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POLYCENTRIC KNEE PROSTHESIS WITH CARBON FABRIC REINFORCED POLYMER: FABRICATION AND STRUCTURAL EVALUATION

POLICENTRIČNA MEHANSKA KOLENSKA PROTEZA IZ POLIMERNE TKANINE OJAČANE Z OGLJIKOVIMI VLAKNI: IZDELAVA IN STRUKTURNO OVREDNOTENJE

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A prosthetic knee is an important, functional, dynamic component of a transfemoral prosthesis. This paper details a step-by-step fabrication procedure for a passive polycentric knee using carbon-fabric-reinforced polymer in a sequential order. The Solidworks® 2022 software package was used for part modelling and assembling. The three-dimensional model developed was the base for planning, visual ideation, feasibility assessment and physical prototyping. The parts of the composite knee were manufactured using a vacuum-assisted resin-infusion method. The moulds for the infusion process were designed and developed by fused-deposition modelling. The experimental static structural testing was performed in accordance with the ISO 10328 standard to evaluate the structural strength of the prosthetic knee.

Key words: polycentric knee, prosthesis, polymer-matrix composites, vacuum resin infusion

Kolenska proteza je pomembna funkcionalna dinamična komponenta stegenske proteze. V tem članku avtorji natančno opisujejo, korak za korakom, postopek izdelave pasivnega policentričnega kolena iz polimerne tkanine ojačane z ogljikovimi vlakni. Pri tem so uporabili programsko orodje Solidworks® 2022 za modeliranje in sestavo. Osnova planiranja so bili razvoj tridimenzionalnega modela, vizualna predstavitev, ocena izvedljivosti in fizična izdelava prototipa. Dele kompozitnega kolena so izdelali s pomočjo metode vakumskega nalivanja oziroma nabrizgavanja. Modele za postopek nalivanja so avtorji dizajnirali in razvili s pomočjo metode FDM (angl.: Fused Deposition Modelling). Eksperimentalno statično strukturno testiranje so avtorji izvedli v skladu s standardom ISO 10328, tako da so dobili oz. ovrednotili strukturno trdnost izdelane kolenske proteze.

Ključne besede: policentrično koleno, proteza, kompoziti s polimerno matrico, vakumska infuzija polimernega veziva

1 INTRODUCTION

The process of amputation is devastating and can greatly impact an individual's overall well-being.[1] Published studies indicate that disease-related (peripheral vascular disease, diabetes, tumor, congenital abnormalities) and traumatic causes account for the majority of lower-limb amputations worldwide.[2,3] The World Health Organization (WHO) estimates 95 % amputees from low-income nations lack access to prosthetic equipment.[4] The level of amputation is the primary criterion for the choice of artificial limb. Transfemoral (TF) prostheses are recommended for lower-limb amputees with above-knee amputations. A TF prosthesis is an assembly of components suggested for TF amputees to provide the necessary comfort and motion. A TF prosthetic system's functioning is complex since perfect coordination between the parts is necessary to synchronize with a natural gait. A significant amount of research and development is conducted both in engineering and medical areas considering various materials, design and fabrication process to achieve better functioning of TF prosthetic components.[5,6] Amputation is one of the leading causes of disability in India; however, barely 5 % of amputees utilise prosthetics.[7] Indian amputees are dissatisfied since their prosthetic device needs and expectations are rarely met. Most prosthetic knee items in India are imported from abroad.

In earlier times, orthoses and prostheses were built using steel, wood and leather. In the present scenario, polymers are utilised because of their superior properties necessary for prosthesis, while composite materials and alloys make well-built and lightweight prosthetic parts. Material properties such as strength, modulus, fracture toughness etc. are considered while choosing materials for prosthesis design. Aluminium is often used over steel for the rotating parts in lower-limb prostheses.[8,9] Polymer matrix composites (PMCs) are lightweight materials made from bonding layers of glass fibre, nylon or carbon with thermosetting resin. It is possible to adapt the type, quantity, mix of fibres and resins based on the patient's weight and degree of activity.[10–12] While aluminium, steel, and titanium are expensive and complicated options, PMC can be used in place of metals when a lighter

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weight and higher strength are required. Fibre-reinforced composites are governed by the mass proportions, reinforcement attributes like the type and orientation. In reality, the majority of research focuses on the production of composite socket components and the majority of high-end commercial foot prosthesis are manufactured using carbon-fibre-reinforced polymer (CFRP) composites for their superior mechanical properties.[13,14] CFRP composites are PMCs with good rigidity, high strength, low density, corrosion resistance, vibration resistance, high ultimate strain and high fatigue resistance. Traditional ways of fabricating lower-limb prosthetic components include forming and moulding techniques, whereas current manufacturing methods prefer additive technologies.[15–23] The components fabricated are assembled using bolts and glue. When making prostheses out of lightweight composite materials, techniques and process parameters have to be considered. Composite materials offer a solution to develop lightweight prosthetic components. A reduction in weight reduces the amputee's effort when using the prosthesis during their regular activities.

