Pawai. Mumbai
CUSTOMER REF.NO & DATE	: Letter Dated : 27/12/2021
QUANTITY	: 01 No.
DATE OF RECEIPT	: 27/12/2021
SOURCE OF SAMPLE	: MASC KAFO (ATPL/21/02)
CONDITION OF SAMPLE ON RECIEPT	: Satisfactory
TEST METHOD	: Custom Method

LOAD TEST REPORT OF MASC KAFO (ATPL/21/02)

TEST AT TEMP. (°C)	: 28.6
DESCRIPTION	: Mechanical Actuated Stance Control Knee Ankle Foot Orthosis (M.A.S.C. K.A.F.O)
DATE OF TESTING	: 27/12/2021

Sr. No.	Particulars	Specimen-01
1	ID MARK	NA
2	ULTIMATE LOAD, kg	197.60
3	LATERAL DISPLACEMENT @ ULTIMATE LOAD, mm	18.93

NOTE:

-- Sample/s was/were not drawn by laboratory.
-- The Reported result/s is/are valid only to the sample submitted to the laboratory.
-- No part of the report, except in full, shall be reproduced without written consent of the laboratory.
-- The report is valid only when Global Lab hologram is available on the report.

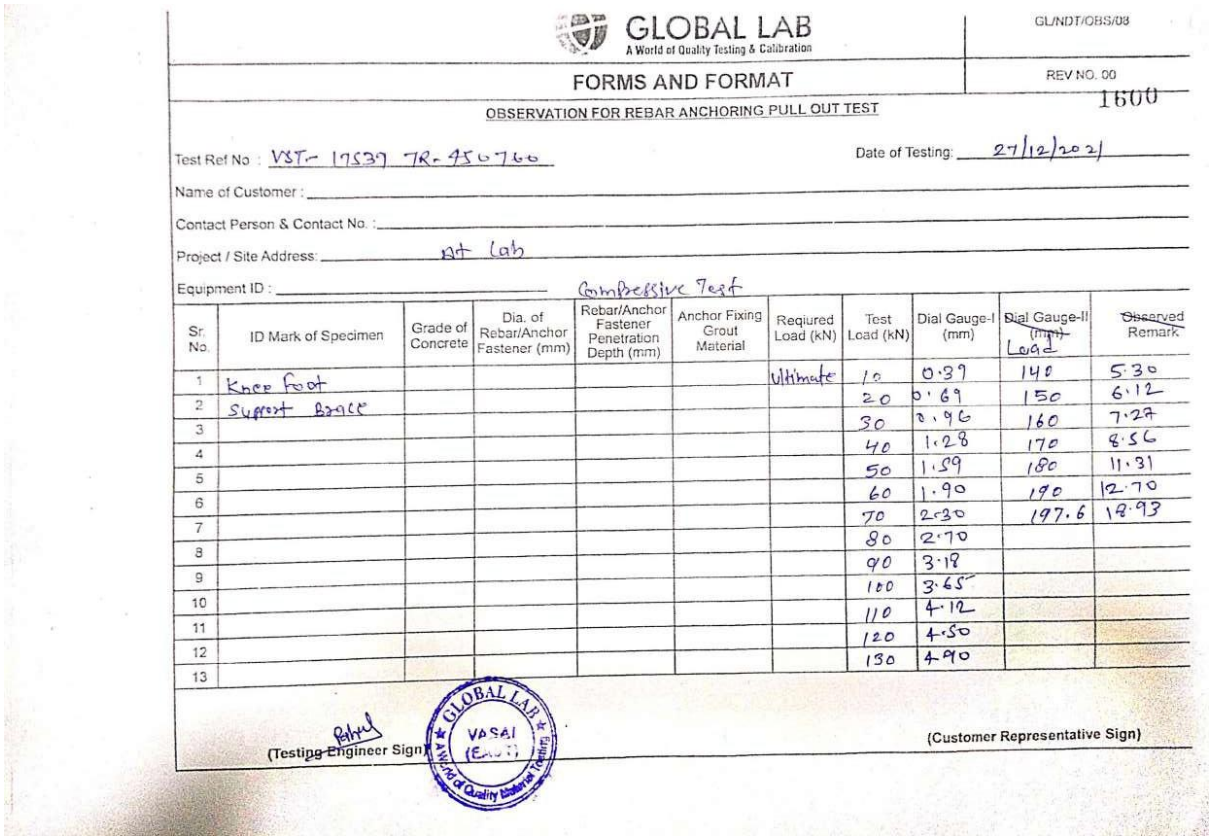
**********End of Report**********

(Authorised Signatory)

GLOBAL LAB VASAI (EAST) A World of Quality Material Testing

Page 1 of 1

Central Lab (Location-01) : Unit No. 31 & 32, Sethia Industrial Park, Opp. Sayali Petrol Pump, Sativali, Off NH No. 8, Vasai (E), Palghar - 401 208. Tel :9323712211
Regional Lab (Location-02) : 29 & 30, Krishi Industrial Estate, TTC Industrial Area, Turbhe, Navi Mumbai - 400 613. Tel : 022-6060 0679
Branch Lab : Borivali (W), Mumbai - 400 092 Tel : 022-2864 5431 | Kurla (W), Mumbai - 400 070 Tel : 022-6448 1925
Email : globalconcretesolution@gmail.com | Website : www.globallab.co.in | Customer Care : +91 9930280649 / 9167794009



GLOBAL LAB
A World of Quality Testing & Calibration

GL/NDT/OBS/08

FORMS AND FORMAT

REV NO. 00

OBSERVATION FOR REBAR ANCHORING PULL OUT TEST

1600

Test Ref No : VST- 17539 TR-450760

Date of Testing: 27/12/2021

Name of Customer :

Contact Person & Contact No. :

Project / Site Address: At lab

Equipment ID : Compressive Test

Sr. No.	ID Mark of Specimen	Grade of Concrete	Dia. of Rebar/Anchor Fastener (mm)	Rebar/Anchor Fastener Penetration Depth (mm)	Anchor Fixing Grout Material	Reqiured Load (kN)	Test Load (kN)	Dial Gauge-I (mm)	Dial Gauge-II (mm) Load	~~Observed~~ Remark
1	Knee foot					Ultimate	10	0.39	140	5.30
2	Support Brace						20	0.69	150	6.12
3							30	0.96	160	7.27
4							40	1.28	170	8.56
5							50	1.59	180	11.31
6							60	1.90	190	12.70
7							70	2.30	197.6	12.93
8							80	2.70		
9							90	3.18		
10							100	3.65		
11							110	4.12		
12							120	4.50		
13							130	4.90		

(Testing Engineer Sign)

GLOBAL LAB VASAI (E.) A World of Quality Testing

(Customer Representative Sign)

GLOBAL LAB
A World of Quality Material Testing

Format No: 01 / 09 Rev. No.- 01

TEST REPORT

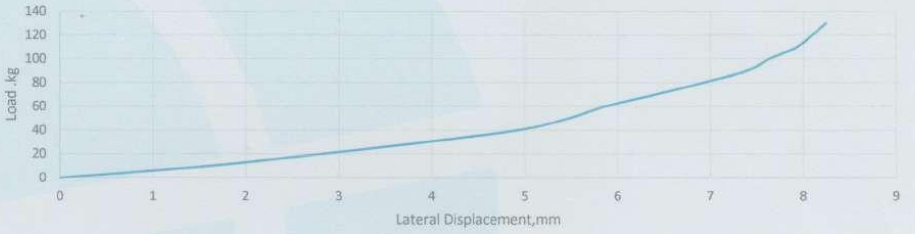
TEST REPORT ISSUED BY : LOCATION-01: VASAI LAB (TEST)	**: SAMPLE TESTED BY / AT :LOCATION-01: VASAI LAB (TEST)**
TEST REPORT NO.	: VST-17539-TR-450759
TEST REPORT DATE	: 28/12/2021
NAME OF CUSTOMER :	**PROJECT / SITE ADDRESS :**
M/s. Aummesh Tech Pvt Ltd., Gala No. 01, Hanuman Road, Opp IIT Market gate, Pawai. Mumbai	Aummesh Tech Pvt Ltd., Gala No. 01, Hanuman Road, Opp IIT Market gate, Pawai. Mumbai
CUSTOMER REF.NO & DATE	: Letter Dated : 27/12/2021
QUANTITY	: 01 No.
DATE OF RECEIPT	: 27/12/2021
SOURCE OF SAMPLE	: MASC KAFO (ATPL/21/02)
CONDITION OF SAMPLE ON RECIEPT	: Satisfactory
TEST METHOD	: Custom Method

