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Research Article

Design of an Adaptive Knee-Brace to Assist Post Arthroplasty Locomotion

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ABSTRACT

With the continuous improvement in medical technology, arthroplasty surgeries have become more frequent over the decades. DFMA (or Design for manufacturing and assembly) techniques [1] are being adopted by the current generation of industrial engineers and product designers in order to provide more accurately detailed and robust solutions to the design requirements. Since modern Arthroplasty relies heavily on replacement prosthesis, it is essential to provide an external support source to allow the patient to accommodate to the current surgical changes in their body. It is an immediate requirement that, after total knee arthroplasty, the limb actuators during locomotion get external support from a framework or exoskeleton to distribute the loading of the reaction forces during every possible gait action. Since different gait cycles have different load distribution and frequency response for relaxation, it is necessary that an adaptive knee brace considering these parameters is designed for our patients. We address these aforementioned objectives through rapid prototyping design techniques.

Keywords: Knee arthroplasty, Exobrace, Exoskeleton, Knee Support, Biomechanics, 3D-printing

INTRODUCTION

A systematic design pipeline is very essential for increasing the overall efficiency in a modern product lifecycle. A designer should not only follow the necessary protocols to cover the essential features from the consumer forefront but should also be able to optimize their product in terms of failure reduction, material consumption, processing liabilities and other cost investment parameters from an industrial production outlook. Several products in the field of passive and quasi passive exoskeletons [2][3] for arthroplasty patients have been designed over the years, but none have been fabricated from this necessary outlook.

Knee arthroplasty is one of the more frequent surgeries in patients with advanced osteoarthritis [4] and is considered only in the exhaustion of other noninvasive conservative treatments. A series of universities, medical research centers, and arthroplasty professionals have emphasized the need to externally support the surgical structure of the patient for a detailed duration before their complete recovery. Limb-exoskeletons have been constantly being reviewed as potential performance enhancers in routine activities that centralize around body frame strength, endurance, and speed of action.

The applications of exoskeleton modules as framework support for arthroplasty patients, have initiated an immensely diverse research domain in the field of biomedical engineering and design. Modern rapid prototyping technologies have heavily restructured the manufacturing economy [5] and its layout in the recent years. Product engineers are given the liabilities to design custom products with each being prototyped accordingly as per consumer requirements. Since every patient is unique, structural braces are required to be designed as custom fit essentials, and this is achieved through modern rapid prototyping processes like additive manufacturing, and 3D-printing.

It has been observed in medical records of TKA (or Total Knee Arthroplasty) [4] patients' post-surgery, that in due course of time, they experience notable decline in their accessibility to voluntary control their range of motion and they are able to clearly identify their lack of quadricep strength. It is therefore essential for us to design a structural brace or knee-brace to compensate for this loss in muscle strength, reduce pain or injury risk and improve coordination for a complete traversal activity.

Figure1: Anatomy of the human knee joint, reference image from [6]