A polycentric knee prosthesis typically incorporates four-bar mechanisms with an instantaneous centre of rotation (ICOR) to replicate the motion of the human knee.[24] The prosthetic knees presently available can be controlled either mechanically or with a microprocessor. The process of microprocessor control entails the utilisation of an electronic device that assesses and internally modifies the movement of the knee. The process of mechanical control utilises a mechanical hinge that is operated through a four-bar mechanism, which can be actuated either manually or via pneumatic or hydraulic control. The ICOR of the polycentric knee is situated at the intersection of the anterior and posterior links, which is positioned above the knee joint.

In spite of extensive research in the development of fibre-reinforced polymer (FRPs) lower-limb prosthetic components, there are few reports related to the development of a composite passive prosthetic knee.[25–27] FRP offers several advantages: quick production and installation time, light weight, long-term cost savings, resistance to corrosion, and durability. The basic step-by-step procedure for the fabrication of a composite-made polycentric knee through a vacuum-assisted resin-infusion method (VARIM) was explained exclusively. The present research work presents the sequential processes of fabricating a polycentric knee using FRP for the benefit of prosthetists and researchers in the field of composite materials, bio-medical and engineering. A newer way of developing a composite part with VARIM, assisted by 3D printing technology, was suggested in this research. Efforts have been made to design moulds suitable for VARIM based on the mould dimensions and ease of resin flow. The procedure outlined in this paper might be helpful for the development of lightweight composite prosthetic parts. The proposed research focuses on the following three phases of work:

- Initially, a 4-bar mechanism based passive polycentric knee was designed and modelled using a computer aided design (CAD) application.
- The modelled parts for the CFRP polycentric knee were fabricated by VARIM and assembled subsequently. Closed moulds for the process were developed in this phase using a fused-deposition modelling (FDM) technique.
- Finally, the fabricated CFRP knee was subjected to static structural testing as per the International Organization for Standardization (ISO) requirements.

2 MATERIALS AND METHODS

2.1 Reinforcements

Carbon fibre was opted as the reinforcement for fabricating the composite polycentric knee.[28] The carbon fabric for the research was procured from Urja Fabrics Pvt. Ltd., Ahmedabad, India.[29] The material properties of the carbon fabric are listed in **Table 1**. Carbon fibres may offer a number of advantages in the development of high-performance composites where lightness with high mechanical qualities are required.[30] Carbon fabric is a bendable, small-diameter, high-strength-to-weight ratio and high-modulus material that can be adapted into intricate curved areas for a variety of application variations.

Table 1: Properties of carbon fabric material

Parameters		Values
Weave type		Plain
Weight		200 GSM
Thickness		0.23 mm
Yarn details	Warp	3K
	Weft	3K
Density		1.76 gm/cm^3
Filament Diameter		7 μm
Tensile Strength		3530 MPa
Tensile modulus		230 GPa

2.2 Matrix

Epoxy resins are thermosetting resins that are widely employed in the production of composites.[31] Polymerization is the cross-linking process through which epoxy changes from a liquid to a solid. When thermoset resins are used to make composite parts, a hardener is employed to cure them. In the chemical process that occurs during stirring, a hardener may serve as a reactant or a catalyst. Thermoset resins that have once solidified cannot be returned to their liquid phase. The physical properties of the acquired resin and hardener are detailed in **Table 2**. In terms of shrinkage, epoxy resins are much better than other unsaturated polyester resins. Epoxies are widely used to manufacture high-performance composites that have great mechanical capabilities, resistance

to corrosive liquids and conditions, exceptional electrical characteristics, high-temperature performance and good adherence to a substrate.

The resin and hardener were purchased from Huntsman International (India) Private Limited for this research. Araldite LY 556 is an epoxy resin that has the ability to make quality composite products. It is anhydride-cured and features a low-viscosity standard matrix structure with good chemical resistance.