LOAD TEST REPORT OF MASC KAFO (ATPL/21/02)

TEST AT TEMP. (°C)	: 28.6
DESCRIPTION	: Mechanical Actuated Stance Control Knee Ankle Foot Orthosis (M.A.S.C. K.A.F.O)
DATE OF TESTING	: 27/12/2021

Sr. No.	Particulars	Specimen-01
1	ID MARK	NA
2	LOAD REQUIRMENT GIVEN BY CUSTOMER, kg	120
3	LOAD APPLIED, kg	127
4	DISPLACEMENT @ APPPLIED LOAD, mm	8.24

Graph : Load V/S Displacement



NOTE:

-- Sample/s was/were not drawn by laboratory.
-- The Reported result/s is/are valid only to the sample submitted to the laboratory.
-- No part of the report, except in full, shall be reproduced without written consent of the laboratory.
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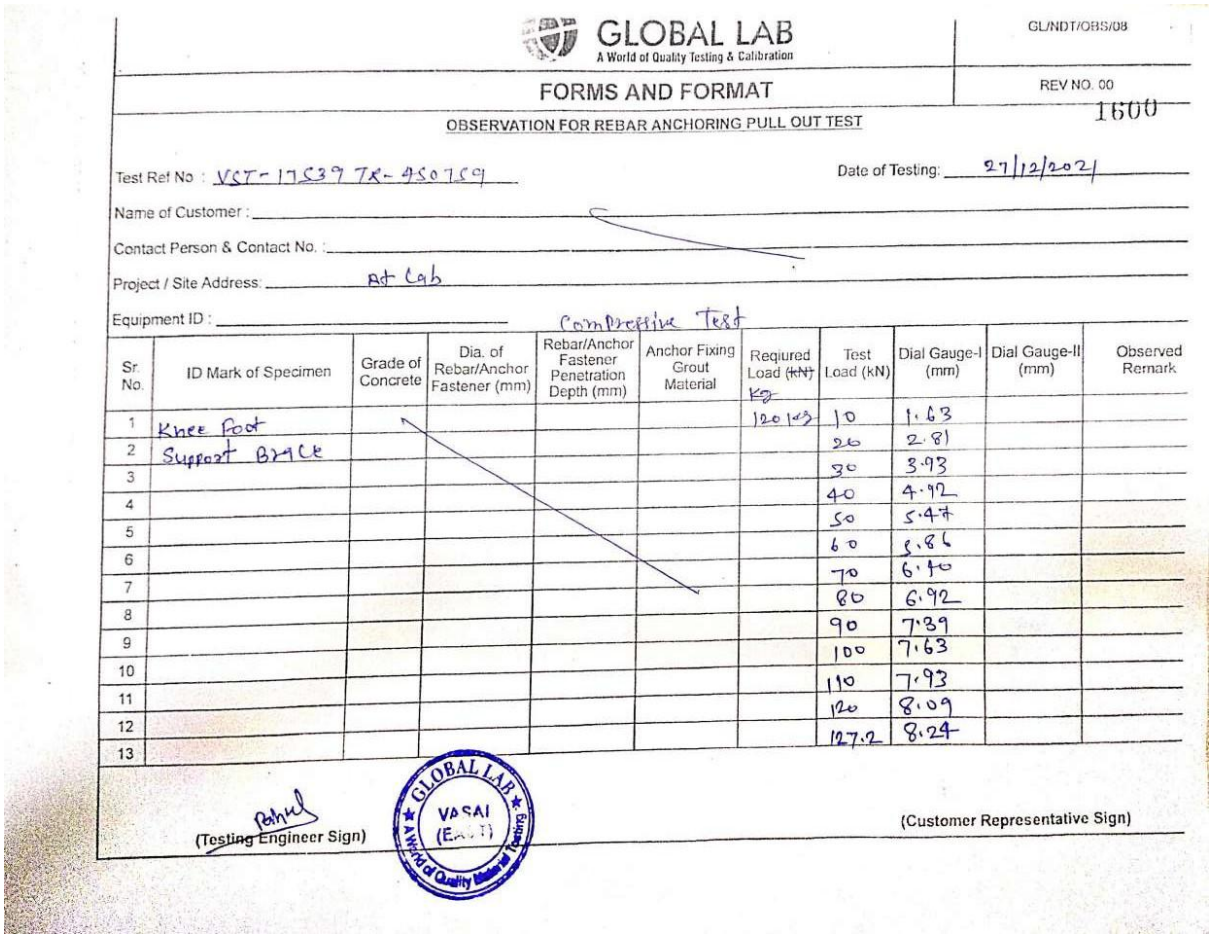
**********End of Report**********

GLOBAL LAB VASAI (EAST) A World of Quality Material Testing

(Authorised Signatory)

Page 1 of 1

Central Lab (Location-01) : Unit No. 31 & 32, Sethia Industrial Park, Opp. Sayali Petrol Pump, Sativali, Off NH No. 8, Vasai (E), Palghar - 401 208. Tel :9323712211
Regional Lab (Location-02) : 29 & 30, Krishi Industrial Estate, TTC Industrial Area, Turbhe, Navi Mumbai - 400 613. Tel : 022-6060 0679
Branch Lab : Borivali (W), Mumbai - 400 092 Tel : 022-2864 5431 | Kurla (W), Mumbai - 400 070 Tel : 022-6448 1925
Email : globalconcretesolution@gmail.com | Website : www.globallab.co.in | Customer Care : +91 9930280649 / 9167794009



GLOBAL LAB
A World of Quality Testing & Calibration

GL/NDT/ORS/08

FORMS AND FORMAT

REV NO. 00

OBSERVATION FOR REBAR ANCHORING PULL OUT TEST

1600

Test Ref No : VST-17539 TR-450759

Date of Testing: 27/12/2021

Name of Customer :

Contact Person & Contact No. :

Project / Site Address: At Lab

Equipment ID : Compressive Test

Sr. No.	ID Mark of Specimen	Grade of Concrete	Dia. of Rebar/Anchor Fastener (mm)	Rebar/Anchor Fastener Penetration Depth (mm)	Anchor Fixing Grout Material	Required Load ~~(kN)~~ Kg	Test Load (kN)	Dial Gauge-I (mm)	Dial Gauge-II (mm)	Observed Remark
1	Knee Foot					120	10	1.63		
2	Support BYCE						20	2.81		
3							30	3.93		
4							40	4.92		
5							50	5.47		
6							60	5.86		
7							70	6.40		
8							80	6.92		
9							90	7.39		
10							100	7.63		
11							110	7.93		
12							120	8.09		
13							127.2	8.24		

(Testing Engineer Sign)

GLOBAL LAB VASAI (E...T) A World of Quality Material Testing

(Customer Representative Sign)

Annexure H

Copy of Safety Analysis: Ansys Report

FEA and Simulation - MASCKAFO

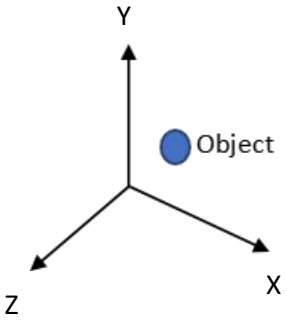
Report

Aumeesh Tech Pvt. Ltd.