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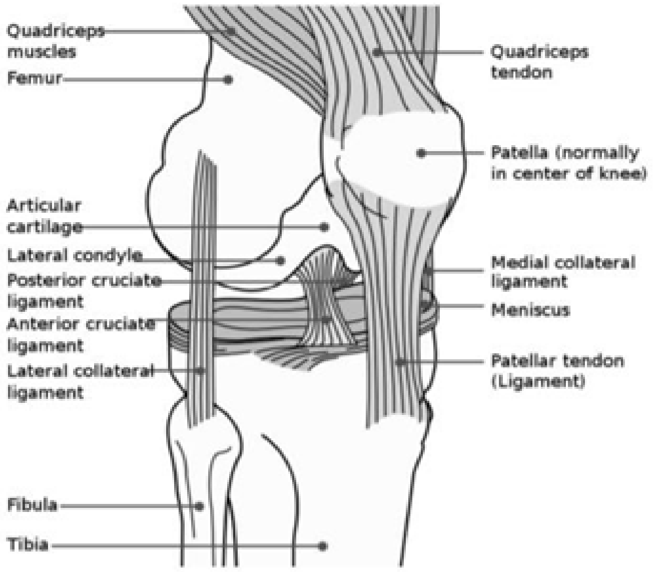
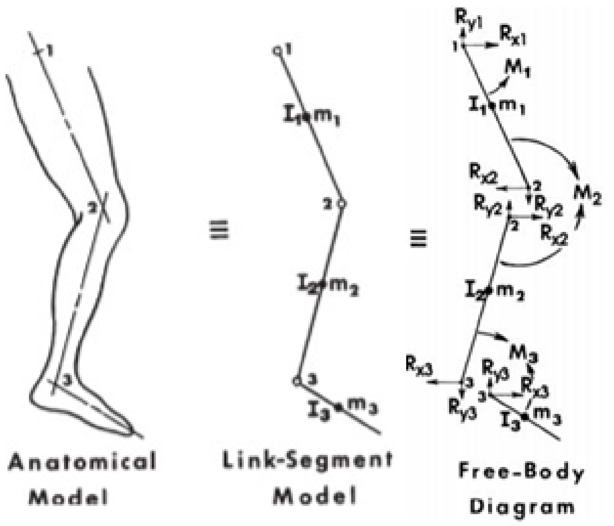


Figure 2: Link segment modeling, mapping reaction moments and forces, reference image from



LITERATURE REVIEW

A thorough understanding of the analytical pipeline of the environment is very essential to assess the limitations and parameters involved in the fabrication cycle of our required product, in which it will be working. In our case, in order to proceed with a non-invasive design of the structural brace, it is necessary to first understand the anatomy of the knee joint, gather information on the loading limitations, generalize the kinetics for an individual and map the range of motion covered by the entire unit to understand the kinematics behind the unit assembly.

The knee joint (Fig 1.), is a synovial joint that primarily connects the Femur to the Tibia of the body frame, with several segments of muscle fibers and ligaments [6]. The knee cap of the unit is covered with a flat bone, known as Patella, and it increases the leverage area to redistribute the loading of quadriceps tendons over the femur by increasing the solid angle of interaction. The knee also has a secondary ligament that generates a higher degree of contact of the Fibula against the Tibia to maintain structural orthodoxy. The knee covers a dynamic range from 20°±10° to 150°±10° of its flexion angle. The flexion is segregated into the 'passive arc', 'active arc', and 'home flexion' regions (also referred to as 'screw home' in some sources), that individually map the different stages of contact loading and muscle activity during locomotion.

Next, in order to understand the mechanical principles behind the assembly kinetics, it is required to define a series of parameters and equations that can be used to estimate the reaction moments and contact forces to compute the failure limits of our product under activity. Noninvasive estimations of the reaction moments and contact forces of the knee joint through inverse dynamics help us define the kinetics of the assembly through its structural kinematic analogy. They also help us compute the governing constraints through external dynamic quantities that can be assessed or mapped with an instrument or sensor. The process through which these estimates are calculated is commonly referred to as link segment modeling (Fig 2.) [7]. We need to define the most adequate kinematic chain resemblance, that not only distinctively preserves the motio0n description of the joint but also records accurate anthropometric measurements.

The primary steps, that are an absolute necessity in mapping the anatomical model to its subsequent link segment layout, focus on the substitution of the knee joint axis with a concentric parallel revolute joint. They are also responsible to connect the links that correspond to the physical and dynamical properties (such as length, rotational inertia 0, center of mass) of the Femur, Tibia and foot. We record failure parameter analysis and influence of segment parameters by estimating ground reaction and contact forces in addition to their kinetic profile along the link segment model. Conservation of angular momentum and Newton's second law of motion help us navigate, step by step, the reaction activity of the entire unit and the load distribution profile among the various ligament fibers. The governing equations are enlisted to estimate the analogy dynamics are computed in the plane for both components of action as:

$$m\ddot{x} = ma_0 + \sum_{i=0}^{n} F_x^i \qquad (1)$$

$$R_{x2} = ma_x + R_{x1} \qquad (2)$$

$$I_0\alpha = \sum_n M \qquad (3)$$

Simultaneously compute the angular displacement θ, instantaneous angular velocity $\dot{\theta}$ or ω, and instantaneous angular acceleration $\ddot{\theta}$ or α between two connected limb segments. In order to compute the aforementioned dynamic relations, we estimate the kinematic variables as follows