Table 2: Matrix material properties

Product name and code	Parameters	Values
Araldite LY556 (Epoxy resin)	Viscosity at 25 °C	10000 – 12000 mPa s
	Density at 25 °C	1.15 – 1.2 g/cm^3
	Epoxide index	5.30 – 5.45 Eq/kg
Aradur HY951 (Hardener)	Viscosity at 25 °C	10 – 20 mPa s
	Density at 25° C	0.98 g/cm^3
	Flashpoint	110 °C

2.3 Vacuum-assisted resin-infusion method

VARIM is a cost-effective technology for producing premium, high-strength composite parts in small batch sizes. This procedure creates composite materials by combining a low-viscosity resin with reinforcements.[32] The method is performed in a closed system, between a sealed bag and a mould, or between two sealed moulds, avoiding workplace exposure to fibre and resin. Adverse responses due to resin and fibre can be minimized. The infusion method is much superior to procedures such as chopped strand spraying and hand lamination, which expose employees to materials directly. By utilizing multiple-use moulds infusion can reduce the manufacturing costs compared to hand lay-up, especially for smaller/repeat parts without compromising the part quality. Eliminating air leaks is crucial in VARIM for achieving composite products with better quality. The products manufactured using VARIM have better mechanical characteristics when compared to a traditional hand layup process. In the VARIM process, vacuum pressure is applied to drive the resin into the fibre arrangement. After generating a complete vacuum, the resin-hardener mixture is effectively drawn into the reinforcements precisely through positioned tubes.

3 STRUCTURAL GEOMETRY

When modelling the linkages of the four-bar knee, the kinematics of the entire system was analysed. To simulate the flexion of the joint and visualize the three-dimensional appearance, a solid assembly model with all knee components was constructed using the Solidworks®2022 modelling package. A 2-dimensional (2D) line sketch of the design with the links in normal and actuated position is represented in **Figure 1a**. The four-bar mechanism exhibits multiple ICOR depending on the configuration of the four links. The link lengths for the present study were designed based on Grashof four-bar linkage equation with the sum of its smallest and largest link being smaller than the sum of the remaining two links. The dimensions of the links are $L_1 = 40$ mm, $L_2 = 60$ mm, $L_3 = 46.25$ mm, $L_4 = 24.17$ mm, where L_1 to L_4 represents link 1 to Link 4.

The 3-dimensional (3D) solid model of the design is shown in **Figure 1b** with the major dimensions a = 100 mm along longitudinal direction, b = 62 mm and c = 78 mm along the lateral directions. The ICOR was found by extending the links L_3 and L_4 to the point of their intersection. This point of intersection defines the axis about which the links are rotating. This position of the ICOR with reference to the load line is critical in the stability of a four-bar prosthetic knee.[33,34] The knee was determined to be capable of a range of motion from 0 degrees to 95 degrees, where 0 degrees is defined as the neutral position when the limb is fully extended. The initial model is expected to occupy a length of 100 mm

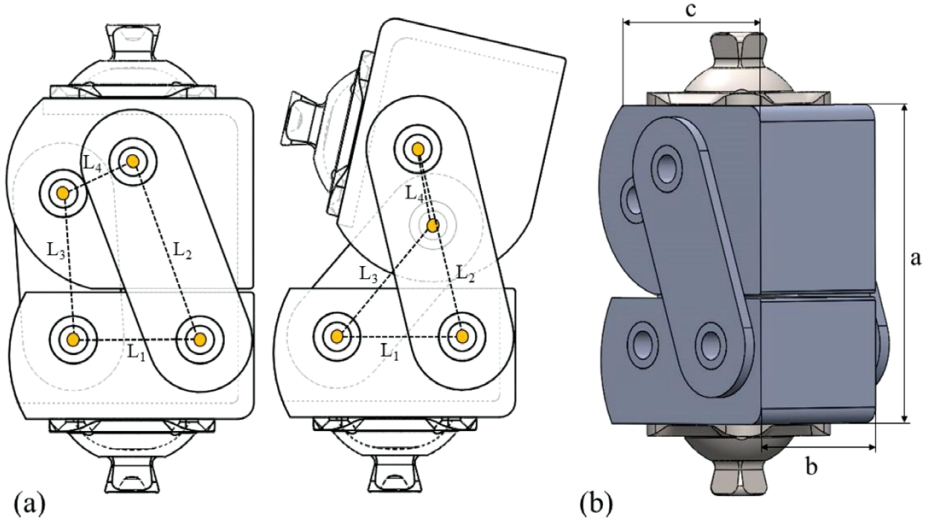

Figure 1: a) 2D representation of linkge mechanism, b) 3D CAD model of the knee

when fitted in a TF prosthesis and has a width of 62 mm. The thickness of the parts was limited to 5 mm uniformly considering the fabrication process and aesthetics.

4 DEVELOPMENT OF MOULDS FOR INFUSION PROCESS

Mould design is an essential component in the prototype development process, since the contour and finish of the moulded object has a direct impact on the process, the time required to create the mould and the cycle time of the moulding. The top and bottom parts of the knee prosthesis were preferred to be made using the closed core-cavity-based infusion process. The core part was modelled with provisions of both the resin port and the vacuum port. Threaded slots were provided on the core part so that a push-fit connector (male straight connector outer diameter 12 mm × 0.25-inch male thread) can be located at those slots.