1. Finite Elements Analysis for Mechanical Actuated Stance Control Knee Ankle Foot Orthosis (M.A.S.C K.A.F.O)

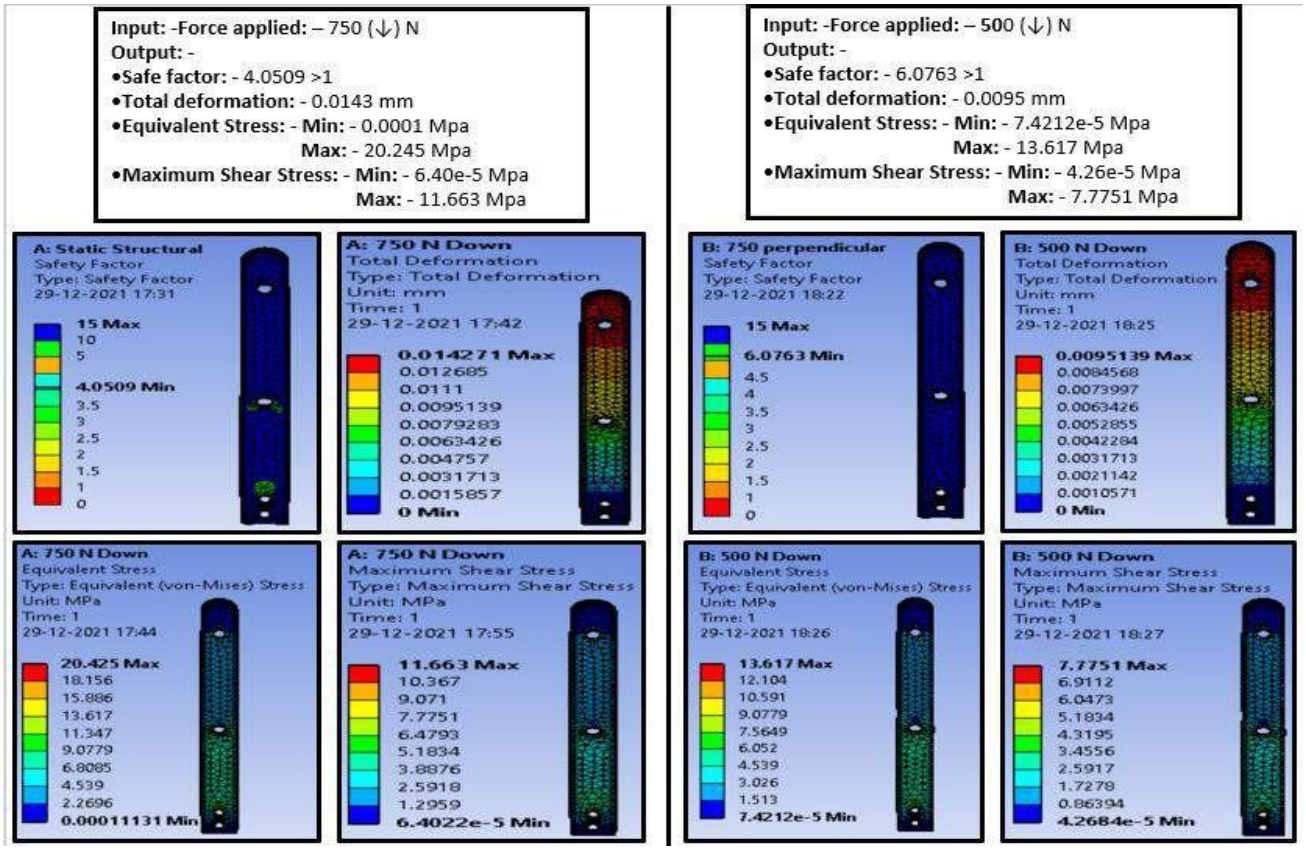
Thestress analysis ofindividualparts is doneinthisreport.
The assembly contains Mechanism base plate, ratchet, pawl, Connecting Rod 1 and connecting rod 2.Thefinite elementanalysis isdoneusing AnsysSimulationV 19.0.
Thematerialusedforrespectiveare:

Sr.no	Parts	Material
1.	Mechanismbaseplate	Stainless Steel 410 (UNS S41000)
2.	Ratchet	Stainless Steel 410 (UNS S41000)
3.	pawl	Stainless Steel 410 (UNS S41000)
4.	Connecting Bar1	Aluminium Alloy (7075 SS Plate) or(6000Series)
5.	Connecting Bar2	Aluminium Alloy (7075 SS Plate) or(6000Series)



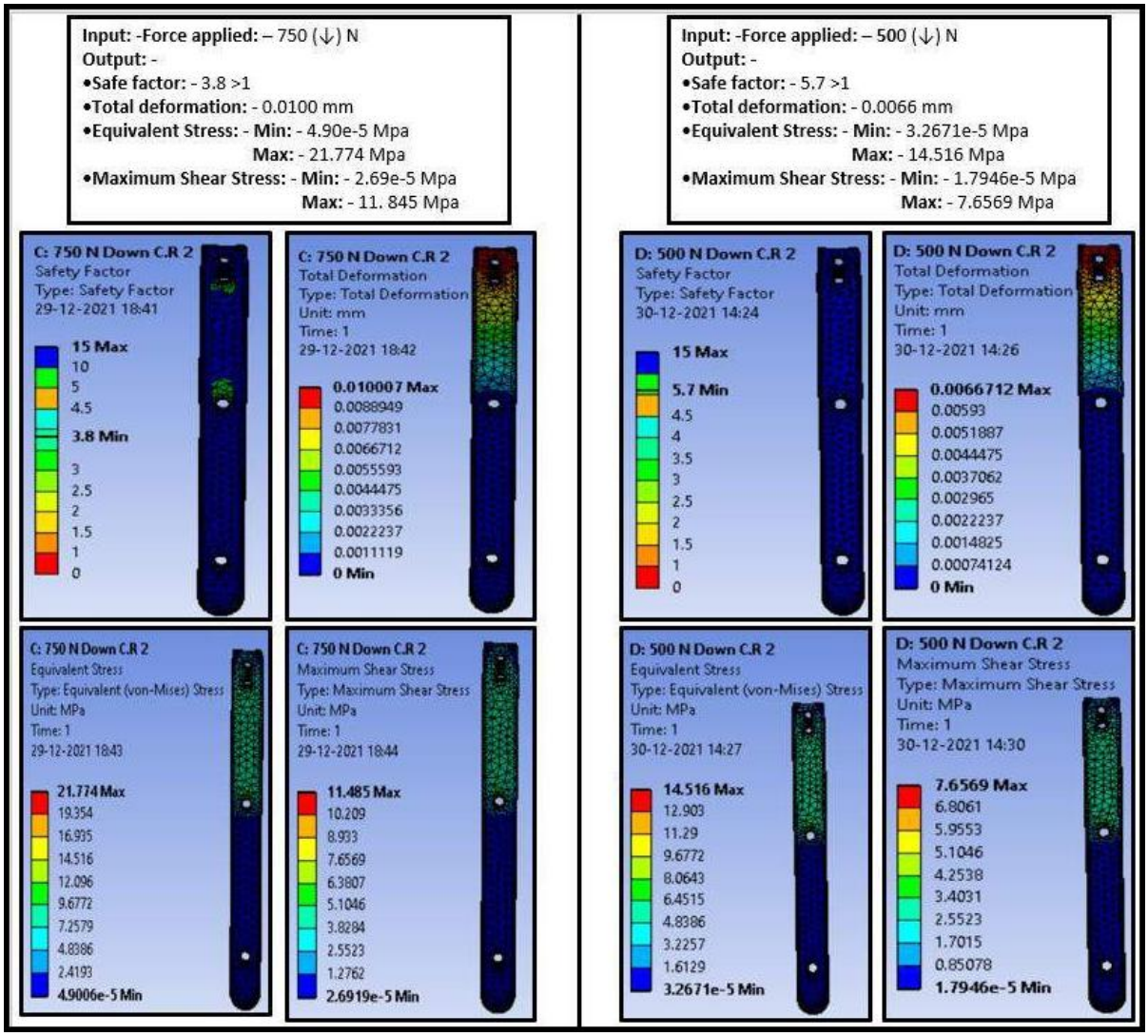
2. CONNECTING ROD 1 (Connecting from thigh brace to ratchet): -