For the estimation of all essential dynamic quantities it is necessary to first record a measurement of all the kinematic variables involved, namely, displacement x, instantaneous velocity $\dot{x}$, and instantaneous acceleration $\ddot{x}$ for the center of mass for a particular segment. It is also mandatory to simultaneously compute the angular displacement θ, instantaneous angular velocity $\dot{\theta}$ or ω, and instantaneous angular acceleration $\ddot{\theta}$ or α between two connected limb segments. In order to compute the aforementioned dynamic relations, we estimate the kinematic variables as follows:

$$\ddot{x}_2 = \ddot{x}_1 + \overrightarrow{\omega_{12}} \times (\overrightarrow{\omega_{12}} \times \overrightarrow{r_{12}}) + \overrightarrow{\alpha_{12}} \times \overrightarrow{r_{12}} \qquad (4)$$

$$\dot{x}_2 = \dot{x}_1 + \overrightarrow{\omega_{12}} \times (\overrightarrow{r_2} - \overrightarrow{r_1}) \qquad (5)$$

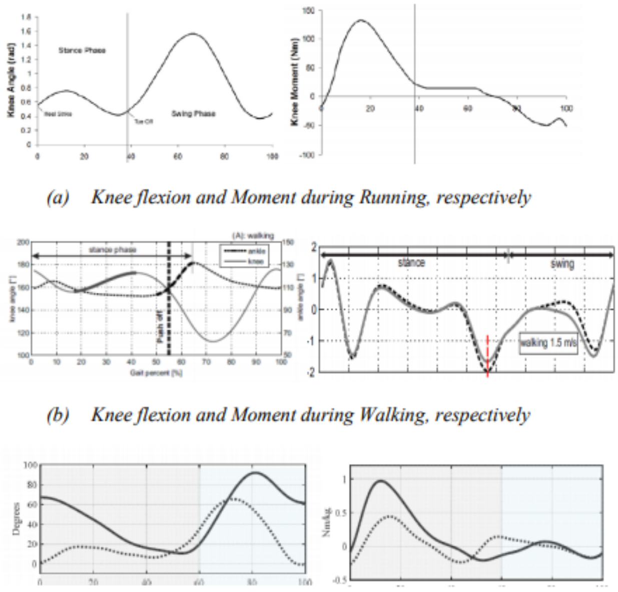
$$\dot{x} = \frac{dx}{dt} \qquad (6)$$

Where, $\overrightarrow{r_{12}} = \overrightarrow{r_2} - \overrightarrow{r_1}$, defines the position vector along the limb segment length directed from point 1 to point 2. We substitute these kinematic relations to estimate the dynamic quantities mentioned in Equations 1.,2., and 3. The resultant external force on the system is represented by $\sum_{i=0}^{n} F_x^i$ and resultant effect of all conservative field is represented as ma_0in Equa.1. The resultant contact reaction force in the direction, $\overrightarrow{r_{12}}$ is given by $'R_{x2} - R_{x1}'$ for x-component of the force, and correspondingly a familiar equation represents the y-component of the force. We will get references from these equations [7] for assessment of our controller feedback and prosthesis design.

LOCOMOTION SUPPORT BIOMECHANICS

In order to initiate the design for our exoframe, we should understand the different gait cycles and the stress distribution profiles through each of them. It is necessary to measure the knee flexion relationship for flexion and the moment generated for the individual cycles. In our definition, we will restrict with the primary locomotion cycles including walking, running and stair climbing. From the average flexion measurements recorded from multiple research subjects (Fig 3.), we can clearly correlate the pattern necessary to define the loading profile with respect to flexion angle during any gait cycle. If we are oriented to design a support exoframe, we should keep in mind the feature integrity necessary to adapt to all physical locomotion advances by the user. We cannot expect similar cycle frequency and moment profile generated through among the cycles from an amplitude