Infusion tubes can be readily connected to the core section throughout the operation without any trouble or air leak. An angle of 2° was provided in the mould cavity considering easy removal of the cured part and to deliver the desired surface finish on the parts. The conceptual model of the core-cavity arrangement for part fabrication using the closed-mould infusion process is shown in **Figure 2a**. The top surface of the cavity side was provided with a 3 mm continuous slot to seat a rubber chord. Placing rubber cord and tightening the moulds ensures a perfect sealing, eliminating chances of air leakage. Air-supply leaks may stop the resin circulating inside the closed moulds, leading to the formation of air bubbles, which results in a composite part with void defects. Before the resin is supplied, the materials are laid dry into the mould and the vacuum is checked.

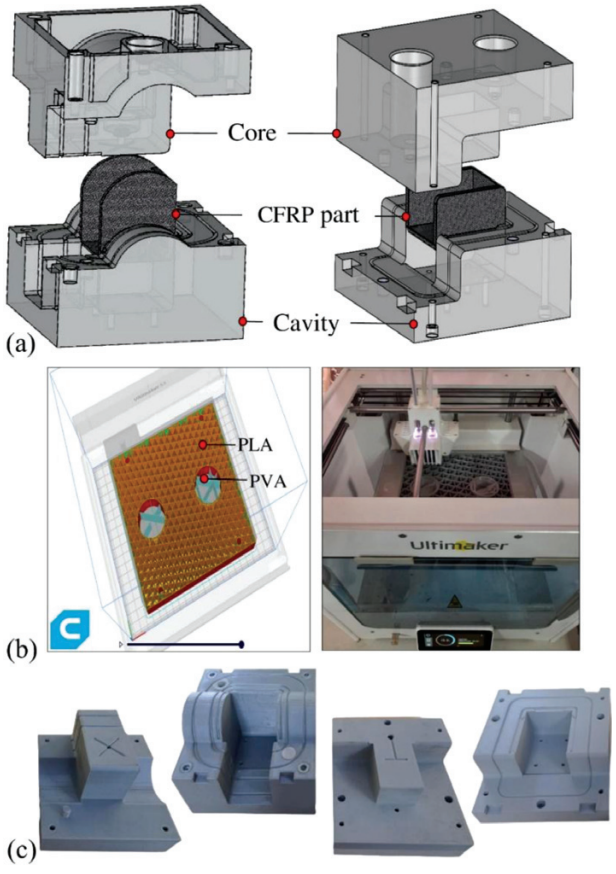

Figure 2: a) 3D model of core-cavity arrangement, b) slicing with Cura and FDM process for mould making (c) 3D-printed moulds

The Ultimaker S3 3D printer was preferred to build the core and cavity for the proposed closed-moulding process.[35] The Ultimaker S3 is a dual-extrusion FDM-based 3D printer suitable for a variety of purposes, including manufacturing assistance, prototype and functional parts development. To achieve the required print quality, the Ultimaker S3 is equipped with sophisticated active levelling, robust feeder wheels, dual-filament flow sensors and high-precision stepper drivers. Ultimaker compatible poly lactic acid (PLA) filaments were used as the raw material. In order to provide constant feeding, stable prints, no clogging with incredibly high success rate, Ultimaker compatible filaments have minimal tolerance and low warping. The surface finish of the printed items is exceptional and precise with a dimensional accuracy of ± 0.02 mm.Ultimaker Cura, an open-source 3D slicer was chosen for converting the part model into layers and generating compatible g-code instructions for Ultimaker S3. The graphical user interface window of the Cura platform loaded with core part and the printing process using Ultimaker S3 for the same can be seen in **Figure 2b**. **Table 3** lists the process-parameter values considered for developing the moulds through FDM. A polyvinyl alcohol (PVA) filament was used to print support structures for the mould parts. PVA is a soft, moisture sensitive, biodegradable polymer. PVA dissolves when exposed to water, which makes it a potentially helpful 3D-printing support structure material. PVA supports are the best choice when printing excessively complicated geometries or components with partly enclosed chambers. Supports can be readily separated by dissolving in water during the post-processing of the product. The FDM made moulds are shown in **Figure 2c**.