- The CONNECTING ROD 1 connects from the Thigh Brace at the Top of the K.A.F.O to the Ratchet. The Connecting rod connects with the thigh brace and ratchet with a Rivets joint. The Rivets hole diameter is6mm.
- For the analysis the cylindrical surface is considered as the fixed support at Bottom which is the condition of maximum loading. Applying 1000N force at the bottom of the Hole. (Considering 100 kg to be patients' mass,and we are taking impact load = 150kg= 1500 N. This 1500N force is distributed in 2 sides hence force on one of the rods is 750N). For analysis I fix the Bottom two Hole (Difference Between Two Hole 11mm) and apply Load(Force)in negative Y axis.
- After Analyzing the part, we got Safe factor up to 4.0509 for 750N (Impact Load) and 6.0763 N (Normal Load)which is greater than2that makes the Design Safe.



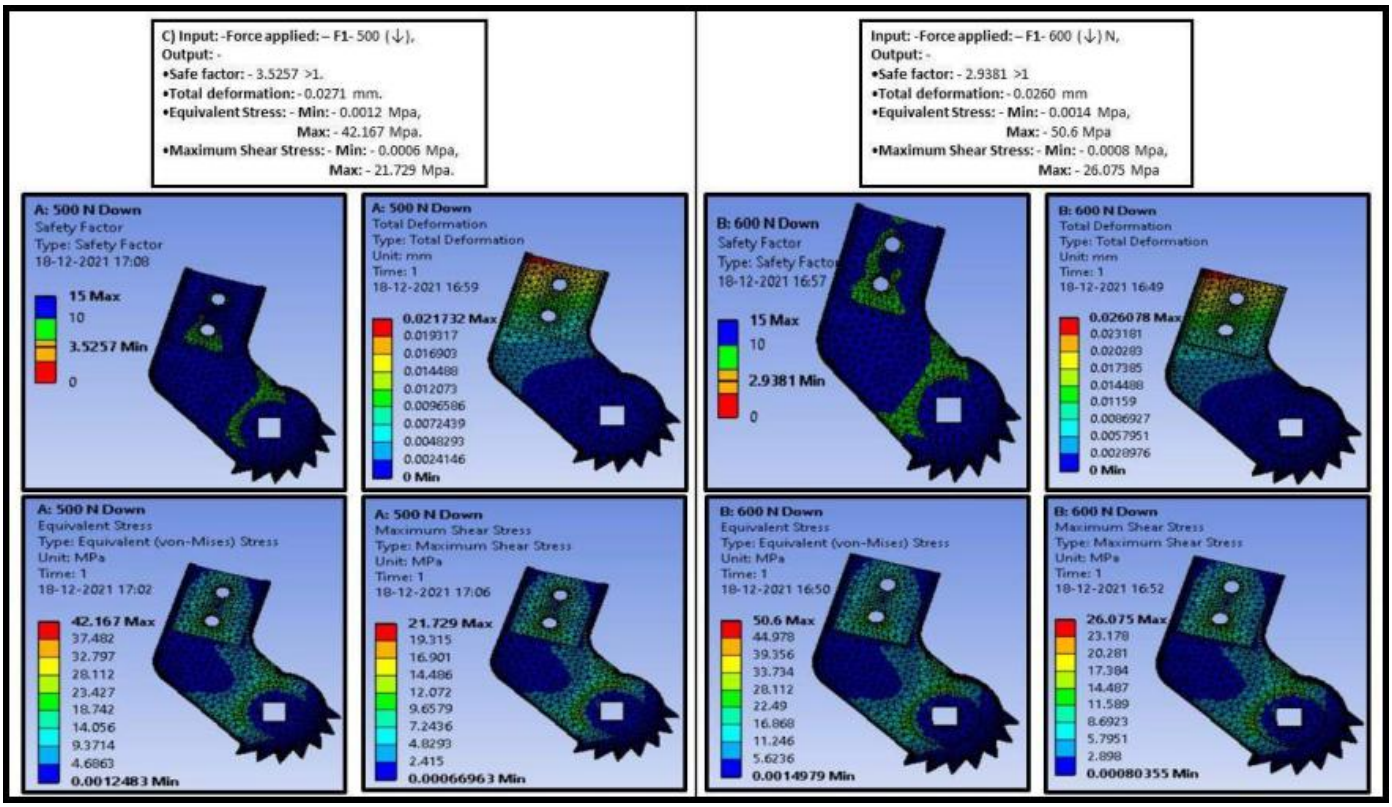
3. CONNECTING ROD 2 (Connecting mechanism base plates to shank brace):

- The CONNECTING ROD 2 connects from the Mechanism base plate at the Top of the KAFO to the Shank Brace(Lower). The Connecting rod connects with the Both mechanism base plates and with a Rivets joint. The Rivet's diameter is 6mm.
- For the analysis the cylindrical surface is considered as the fixed support at Bottom which is the condition of maximum loading. Applying 1000N force at the bottom of the Hole. (Considering 100 kg to be patients' mass,and we are taking impact load = 150kg= 1500 N. This 1500N force is distributed in 2 sides hence force on oneoftherodsis750N).
- After Analyzing the part, we got Safe factor up to 3.8 for 750 N (Impact Load) and 5.7 N (Normal Load) for500N which is greater than 2thatmakesthe Design safe.