Figure 3: Knee joint gait profile during (a) Running, (b) Walking and (c) Climbing, reference image from [8,9]



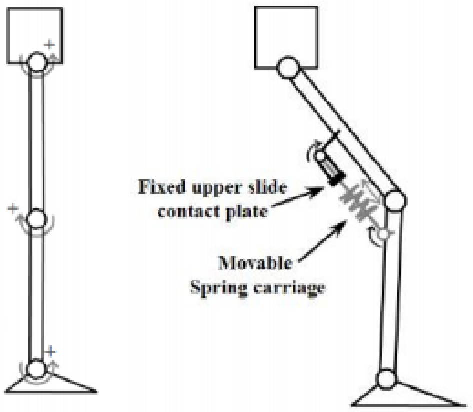
(a) Knee flexion and Moment during Running, respectively

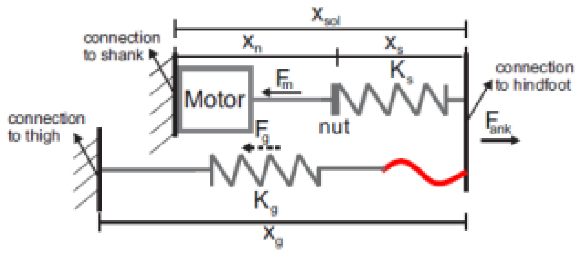
(b) Knee flexion and Moment during Walking, respectively

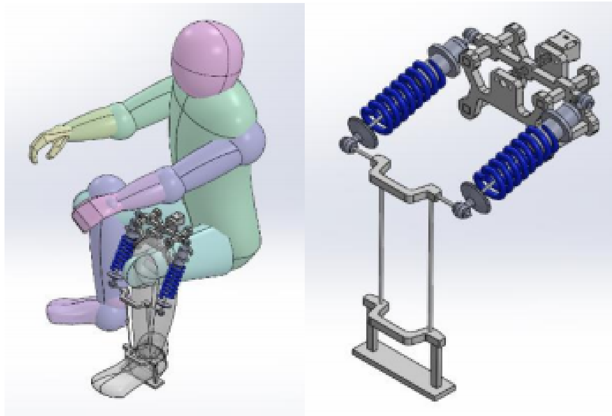
(c) Knee flexion and Moment during Stair climbing, respectively

Hence it is recommended to design an adaptive bracing that can self-adjust the damping or impulse absorption tolerance accommodating to the user environment. As practice, most knee exoframe braces follow link assisted damping design (Fig 4.) for frame support. A channel or frame guide is designed to transmit the compressive quadricep force generated in the stance phase of the gait cycle, from the calf under muscle contraction to the thigh of the connected limb segment through a passive damperspring actuator. Every stance during a locomotion activity generates a necessity for skeletal balance. Since, the patient's body is not equipped with the adequate knee rigidity to comply with the demand, it rests over the support from the additional force generated on compression of the damper-spring actuator. Collectively, shock or impulse absorption and frame support, both are assisted by this actuator, and designers are individually mapping these critics to the damping coefficient and spring stiffness coefficient of the actuator system respectively, according to their application requirements. When necessary flexion is introduced through the Gait cycle, the kinetic energy during flexion is conserved and stored as potential energy that subsequently releases during the swing phase of the cycle. Overall, this actuator design significantly contributes for the additional moment required by the joint assembly. These designs, once installed lack the adaptability to adjust accordingly to individual requirements to micromanage individual gait profiles.

Figure 4: Current Link Assisted Damping Exobrace Design, reference image from [8,9]