Table 3: FDM process parameters

Parameters	Values
Layer height	0.1 mm
Wall thickness	2 mm
Wall line count	5
Top/bottom thickness	1.5 mm
Top layers	15
Bottom layers	15
Infill-layer thickness	0.1 mm
Infill density	40 %
Printing temperature	200 °C
Build-plate temperature	60 °C
Print speed	50 mm/s

Initial layer speed	20 mm/s
Retraction speed	30 mm/s
Flow	100 %
Support overhang angle	60°
Support density	5 %

5 DEVELOPMENT OF CFRP POLYCENTRIC KNEE

Carbon fabric of the necessary size is cut from the bundled roll of fabric. The part for fabrication is of small size so the circumferential dimensions of the part was used to achieve the shape of the carbon fabric ply to be laid inside the cavity. As multiple layers of similar dimensions were required for fabrication, a cardboard jig (**Figure 3a**) was used as a guide to maintain the repeatability of the layers. The mould was properly cleaned with WD-40 spray and wiped off with a cotton cloth to ensure there were no dust particles trapped. The cleaned surface of the moulds both core and cavity were applied with PVA release agent, a suitable, effective release layer for vinyl ester, polyester and epoxy composites. The closed moulds used were 3D printed, while the application of a thick film of PVA helps in levelling out the layers created during the FDM process and in turn increases the surface finish of the finished part. After applying a coat of PVA, the moulds were left undisturbed for 45 min until the PVA fully dried. A coating of PVA also ensures the easy removal of the part after curing. The carbon fabric plies were carefully arranged inside the cavity portion of the mould without any distortion. The plies were stacked up one above the other ensuring that the carbon fabric comes into contact with inner faces of the core and cavity when the mould is closed. **Figure 3b** shows the initial arrangement of carbon fabric inside the cavity of the mould for the knee joint part.

A challenge in this process is to properly arrange the carbon fabric layers without the fiber strands getting separated from the fabric. Use of an adhesive spray prevents end strands separation, wrinkling and easy handling of the carbon fabric. A 995 multipurpose spray adhesive compatible for carbon fabric was used. The 20 layers of carbon fabric with the 0°/90° orientation where tightly arranged inside the cavity. The unwanted pieces and strands of the Carbon Fabric protruding outside the cavity during the stacking process were removed gently from the surface of the mould. A rubber cord of 3 mm diameter is seated inside the groove on the surface of the cavity to provide proper sealing and generate a good vacuum.

Once the stacking process is complete, the core was placed over the cavity and is tightened in a bench vice. Fasteners were used to provide uniform compression of the mould and also to prevent any air leakage. **Figure 3c** shows the closed mould with fasteners and sealant tape. **Figure 3a** to **3e** shows the entire VARIM arrangement for developing the bottom component of the knee prosthesis. The fabrication process includes a vacuum pump, catch pot and other connectors. A double-stage oil vacuum pump was employed to produce the vacuum and the closed moulds were ensured leak proof before impregnating the epoxy resin and hardener mixture. The catch pot was used to trap the excess resin after the infusion was complete. Based on the weight of the fabric ar-