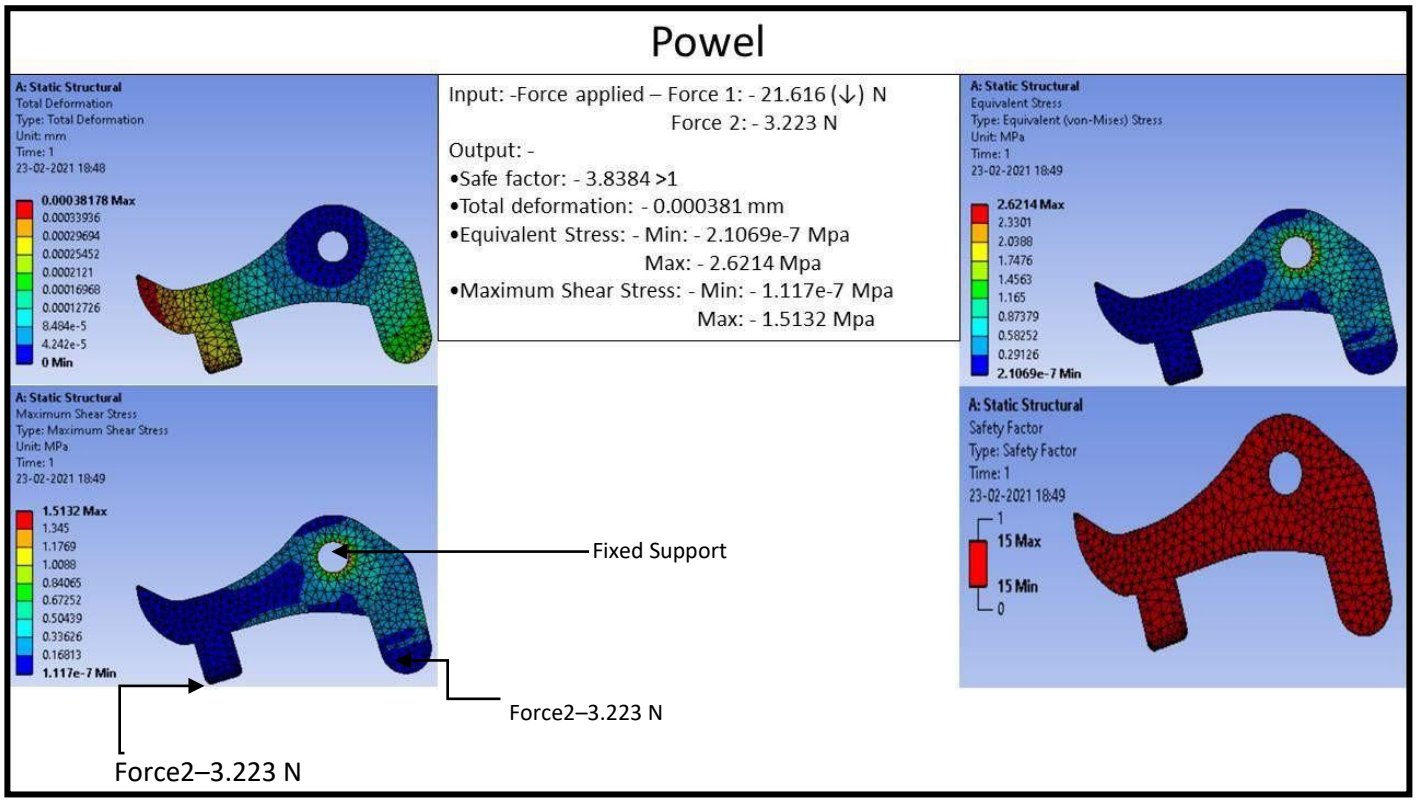
4. Ratchet: -

- The Connecting rod 1 connects from the Thigh Brace at the Top of the KAFO to the Ratchet at bottom with the help of a Rivet joint.The Rivet's diameter is 6mm.
- For the analysis, we consider to fix Bottom hole of Ratchet Diameter 10 mm. The force applied on top on two Hole of the ratchet with 600N force and500N on negative Y axis.
- After Analyzing the part, we Got Safe factor up to 3.5257 for impact Load and 2.9381for Normal load which both is great than1Safe factor that make our Design safe.
- In the given figure, we have calculated both Impact Load and Normal load.



5. Powel: -

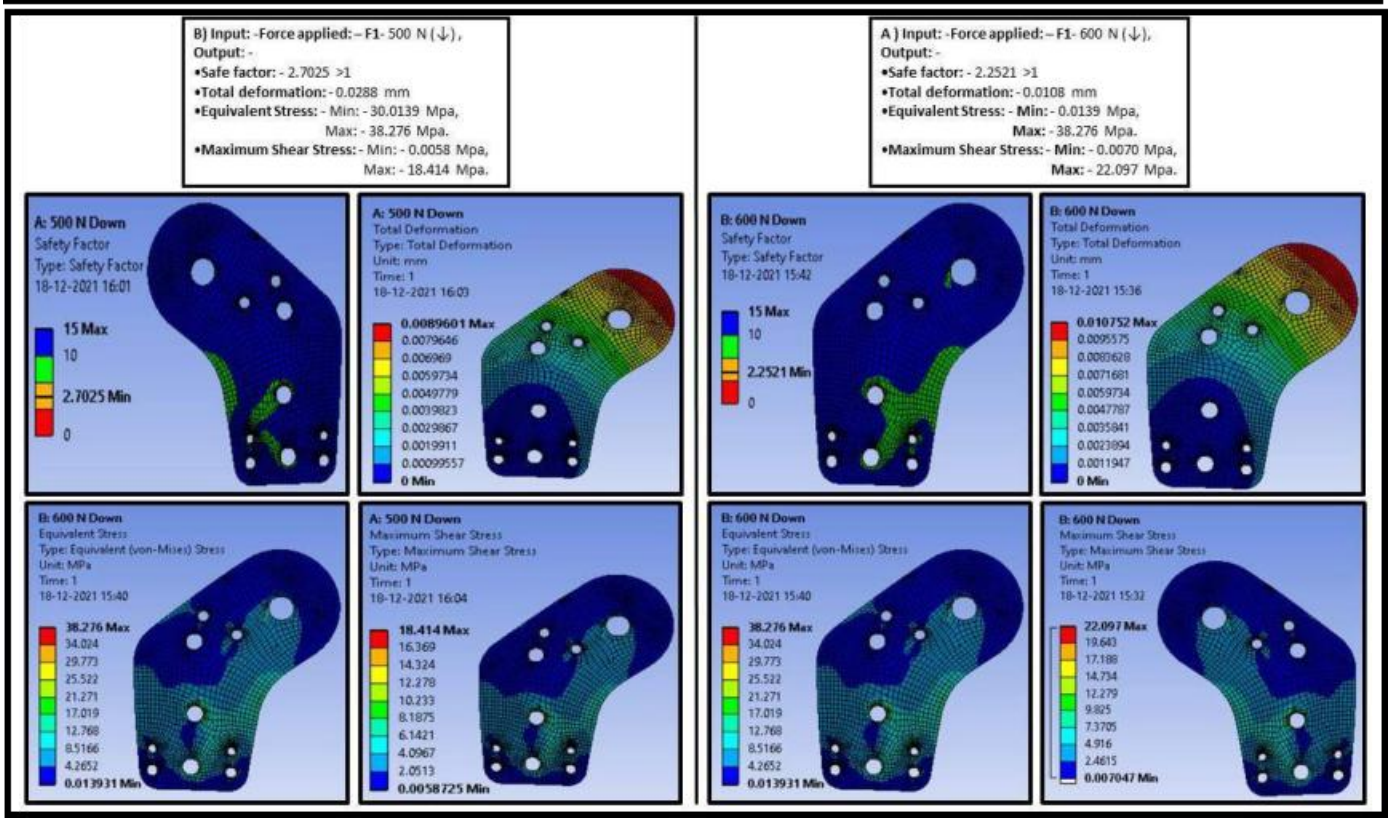
- The Tension Spring which is connects from the Mechanism base plate of the KAFO to the pawl one end hole and on other pawl the connecting Wire is Joint in the 2.2 mm Hole. Fixing the pawl in the Middle with the help of male and female screw and bolt (Coupling screw and Bolts)of6mm.
- For the analysis, we consider to Middle hole of pawl Diameter 6 mm as Fixed support and put maximum loading. The Middle Hole of the pawl is Fixed and Put a vice - versa Force either side of pawl. Putting force 1of 21.616 N with respect to Y axis and force 2 of 3.223 N on another side of pawl with respect to negative Y axis.
- After Analyzing the part,we GotSafefactorupto15whichis greaterthan1thatmakestheDesignsafe.



6. Mechanism base plate: -

- The mechanism base plate is connected with the ratchet on Top with the help of male and Female Screw and Bolt (Coupling Screw and Bolt) of M10 and connecting Rod 2 at the bottom with the help of Rivets, the rivets we are using the diameteris6mm.
- For the analysis, we consider to Fixed two hole of Mechanism base plate Diameter 6 mm at bottom and put maximum loading on top of the hole. The distance between the two hole is 20mm. Putting load on upper Putting a force of600N (Impact Load)and500 N(Normal load)on negative Y axis.
- After Analyzing the part, we Got Safe factor of 2.2521 For Impact Load and 2.7025 For Normal Load which isgreaterthan1thatmakeourDesignsafe.
- In the given figure, we have calculated both impact load and normal load.

MECHANISM BASE PLATE



7. Conclusion:

TheaboveFiniteElementAnalysis(FEA)andsimulationofthestrengthofthePrototype's designproves thatitis safefor use.