(a) *CAD assembly of the Exobrace*

(b) *Isometric and front view of the Exobrace*

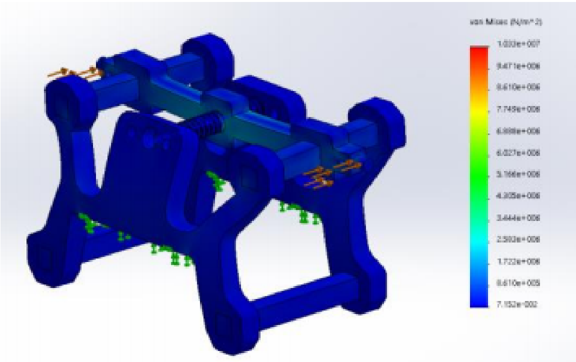
Additionally, there is no transit support provided to reduce the overall burden on the joint itself. A transition relay is absent to diverge the body weight loading from the knee joint, which is an absolute must in order to encourage joint recovery. So in order to design a desirable product that is adaptable to different locomotion cycles and reduces the overall knee joint loading, it is necessary to revise the existing design by including an external feedback based damper-spring actuator and an additional exoframe to channel the body weight through it to reduce to overall joint loading.

PRODUCT SOLUTION

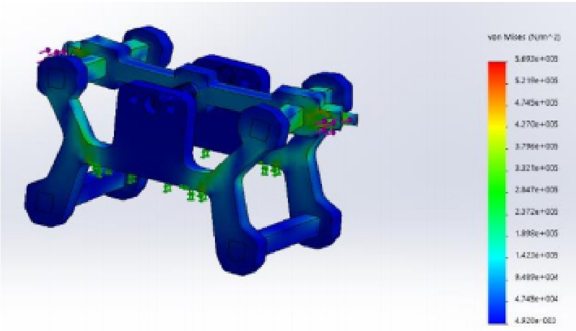
Exobraces should be defined as distinctive wearables and accordingly should be designed as comfortable, lightweight and dynamic products to accommodate the user specifications. Instead of manufacturing the entire assembly from an alloy, we can substitute the core frame material with PLA (Poly lactic acid, Tensile strength 37MPa, Flexural strength 43MPa for 0.1 mm filament) that is easy to fabricated with modern rapid prototyping manufacturing machines. The mesh regions where more composite rigidity and yield strength is required will be supported by SS Alloy assembly components. It is necessary to have a brace designed to adjust and support the limb segments and accordingly a frame structure to support the joint contact forces. Topology optimization algorithm encourages on conducting reiterations of the Von Mises stress profile simulations of the existing design under the pre-determined set of external conditions and requires the designer to substitute the stress hotspots with a material of higher yield strength.

Figure 5: Exobrace prototype and assembly

It also encourages seam curvature over surface finishes to avoid edges and corners as much as possible in the current geometry and promotes removal of material from the regions where stress profiles are negligible in amplitude, to minimize product weight and reduce material consumption. The design dependency of the variable stiffness actuator is dependent on the initial compression of the shock absorber [10]. From Hooke's Law it is clearly evident that every for every infinitesimal extension in the spring from its mean position a higher force is required. In every different gait cycle the reaction contact force is dependent on the weight of the patient and the non-referential acceleration during locomotion (pseudo force). Hence, more muscle activity is required to climb the stairs, rather than descending them. During running, the joint experiences more loading on the structure over walking. And cycling reflects as a period continuous reaction force dependent on the user's throttle. The damper-spring actuator joins the knee brace of the patient to their tibia brace, which is connected with a link segment bypass to the ground (Fig 5.). When the user stands, the actuator absorbs all impulses generated and minimizes the strain on the knee joint.



(a) Static Analysis-Von Mises Stress profile for composite design



(b) Static Analysis-Von Mises Stress profile for SS alloy

Figure 6: Simulation study for core replacement

The segment connected to the tibia brace supports the shocks absorbed by the actuator by serving as a channel to dissipate energy stored in the spring actuator. The foot support has a FDR(or force sensor), to measure the reaction force from the ground, an encoder installed at the rotary joints estimates both angular displacement θ and instantaneous angular velocity ▯ . We substitute these parameters in the equations (1) – (6) and obtain the remaining values. The data is mapped to a threshold based function that determines the spring extension necessary for impulse reduction. A stepper motor circuit comprising of Nema-17(200 steps equals 1 revolution) with an 12V, 2A DRV8825 motor driver, and Arduino Uno R3 then proceeds to rotate the lead screw (M80x4) to shift the actuator joint position towards the front that in effect compresses the spring or vice versa. In order to estimate the component parameters of the damper spring actuator, we look into the power dynamics of the subassembly unit. In the current loading drive unit, we are using a damper assembly that has an adaptive power screw compliance. Considering the weight of the user to be around 90 Kilograms and noting the fact the peak stress during all the gait cycles combined does not crosses a loading of 2 times the B.W. we can estimate the spring stiffness (K) over the shift of support revolute joint at the lead screw of 10 cm with a compression of 1 cm to normal extension (δx=1cm), to its maximum possible limit. Then for the combined loading distribution at both spring-damper units.