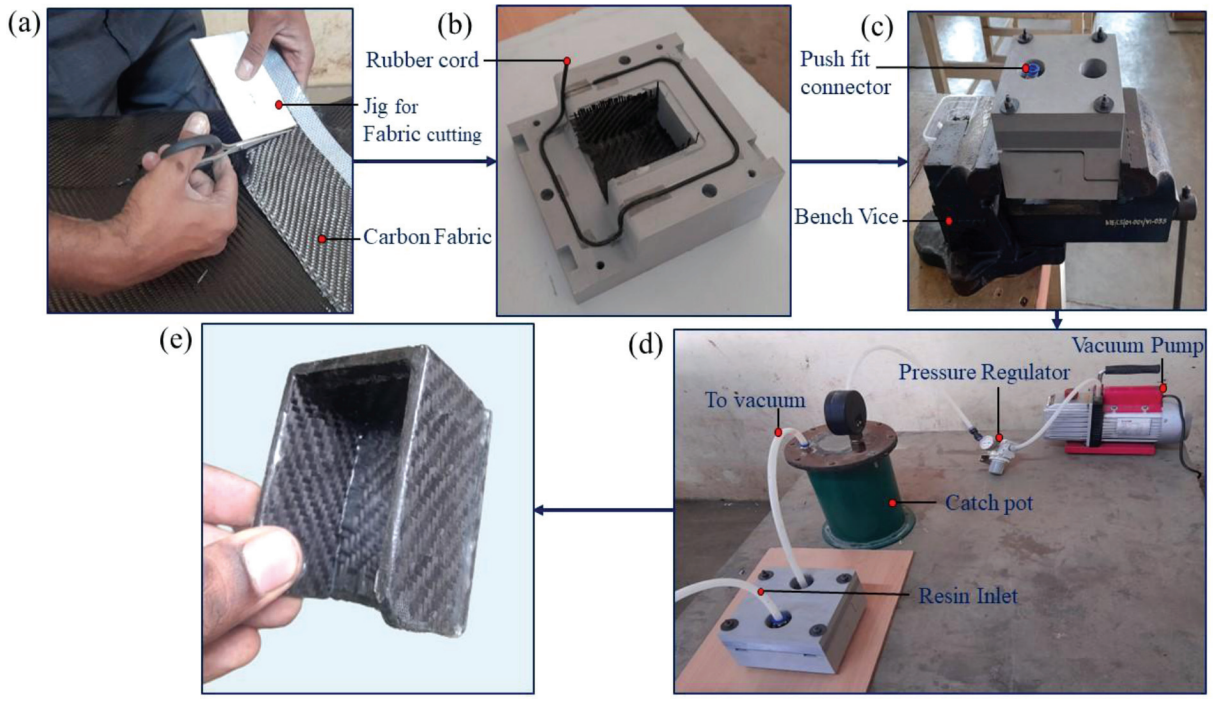

Figure 3: Schematic of fabrication process using closed moulds

ranged inside the mould for each part, the resin-hardener mixture is weighed and taken inside a beaker. The resin and hardener were mixed in the ratio of 10:1. The vacuum pump was turned on after preliminary arrangements for flushing out the air trapped inside the moulds to ensure the flow consistency while infusing the resin. As soon as the vacuum was checked, the resin-hardener mixture from the beaker was infused into the moulds via tubes. The liquid mixture was forced into the moulds and the stacked fabric layers were impregnated with the resin. The leftover resin was trapped in the catch pot. Both the ports were confirmed airtight throughout the process. The connector tube was disconnected after an hour of the infusion process and the setup was left undisturbed 12 h for the resin to cure. After curing is complete, the moulds were removed carefully and the CFRP part was ejected out. PVA sticking on to the part was washed off. Slight patch works with chopped carbon fiber and resin mixture were done to ensure a proper look. The extra protrusions and other projections were trimmed off to achieve a better appearance. Holes were drilled as per necessary dimensions, at proper locations for sleeve insertion during the assembly of components.

The front and rear links of the polycentric knee were cut from a CFRP laminate of size 250 mm × 180 mm × 5 mm as per appropriate dimensions precisely by an abrasive water jet cutting process (AWJCP). For laminate preparation, a glass plate was cleaned with release agent and coated with PVA. Over the base glass plate the carbon fabric was placed over it. The sides of the fabric cut were taped to avoid separation of the fibres. The fabric layers were stacked one above the other with normal orientation. The poly spiral hose and the sealant tape were arranged surrounding the stacked fabric layers. The peel ply, green infusion mesh and polyethylene vacuum bagging film (0.05 mm thickness) were placed over the fabric and sealed along the sides completely. The resin flow port is fixed at the centre of the arrangement and sealed (**Figure 4a**). The inlet of the poly hose around the fabrics was connected to the vacuum pump. The pump was

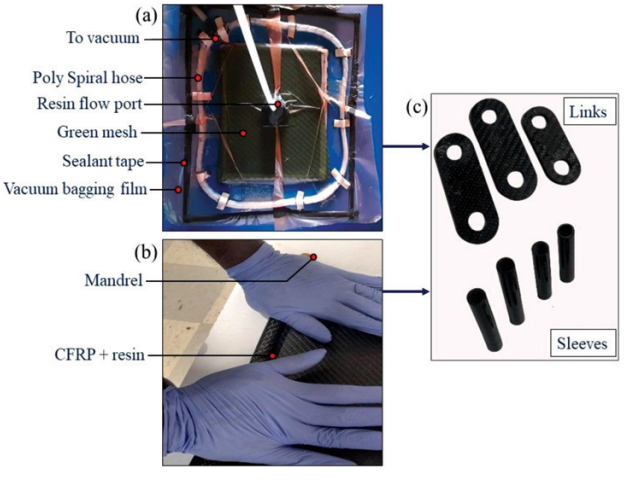

Figure 4: Fabrication of sleeves and links

Figure 5: Fabricated CFRP made polycentric knee

switched on and the vacuum was developed inside the sealed arrangement. The resin flow port is connected to the container with the resin hardener mixture. The vacuum generated draws the resin hardener mixture and the mixture starts to flow through the fabric layers. The air bubbles and the excess resin were removed out through the poly spiral hose attached along the sides. After curing, the accessories were removed and the laminate was

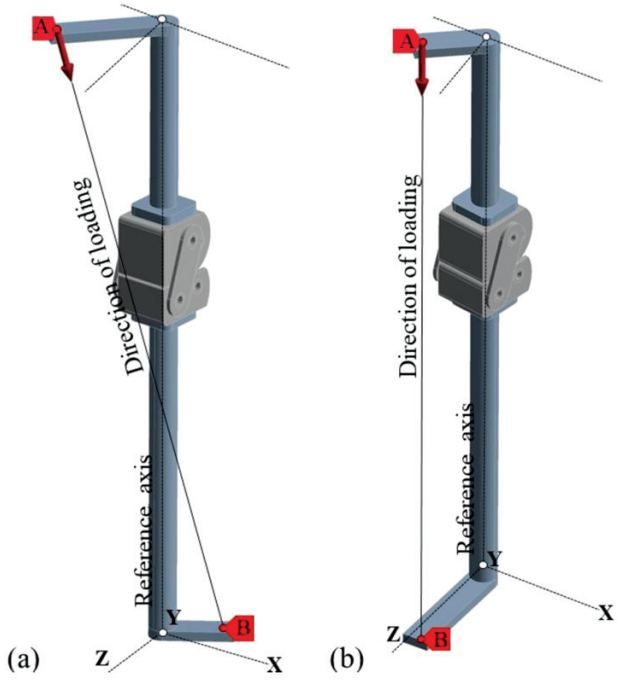

Figure 6: Representation of: a) loading configuration I, b) loading configuration II