Annexure I

Copy of Patent Licensing agreement between IITB and Amumeesh Tech

PATENT LICENSE AGREEMENT

1. **THE AGREEMENT**

THIS AGREEMENT is made and entered into on **7th September 2020** (Effective Date)

BETWEEN

Indian Institute of Technology Bombay, an Indian autonomous organisation governed by Institutes of Technology Act, 1961, having its registered office at IIT Bombay, Powai, Mumbai 400076, Maharashtra, India, represented by Dean Research and Development and execute this Patent License Agreement (hereinafter called "LICENSOR") of the first part

AND

Aumeesh Tech Private Limited, a company incorporated under the Companies Act, 2013; having its registered office at, **Aumeesh Tech Private Limited**, F/16, Sri Krishna Housing Society, Sundarbaug, Kamani, Kurla, Mumbai, Maharashtra, India-400070, represented by Mr. Aneesh Karma, Founder & CEO of Aumeesh Tech Private Limited (hereinafter called "LICENSEE or ATPL") of the second part.

LICENSOR and LICENSEE will hereinafter together be referred to as the **PARTIES.**

2. **PREAMBLE**

2.1 The LICENSOR, Indian Institute of Technology Bombay, Mumbai, is engaged in providing comprehensive undergraduate and graduate educational program and offering doctoral degrees in various areas of Science, Technology, Engineering including life sciences, social sciences, design and management.

2.2 The LICENSEE, Aumeesh Tech Private Limited is a Company incorporated in the state of Maharashtra having registration no. CIN U33100MH2019PTC328588 under the Companies Act 2013, engaged in manufacturing and trading in the field of Medical Devices and Healthcare.

WHEREAS

a. The LICENSOR has undertaken a project at Biomedical Engineering and Technology (Incubation) Center (BETiC), funded by Rajiv Gandhi Science and Technology Commission (RGSTC), Government of Maharashtra, for developing innovative and affordable medical devices and technologies. Under this project Prof. B. Ravi and his team, Mechanical Engineering Department has developed an Intellectual Property and the LICENSOR is in full possession of and has full

IITB	ATPL
	

intellectual property rights in respect of Patent Application No 201921005973 filed in India on 15th February 2019 titled 'A STANCE-CONTROLLED KNEE ANKLE FOOT ORTHOSIS' with the inventors as Aneesh Karma, Ex- Project Staff, BETiC, IIT Bombay; Rupesh Ghyar, Senior Executive Officer, BETiC, IIT Bombay; Bhallamudi Ravi, Professor, Department of Mechanical Engineering, PI BETiC.

b. Said Indian patent application is specified in "APPENDIX- A" attached hereto and hereinafter referred to as PATENT.

c. Whereas ATPL is formed by ex-BETiC-IIT Bombay researcher Mr Aneesh Karma incubated at SINE, IIT Bombay, and is desirous of developing, manufacturing and commercializing the PATENT. In this regard ATPL has approached IITB with a request for a license for the same vide their letter dated. 12th Aug 2020 (APPENDIX - B).

d. The ATPL desires to obtain license for PATENT (as specified in "APPENDIX-A") owned by LICENSOR to further develop, practice/use, commercialize, market and sell in accordance with terms and conditions of this agreement.

e. The LICENSOR has agreed to license said PATENT to the ATPL on terms and conditions mentioned herein below.

Now therefore in consideration of the premises and mutual covenants hereinafter contained, the PARTIES hereto agree as follows:

3. EFFECTIVE DATE AND DURATION

This Agreement shall become effective from the date of execution of the agreement. The Agreement shall be valid initially for a period of five (5) years from the Effective Date **7th September, 2020** and may be extended for the life of the PATENT if granted.

4. SCOPE OF AGREEMENT

This Agreement is the sole repository of the details, modalities and the terms and conditions for the grant of license by LICENSOR to LICENSEE for utilizing said PATENT, the rights and obligations of either party thereto and the financial arrangements between the parties.

5. LICENSING TERMS

5.1 License Grant

a. Subject to the limitations set forth in this Agreement, LICENSOR hereby grant to

IITB	ATPL

the LICENSEE an exclusive royalty-bearing license, to use said PATENT as specified in (APPENDIX-A) for worldwide commercial deployment including design, develop, manufacture, and/or sell products in the field of Medical Devices and Healthcare during the term of this agreement.

b. Reservation of Rights. Except as expressly granted under this Agreement, LICENSOR reserve for themselves all of their rights, title and interest in and to the PATENT owned by LICENSOR.

c. Notwithstanding anything said in this agreement
   i. LICENSOR will review the progress of LICENSEE towards commercialization (the progress in commercializing the PATENT shall be evaluated by the progress demonstrated by LICENSEE towards converting the patented technology into product or service offering(s) and efforts to mobilize resources and as reported in the annual and periodic reports) after expiration of 3 years from the date of agreement and if LICENSOR concludes that the LICENSEE has made insufficient progress in commercializing the patented technologies, product development or fund raising activities then LICENSOR shall retain the right of converting the exclusive license granted to LICENSEE to a non-exclusive License, and shall be free to license the PATENT to any third party.

   ii. Any sub-license of the PATENT by the LICENSEE to any third party for any purpose shall be based on prior express written consent of LICENSOR.

   iii. Notwithstanding the foregoing, LICENSOR reserves a non-transferable royalty-free right to use the PATENT in the Field of Use itself, including use by its faculty, staff and researchers, for educational, research and any non-profit purposes only.

5.2 Financial Arrangements

a. LICENSEE shall pay to LICENSOR an initial down payment of Rs.1,00,000/- (Rupees One Lakh only) plus applicable Goods and Service Tax (GST) within one twenty (120) days of signing of the agreement).

b. LICENSEE shall pay to LICENSOR a royalty of 1% of SALES generated from product based on PATENT, where SALES is defined as NET sales (total sale value minus sales returns, sales allowances, and sales discounts) and Government taxes and duties, if any during the term of this agreement. Royalty payment shall be made on or before 31st March each year.

c. Within 45 days after 31st March of every year, beginning immediately after the

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effective date, LICENSEE shall deliver to LICENSOR a true and accurate written report, even if no payments are due to LICENSOR, giving the particulars of the business conducted by LICENSEE or its sublicense(s) if any exist, during the preceding financial year under this Agreement. An audited statement of accounts will be submitted by LICENSEE every year regarding information about the sales of the PATENT.

d. That for the purpose of calculation of final royalty at the end of year, the statutory audited account of the LICENSEE shall be considered to be final and conclusive basis.

6. GENERAL LICENSING PROVISIONS

6.1 The details of "PATENT" licensed as part of the licensing agreement is set forth in APPENDIX- A.

6.2 The LICENSOR will complete the licensing procedures for PATENT as specified in APPENDIX- A respectively within 30 days from the Effective Date.

6.3 LICENSEE shall be free to continue research and development in same or similar area and if any Intellectual property filed after the effective date of this agreement shall be owned exclusively by the LICENSEE if inventors involved in developing said intellectual property do not have any contractual obligation to assign intellectual property rights to LICENSOR.

6.4 LICENSEE shall include LICENSOR as joint owners/ assignees/ applicants in intellectual property developed as a result of research and development in same or similar area and filed after the effective date of this agreement if, any of the inventors involved in developing said intellectual property have contractual obligation to assign intellectual property rights to LICENSOR.

6.5 The PATENT as specified in APPENDIX-A, if subsequently granted shall not be sold or assign without prior written consent from LICENSOR.

6.6 The date of Agreement will be the date on which this Agreement is signed and will be referred to in future as "EFFECTIVE DATE".

6.7 Provided further that LICENSEE shall seek the approval of LICENSOR to sub-license the PATENT as specified in APPENDIX-A to any third party including any subsidiary or affiliate companies of LICENSEE on such terms and conditions as may be agreed between LICENSEE and LICENSOR. The terms and conditions shall include the financial arrangement between the parties for the grant of sub-license and will be finalized by mutual consent of both LICENSEE and LICENSOR as and when required through a separate agreement and LICENSEE agrees to be responsible for the performance hereunder by its sublicenses.

6.8 Fulfillment of all procedural, legal, operational requirements for the demonstration of

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the process and commercial implementation of the PATENT shall be the sole responsibility of LICENSEE.