$$2 \cdot B.W. = 2 \cdot K \ \cdot \delta x$$

$$K(spring\ stiffness) = B.W./\delta x$$

$$K(spring\ stiffness) = 90KN/m$$

After estimating the Spring stiffness, we can proceed with the estimation of lead screw or power screw parameters. Since we can eliminate the coupling torque that is additionally required, since only a direct feed is present between the screw and the motor, for Nema 17 (TR = 60Ncm), and assuming friction between the inner screw and lead to be 0.15 for Stainless Steel with meshing lubrication, we can easily get the combination of diameter and pitch that will work.

$$T_R = \frac{F \cdot d_m}{2} \cdot \frac{L + \pi \cdot \mu \cdot d_m}{\pi \cdot d_m - \mu \cdot L} + \frac{F \cdot \mu_c \cdot d_c}{2}$$

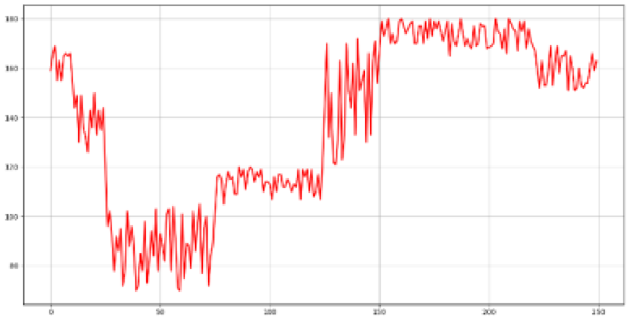
$$T_R = \frac{F \cdot d_m}{2} \cdot \frac{L + \pi \cdot \mu \cdot d_m}{\pi \cdot d_m - \mu \cdot L}$$

$$60 = 180 \cdot \frac{d}{2} \cdot \left(\frac{L + \pi \cdot 0.15 \cdot d}{\pi \cdot d - 0.15 \cdot L}\right)$$

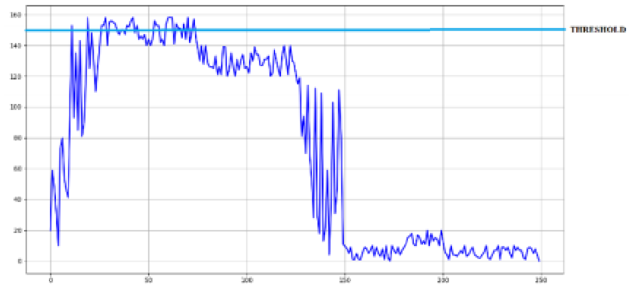
$$2\pi d - 0.3L = 3dL + 0.45\pi d^2$$

We observe that the value sees fit for a threading profile of M45x1.5 with the minimal variance between the LHS and RHS which can be assumed to be compensated for the friction coefficient. The damper spring actuator not only functions as an assist to support gait loading, but also transfers the body weight from just quadricep slightly above the knee joint to directly the foot pivot [11]. In the design study we also assess the failure limit for the cases (Fig 6.) through a simulation when the entire knee brace structure is fabricated from SS Al Alloy 6601 and compare it to a composite of PLA and the same alloy where the alloy is only employed at stress hotpots and rest of the brace is fabricated with PLA. This is an adaptation of Topology optimization and benefits wastage reduction and cost cuttings.