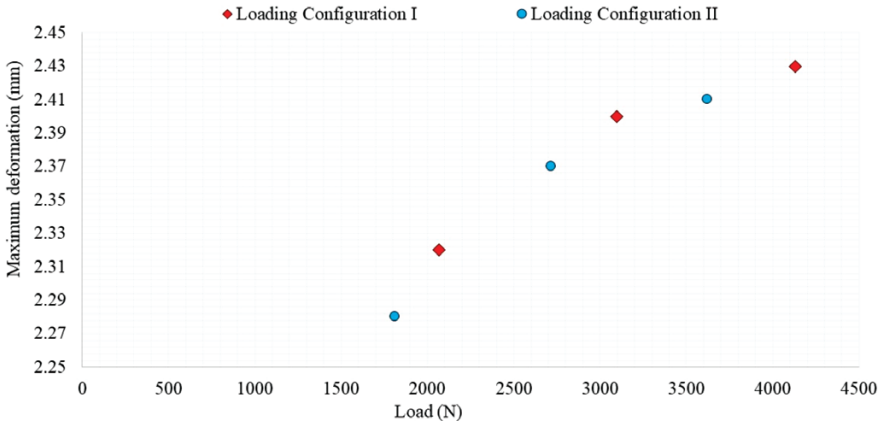

Figure 7: Deformation values for the applied loads as per standard

taken. In AWJCP, Garnet 80 mesh was used as the abrasive with the feed rate of 700 gm/min, travelling speed of 1200 mm/min and working pressure of 3700 Bar.

Sleeves for the polycentric knee were prepared with a roll wrapping process. A wooden mandrel of dimeter 10 mm and length 300 mm with perfect surface finish was taken. The entire surface of the mandrel was applied with PVA and left to dry. The carbon fabric length and width as per the circumference of the tube was cut for the initial layer. For the subsequent layers the size of the carbon fabric was extended on each wrap to allow for increasing in diameter. The carbon fabric was wetted upon with epoxy resin hardener mixture and are laid flat on the glass plate. The mandrel was firmly pressed down and was rocked back and forth so that the fabric should tack down onto the mandrel. Once the process was started it was very important to keep a really positive pressure till the process ends, ensuring that fabric wraps very tightly. A flat plate when kept over the roll allows us to exert a downward pressure and rolls forward. Twelve complete rolls were made to achieve a thickness of 2.5 mm. If the carbon fabric was not wrapped firmly enough, wrinkles occur as the shrink tape contracts, compromising the part's structural integrity and appearance. A shrink tape consolidates the material onto the mandrel so it was wrapped very tightly. The consolidation occurs when it was actually wrapped, maintaining a consistent tension. After curing the shrink tape was peeled off. An ejector pin was placed at the one end of the mandrel, tapped with the hammer and the mandrel falls off.

The sleeve preparation using the roll wrapping process is shown in **Figure 4b** and the links precisely cut from the laminate prepared are shown in **Figure 4c**. Based on the location of the sleeve and dimensions, the carbon fabric tube was cut into separate pieces. The individual parts were assembled together as per the proposed model using fasteners. The initial prototype of the CFRP polycentric knee is shown in **Figure 5**.

6 EXPERIMENTAL TESTING

The testing of the fabricated CFRP prosthetic knee was conducted based on the ISO 10328: 2016 standards.[36] ISO 10328 is a standard that provides guidelines for the mechanical testing procedures for lower-limb prosthetic components. The criteria include proof and ultimate strength tests. The fabricated knee was checked against the P4 loading conditions prescribed in ISO 10328. Proof and ultimate strength tests were performed in Tinus Olsen 10ST Universal testing machine (UTM). A Graphical representation of the test setup with loading direction is shown in **Figure 6a** and **6b**, with top (proximal) and bottom (distal) loading sites A and B. According to standards, the distance between the loading points must be 650 mm and must be positioned with an offset to the reference axis. The necessary offsets of the loading points for loading configuration I are as follows: Point A, positioned 89 mm front to Y axis and 74 mm left of Z axis and Point B positioned 52 mm behind Y axis and 39 mm right of Z axis.