6.9 LICENSEE shall not, at any time, transfer, assign, mortgage, charge, or otherwise deal with possession or control of the license hereby granted.

6.10 LICENSEE shall not file or cause to be filed any application for seeking intellectual property rights in its own name or in the name of other person(s) on any matter relating to the information/ KNOWHOW disclosed to it by LICENSOR (as specified in APPENDIX-C) under this Agreement.

6.11 LICENSEE, being the commercial manufacturer of the PATENT, shall be responsible to carry out due diligence in ascertaining the right to practice the PATENT. LICENSOR shall under no circumstance be liable for PATENT infringement, third party claims or liabilities.

7. GENERAL PROVISIONS

7.1 This Agreement shall neither be construed by LICENSEE as a warranty by LICENSOR of the feasibility of the PATENT on commercial scale nor for the salability of the products made therein. LICENSEE shall be solely responsible for ensuring the economic viability of the project based on the PATENT and the marketability of the products manufactured therein.

7.2 This Agreement shall be the sole repository of the terms and conditions agreed to herein by and between LICENSOR and LICENSEE and no amendment thereof shall take effect and be binding on either of them except as provided for in clause 15 hereunder.

7.3 LICENSEE, its subsidiaries and sublicenses if any shall keep full, true and accurate books of accounts and other records containing all particulars which may be necessary for the purpose of ascertaining and verifying the royalties payable to LICENSOR by LICENSEE hereunder.

7.4 LICENSEE shall give LICENSOR, a prompt notice of any incident of infringement of PATENT Rights coming to its attention. The parties shall thereupon confer together as to what steps are to be taken to stop or prevent such infringement. LICENSOR agrees to use reasonable efforts to stop any such infringement, but shall not be obliged to commence proceedings against the infringer. If LICENSOR decides to commence proceedings however, LICENSOR shall be responsible for any legal costs incurred and will be entitled to retain any damages recovered. Should LICENSOR decide not to commence proceedings, LICENSEE shall be entitled to do so in its own name against the infringer, in which event LICENSEE shall be responsible for all legal costs incurred, without recourse to LICENSOR. In any action to enforce LICENSOR Patent Rights, either party, at the request and expense of the other party shall cooperate to the fullest extent reasonably possible. LICENSEE may not settle any

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infringement action in any way detrimental to LICENSOR Patent Rights without the expressed written consent of LICENSOR.

8. LIABILITIES & DAMAGES

LICENSEE shall indemnify, defend, and hold LICENSOR harmless from and against all damages, losses, and expenses (including legal fees) and liability of any kind whatsoever in connection with or arising out of the use of these PATENT by or on behalf of LICENSEE or third parties as stated in clause 7.1 above.

9. CONFIDENTIALITY

Both the parties undertake on their behalf and on behalf of their subcontractors /employees / representatives / associates to maintain the strict confidentiality and prevent disclosure thereof, of the information/data exchanged/generated pursuant to this Agreement for any purpose other than in accordance with this Agreement.

10. NO GUARANTEES IMPLIED

The scope of this Agreement is to provide LICENSEE, a license to the PATENT mentioned in APPENDIX -A. LICENSOR do not provide any guarantee express or implied regarding the performance of the PATENT or the merchantability or appropriateness of the process or products therein at a commercial scale.

11. FORCE MAJEURE

Neither party shall be held responsible for non-fulfillment of their respective obligations under this Agreement due to the exigency of one or more of the force majeure events such as but not limited to acts of God, War, Flood, Earthquakes, Strikes, Lockouts, Epidemics, Riots, Civil Commotions etc., provided on the occurrence and cessation of any such event the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continue beyond one month, the parties shall within one month of expiry of the period mentioned herein before jointly decide about the future course of action.

12. TERMINATION OF AGREEMENT

12.1 This Agreement may be terminated by either of the parties forthwith if the other party commits breach of any of the terms thereof and fails to rectify such breach within 30 days of the notice in this behalf having been served on it by the other party or it can also be terminated if both parties mutually agree. Failure of either party to terminate the Agreement on account of breach or default by the other shall not constitute a waiver of that party's right to terminate this Agreement.

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12.2 In addition to the reasons for termination as set forth above, this Agreement may be terminated forthwith if either of the parties voluntarily or involuntarily enters into bankruptcy proceedings or if applications invoking such proceedings have been filed or without any intimation to the other party, enters into any composition, amalgamation or similar re-organization.

12.3 In the event of termination as per the above clauses, the PATENT license given by LICENSOR to LICENSEE shall stand revoked.

13. NOTICES

Any notice provided for in this Agreement, shall be in the English language and shall be served by registered mail, postage prepaid and shall be therefore effective from the fifth day after the date of mailing.

Notices to LICENSOR shall be addressed to:
Attention:
Dean R&D
Indian Institute of Technology- Bombay,
Powai, Mumbai 400 076, Maharashtra, India

Notices to LICENSEE shall be addressed to:
Attention:
Director and Co-founder,
Aumeesh Tech Private Limited,
F/16, Sri Krishna Housing Society, Sundarbaug, Kamani, Kurla, Mumbai, 400070,
Maharashtra, India.

14. AMENDMENTS TO THE AGREEMENT

No amendment or modification of this Agreement shall be valid unless the same is made in writing by both the parties and specifically stating the same to be an amendment of this Agreement. The modifications/changes shall be effective from the date on which they are made/ executed unless otherwise agreed to.

15. ASSIGNMENT OF THE AGREEMENT

The rights and/or liabilities arising to any party to this Agreement shall not be assigned by it to any third party except with the written consent of the other party and subject to such terms and conditions as may be mutually agreed upon.

16. GOVERNING LAW AND JURISDICTION

16.1 This Agreement shall be construed in accordance with and be subject to and

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governed by the Laws of India.

16.2 All legal proceedings arising out of or under this Agreement shall be subject to the exclusive jurisdiction of the competent Courts in Mumbai, India.

16.3 In the event of any legal proceedings by or against the LICENSEE, the LICENSOR shall not bear any expenses towards defending the LICENSEE in their individual capacity, including court fees, advocate fees, or any other related or incidental charges.

17. ARBITRATION

In the event of a controversy or claim arising out of or relating to this Agreement or to the breach, validity, or termination of this Agreement, the PARTIES shall first negotiate in good faith for a period of sixty days to try to resolve the controversy or claim. If the controversy or claim is unresolved after mediation, on the written demand of either party any controversy arising out of or relating to this Agreement or to the breach, termination, or validity of this Agreement shall be referred to arbitration of three arbitrators, one each to be appointed by each party and the third arbitrator appointed by the two arbitrators in accordance with the provision of Arbitration and Conciliation Act 1996 and subsequent amendments thereof. The place of arbitration shall be at Pune and shall be conducted in English language. The laws of India shall govern the performance of this Agreement.

18. MISCELLANEOUS

18.1. **Clauses and Headings:**

Unless the context otherwise indicates, references to Clauses, Sub-Clauses and Appendices are to Clauses and Sub-Clauses of, and Appendices to, this Agreement. Headings to Clauses and Sub-Clauses in this Agreement are included for the purpose of ease of reference only and shall not have any effect on the construction or the interpretation of this Agreement.

18.2. **Further Agreement:**

Except as expressly set forth hereunder, nothing herein shall be deemed to provide a commitment by either Party to enter into any further agreement with the other Party.

18.3. **No Assignability:**

Either Party shall not, without prior written consent of the other Party, assign this Agreement or any right or obligation hereunder, in whole or in part, without prior written consent of the other Party.

18.4. **Waiver:**

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No waiver by either Party of any provision of this Agreement shall constitute a waiver of any other provision nor shall any waiver constitute a continuing waiver.