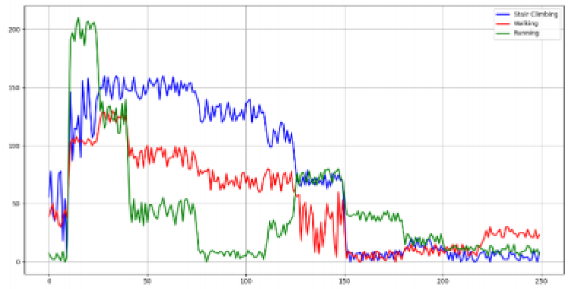
Figure7: Prototype run results for Gait Cycle Analysis



(a) Encoder response for stair climbing



(b) FDR response for stair climbing with threshold

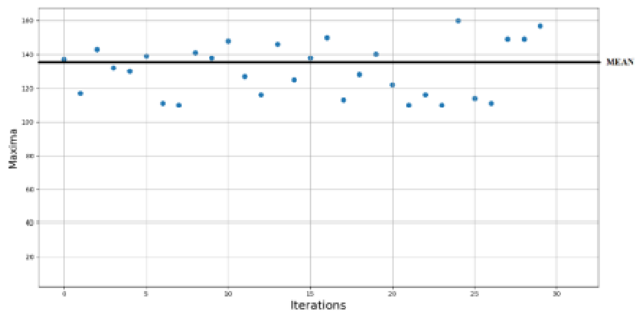


(c) Comparative assessment for Threshold evaluation

ANALYTICAL EVALUATION

In order to map the required compression with the corresponding locomotion activity, we use a multivariate function that is dependent on the force magnitude and the angular frequency as recorded by LDR and encoder respectively [5]. We define a series of threshold for the time stamp and response output recorded for different gait cycles. There is no need to calibrate the force readings to their actual value, just distinctive mapping from (0,255) will be sufficient to note threshold after connecting the voltage divider circuit with it. We map the responses of both the sensors for the gait cycle and mark the frequency and force response. As per data recorded (Fig 7. b), we use the principle of statistics to identify the threshold value, the local maxima are evaluated and its value is plotted for multiple iteration against iteration number to find the mean threshold (Fig 8.) of the model.

Figure 8: Threshold Identification for Stair Climbing



Whenever the threshold is crossed for an activity, the stepper sets the spring compression to a proportional limit of the identified gait cycle. The frequency is estimated by setting a flag, as soon as the system crosses the threshold. All time intervals between the flag sets are recorded and averaged. A higher frequency would seek a lower spring compression, and a higher magnitude of reaction force would be balanced by a higher compression. Thus we encounter a case of Multi objective optimization where the quantity x (spring compression) is a dependent on the ratio of the force magnitude and frequency. An empirical estimation is compiled in Table I, which was observed to be comfortable after multiple manual settings. The table record the value directly from the sensors.

CONCLUSION

Adequate compliance design has always been challenge from an aesthetic, functional and ergonomic standpoint. In gait compliance design, the commercial products that are adaptive to an external feedback always have an active control unit with either a hydraulic SEA [10], pneumatic cylinder drive or electromagnetic couplers [12] to support the frame base. These designs, though are functionally superior than the proposed design, lack commercial affordability, DMF repeatability and the necessity ergonomics all together. Our suggested prototype primarily focuses on unification of these aspects to revamp the existing design approach of exoframes and exosuits. In the aforementioned designed we reflected on the necessity and feasibility of an adaptive response system for the damper-spring actuator within certain thresholds accordingly for different gait cycles. The stiffness variability is determined accurately by the Central Control Unit of the device and it maps the control response of the system model in effect of the magnitude of the external loading on the load cell and frequency of the same. Some alterations are also necessary in the existing design, on one hand design failure can definitely lead to performance degradation.