The necessary offsets of loading points for loading configuration II are as follows: Point A, positioned 51 mm front of Y axis and 44 mm left of Z axis and Point B positioned 124 mm in front of Y axis and 22 mm

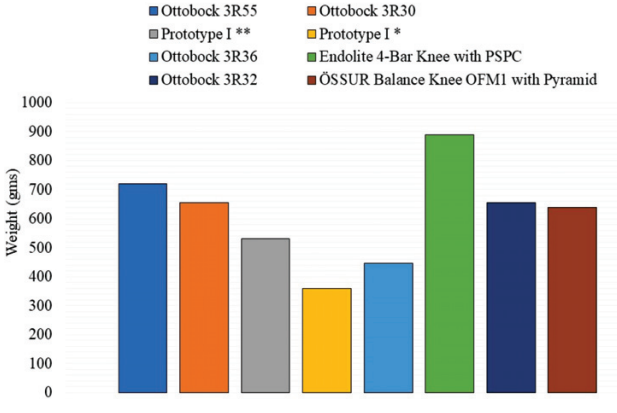

Figure 8: Comparisons in terms of weight with commercially available 4-bar knee prosthesis

right of Z axis. End attachments were fabricated using mild steel as per the requirements and were assembled with the CFRP prosthetic knee in the middle to achieve the required length and offsets. Length and alignment measurements were checked again after the test sample was mounted on the UTM. For Proof tests a load value of 2065 N was applied in loading configuration I and 1811 N was applied in loading configuration II for 33 s at a loading rate of 100 N/s. For ultimate strength tests, 3098 N and 4130 N was applied in loading configuration I and load values 2717 N and 3623 N were applied in loading configuration II for 33 s at the similar loading rate as for the proof tests. The deformation for the given loads was recorded and upon unloading, the CFRP prosthetic knee was checked for any failure after each load test.

7 RESULTS AND DISCUSSIONS

From experimental testing as per ISO standards, it was observed that the fabricated knee was able to sustain the proof and ultimate loading conditions. A load versus displacement plot with datapoints was obtained from the UTM for proof and ultimate strength tests. **Figure 7** is the graphical representation of the maximum deformation values obtained for the applied load values during static structural testing of the fabricated knee.

The maximum deformation recorded was 2.43 mm for the applied load of 4130 N in loading configuration I. As per the standards, for any lower-limb prosthetic component to pass loading conditions the component should withstand loads applied for time period of 30 ± 3 s during the proof and ultimate strength test conditions and shall not deform more than 5 mm for the total specimen length (650 mm). During the physical examination after each test, the fabricated CFRP knee showed no permanent deformations or failure, confirming its structural stability. The total weight of the developed CFRP knee prototype was 531.5 g inclusive of CFRP parts, top and bottom adapter joints, M5 and Joint connector bolt screws with barrel nut which represents a light and resistant model. The top portion of the CFRP knee was connected to a socket via a socket adapter and pyramid adapter, the bottom portion was connected to the pylon tube through the pyramid adapter and a tube clamp adapter. A graphical representation of the weight comparisosns of commercially available 4 bar polycentric knees is presented in **Figure 8**.[37–39] Prototype I* and Prototype I** represents CFRP made knee prosthesis fabricated in the current work without and with four hole male pyramid adapter attached.

Though 3D printing provided an in-house solution for the development of moulds for the infusion process, ejecting the cured product presented complications. To give the cured portions a presentable appearance, trimming and surface finishing were also employed as post-treatments. The composite knee prosthesis developed in this research is a prototype. Additional modifications and iterations are required for clinical trials and implementation. Manual calculations were used to approximate the geometric dimensions of this design. It is anticipated that additional modifications like changes in link lengths, thickness, provisions for including joints will improve the quality and performance of the product. When considering manufacturing aspects, the process time, queue time, inspection time, etc., are expected to be thoroughly analysed prior to launching the commercial production. With standard operating procedures and application of design for manufacturing and assembly methodologies for moulds and the components VARIM has the capability to produce high-quality void-free components with a good finish. Concerns regarding the availability of prostheses for transfemoral amputees can only be addressed when mass production, standard designs, and protocols are considered.

8 CONCLUSION

The infusion technique for the fabrication of a composite prosthetic knee for a TF prosthesis is described in detail. The results are more focused on the mechanical aspects of the CFRP knee prosthesis. The findings indicate that the CFRP knee-prosthesis prototype developed was structurally stable in accordance with ISO 10328 standards. The methodology practised in the present research work can be chosen by future researchers for the design and development of customised composite prosthetic parts with the aid of additive manufacturing technologies. A prosthetist with the available working space, instruments and a VARIM arrangement, can manufacture and offer a workable, reliable and custom composite prosthetic part for an amputee who cannot afford expensive options.

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