18.5. **Severability:**

In case any one of the provisions contained in this Agreement should be invalid, illegal or unenforceable in any respect in any jurisdiction, the validity, legality and enforceability of such provision or provisions shall not in any way be affected or impaired thereby in any other jurisdiction and the validity, legality and enforceability of the remaining provisions contained herein and therein shall not in any way be otherwise affected or impaired thereby.

19. ENTIRE AGREEMENT

This Agreement, together with PATENT (APPENDIX-A) and Request from LICENSEE (APPENDIX-B) appended hereto, constitutes the entire understanding between the PARTIES in relation to Licensing of the PATENT by LICENSOR, and supersedes any arrangements, promises, or agreements in relation with the same, made or existing between the Parties prior to or simultaneously with this Agreement.

SEAL OF PARTIES

This Agreement has been executed in two originals one of which has been retained by LICENSOR and the other by LICENSEE.

In witness whereof the parties hereto have caused their authorised representatives to sign this Agreement on the day, month and year mentioned herein below

For and on behalf of LICENSOR

8/9/2020

Signature:
Name: Prof. A. M. Pradeep
Designation: Associate Dean R&D

सह संकायाध्यक्ष, शोध एवं विकास
Associate Dean, Research and Development
कृते निदेशक, आय आय टी मुंबई
For Director, IIT Bombay

Witnesses: (Name & Address)
1._____
2._____
Date: _____

For and on behalf of LICENSEE

Signature:
Name: Aneesh Karma
Designation: Founder & CEO

AUMEESH TECH PVT. LTD. Director

Witnesses: (Name & Address)
1._____
2._____
Date: _____

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APPENDIX-A

PATENT

Sr. No	Title of the Invention	Application No.	Priority date	Status
1	A STANCE CONTROLLED KNEE-ANKLE FOOT ORTHOSIS	201921005973	15/02/2019	Patent Application has been filed.

Poliomyelitis, often called polio or infantile paralysis, is an infectious disease caused by the poliovirus. In about 0.5 percent of cases there is muscle weakness resulting in an inability to move. Knee ankle foot orthoses (KAFO) are prescribed to patients whose knee joints can't function normally for reasons ranging from injuries to disease so as to support the knee joint. Current KAFO designs lock knee joints in both stance and swing phase resulting in unnatural gait like circumduction causing fatigue. Additionally, imported KAFOs are expensive and an orthosis resulting in natural gait can be useful. A product patent for stance controlled knee-ankle foot orthosis has been filed. It comprises of: a thigh assembly; a knee assembly; a shank assembly; a foot assembly; a base plate on which a foot rests, with a heel pressure plate configured to senses pressure from heel of a wearer of said orthosis in a stance phase of a gait cycle and to sense lack of pressure in a swing phase of the gait cycle or in a squatting phase; an actuating assembly comprising a pawl and a ratchet; a normally compressed resilient element; a normally stretched resilient element; and a connecting wire. The heel pressure plate is configured to sense pressure from heel of a wearer of the orthosis in a stance phase of a gait cycle and to sense lack of pressure in a swing phase of the gait cycle. The pawl and ratchet form the core actuator assembly and engage with each other during said stance phase and disengage with each other during swing phase or squatting phase.

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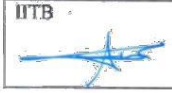	

APPENDIX - B: Letter of Interest from LICENSEE dt. 7th Oct 2019

Aumeesh Tech Pvt Ltd
F/16, Sri Krishna Housing Society
Sundarbaug, Kamani, Kurla
Mumbai, Maharashtra, India-400070
+91 9990864336, aneesh.karma82@gmail.com

CIN: U33100MH2019PTC328588 ; PAN No. : AASCA5566G

AUMEESH TECH
stepping towards a better future

To,

12/08/2020

The
Prof. B. Ravi
BETiC Lab (IIT Bombay)

Sub: Agreement for licensing of IP 'A stance-controlled Knee Ankle Foot Orthosis' – 201921005973 to the company 'Aumeesh Tech Pvt Ltd'

Respected Sir,

As you are aware, I, Aneesh Karma (BETiC Research Assistant) had applied and got approval for the Biotechnology Ignition Grant (BIG) for Proposal Title: Development of a mechanically actuated stance-controlled Knee Ankle Foot Orthosis.

Earlier, a provisional patent for 'A stance-controlled Knee Ankle Foot Orthosis' was filed on 15/02/2019 (application number 201921005973) under BETiC, IITB with inventors as Aneesh Karma, Rupesh Ghyar, and B. Ravi. Further a company AUMEESH TECH PVT LTD has been formed by Mr Aneesh Karma as suggested and encouraged by BIG partners. SINE has shown support in incubating the BIG project and the start-up.

The BIG proposal involves further developing and enhancing the device mentioned in the IP. An extensive effort and funding will be required in translating the patent to product. We have already secured about Rs 50 Lakhs for developing the usable product. The Aumeesh Tech team will exclusively work over next 18 months for translating the said IP to a product in clinical use.

In this perspective the BIG project and SINE needs a new licensing agreement between IITB and Aumeesh Tech Pvt Ltd for the above IP. As per their request this agreement should allow the company to further develop and exclusively commercialize the above IP and raise capital from investors.

I request you to guide us in obtaining an appropriate licensing agreement to the company so that the IP can be developed further and commercialized reaching the users for which it is designed. I kindly request you to guide and support us further regarding the same.
Also request you to help our organization for obtaining license before completion of first milestone of BIG started from 1st November, as we commit our BIG partner that we will done licensing of patent before completion of first milestone

Yours sincerely

Aneesh Karma
(Project Technical Assistant)
BETiC, IIT Bombay

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Annexure J

Proof of Birac BIG Grant approval

Dear Shahnaj,

Greetings from Venture Center!

We are happy to inform you that your proposal under BIG Round 14 has been accorded an **in principle approval** by the Expert Selection Committee (ESC) for grant funding support under Biotech Ignition Grant.

Please find below the comments received during the ESC meeting along with detailed Objectives & Milestones. Please provide the clarifications asked by the ESC, if any. Make sure to incorporate the same in your DD.

Proposal Ref. No.	BIRAC/VENTURE0461/BIG-14/19
Applicant Name	SHAHNAJ
PI Name	SHAHNAJ
Title of the project	Mechanically Activated Stance Controlled Knee Ankle Foot Orthosis
Research Area	Healthcare-Devices and Diagnostics
Technical Officer's Input	The invention is related to healthcare assistive devices and focusses on providing a better alternative to the existing orthotic calipers in the market. It is an orthotic device called Stance Controlled Knee Ankle Foot Orthosis (SCKAFO). As the name suggests, it locks and unlocks according to the phase of the gait of the user. It locks in the stance phase and is unlocked in the swing phase. This leads to an intuitive and comfortable operation by the user.A preliminary proof-of-concept was fabricated and preliminary tests were conducted to test the performance of the device. Based on test data and feedback received from the users, the device was improved. In view of the above the proposal was recommended for funding.
ESC Recommendations	The proposal was recommended subject to setting up of a company involving all team members and assignment of IP to the company. **Objective & Activities:** 1. Clinical Need Identification Interview 100 Patients, doctors and experts 2. Product Development Finalize specs; detailed design; new IPR filing 3. Functional Prototyping mfg process plan; functional product prototyping. 4. Functional Prototyping Mechanical testing, clinical validation, initial marketing **Milestones:** M1: Final prototype satisfying all FRs manufactured (6 Months) M2: Product tested after ethical trials and ready for the production (12 Months) M3: DISBURSING 100 MASC KAFO and gathering the data from the users (18 Months)
IP Comments	As this proposal is recommended subject to forming a start up. Applicant has filed 2 Indian Patents 341/DEL/2015 & 201921005973, applicant should assign this patents to applicant company
Status	Recommended

Congratulations on reaching this stage!

Please acknowledge the receipt of this email.

Thanks and regards,
Kirtee
BIG Team @ Venture Center
100, NCL Innovation Park
Dr. Homi Bhabha Road
Pashan, Pune – 411008