Table 1: Activity based compression

Locomotion Activity	Average Threshold	Average Frequency	Spring Compression
	Force(bits)	(Hz)	(stepper steps)
Running	191.2	6.1(8kmph)	1410
Walking	117.4	2.7(5kmph)	1180

Stair Ascent	158.9	1.4	1850
Stair Descent	134.3	1.9	1620

Table 2: Component List

Component	Specifications	Quantity
PLA Filament	1.75 mm dia	800 grams
SS rod	5mm, 25cm	2
Lead Screw	80x4mm, 10cm	1
Damper-Spring	90 KN/m	2
FDR	38.1mm, square	1
Arduino Uno	R3	1
Nema17	200 steps, 12V	1
Stepper		
Drv 8825	2A, 12V	1
Driver		

Since the aforementioned concept of Exobrace is currently designed from PLA, it cannot be expected to have high resistance to external deformation and is thus more prone to fatigue failure over long term use. The parts however are relatively very affordable to reprint and replace the worn out or broken components. The entire brace is very easy to assemble and worn and if the user has the resources to replace the core material from PLA to Polycarbonate or Carbon fiber, that have flexural strength over 6 times that of PLA, a higher tensile strength (72MPa PC,37MPa PLA) and more durability, we can achieve much better results from the assembly frame as a complete product. It is important that design adjustments should be introduced by scaling the assembly dimensions according to each individual patient [13]. Misalignment of the links should be minimized as much as possible and the designed should be operated in only as sub-optimal manner to prevent product failure and unconformable irritation to the user.

REFERENCES

1. T Mangera, F Kienhöfer, K Carlson, M Conning , T Purkis and G Govender et al. “Design for manufacture and assembly of a polycentric paediatric prosthetic knee,” Proceedings of the Institution of Mechanical Engineers, Part B: Journal of Engineering Manufacture, vol. 233, no. 14, pp. 2566–2576, Apr. 2019.
2. J. E. Pratt, B. T. Krupp, C. J. Morse and S. H. Collins, "The RoboKnee: an exoskeleton for enhancing strength and endurance during walking," IEEE International Conference on Robotics and Automation, 2004. Proceedings. ICRA '04. 2004, New Orleans, LA, USA, 2004, pp. 2430-2435 Vol.3.
3.
4. E. Rogers, P. Polygerinos, S. Allen, F. A. Panizzolo,
5. C. J. Walsh, and D. P. Holland, “A Quasi-Passive Knee Exoskeleton to Assist During Descent,” in Bio systems & Bio robotics, Springer International Publishing, 2016, pp. 63–67.
6. R. Ezzibdeh, P. Arora, and D. F. Amanatullah, “Utilization of a pneumatic exoskeleton after total knee arthroplasty,” Arthroplasty Today, vol. 5, no. 3, pp. 314– 315, Sep. 2019.
7. N. B. Bolus, V. G. Ganti, and O. T. Inan, “A 3D- Printed, Adjustable-Stiffness Knee Brace with Embedded Magnetic Angle Sensor,” in 2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), 2018.
8. G. Fekete, “Kinetics and kinematics of the human knee joint under standard and non-standard squat movement,” Ghent University and Szent István University, Gent, Belgium, 2013.
9. D. A. Winter, “Biomechanics and Motor Control of Human Movement.” John Wiley & Sons, Inc., 23-Sep- 2009.
10. A. M. Dollar and H. Herr, "Design of a quasi-passive knee exoskeleton to assist running," 2008 IEEE/RSJ International Conference on Intelligent Robots and Systems, Nice, 2008, pp. 747-754.
11. M. Eslamy, M. Grimmer and A. Seyfarth, "Adding passive biarticular spring to active mono-articular foot prosthesis: Effects on power and energy requirement," 2014 IEEE-RAS International Conference on Humanoid Robots, Madrid, 2014, pp. 677-684.
12. Z. Chu, J. Luo and Y. Fu, "Variable stiffness control and implementation of hydraulic SEA based on virtual spring leg," 2016 IEEE International Conference on Mechatronics and Automation, Harbin, 2016, pp. 677-682Gaventa J. Towards Participatory Governance: Assessing the Transformative Possibilities. In: Hickey S, Mohan G. Participation: From Tyranny to Transformation: Exploring New Approaches to Participation in Development. London: Zed Books; 2004. pp. 25–41.
13. Global Environmental Outlook, United Nations Environment Programme Higgins, B. 1956. “The ‘Dualistic Theory’ of Underdeveloped Areas.” Economic Development and Cultural Change (2000) 4(2): 99-115.