Proceedings of the International Conference on Industrial Engineering and Operations Management

Publisher: IEOM Society International, USA DOI: 10.46254/NA10.20250006
Published: June 17, 2025

Applications for Additive Manufacturing Techniques and Material Selection Investigations for Fabrication of Prosthetic and Orthotic Devices

M.S. Jumani, Asif Nawaz Wassan, Irfan Ahmad and Athar Khoso
Mehran University of Engineering and Technology
Jamshoro, Pakistan
saleh.jumani@faculty.muet.edu.pk, asif.wassan123@gmail.com
khoso.irfan2017@gmail.com, Akhoso@hanger.com

Abstract

Applications of additive manufacturing techniques have received tremendous attention worldwide in different manufacturing sectors, including the medical sector. The techniques fabricate products layer-by-layer additive-based fabrication process guided through CAD CAD-based designed product model. This has given the designers much more design freedom and has minimized the product design limitations. The techniques have shown the advantage of production of custom-made complex designed products with higher accuracy and repeatability. In the medical sector for the manufacturing of prosthetic and orthotic devices and rehabilitation aids, these techniques have the optimum solution for manufacturing patient-specific and individual anatomy fit-based devices and satisfy customization requirements. In the medical sector foot orthosis is a medical device prescribed in the prosthetics and orthotics practices for the treatment of foot-related diseases. In this research for the fabrication of custom-made foot orthosis, six of the well-established commercial additive manufacturing techniques were used. The research also investigates the material selection and different properties of the materials used in different additive manufacturing techniques and examines the different material properties, including mechanical properties, strength, toughness, and stiffness. The goal is to identify the optimal materials that withstand during the operational phase of the custom-made devices with patients and enhance the product durability and improve overall quality of life of the patients while supporting sustainable practices and meeting regulatory requirements of the AM-based produced devices and aids.

Keywords
AM techniques, CAD design, foot orthosis, AM materials, bending stiffness

1. Introduction
Additive manufacturing, also known as 3D printing techniques, is a group of techniques that directly fabricate the 3D parts guided by a computer-aided design (CAD) product model. Thus, eliminates the conventional methods of molding, casting, and tooling in the fabrication process. The techniques directly fabricate the CAD-designed parts through the addition of materials layer-by-layer without using tools and equipment (Lawrence 2016). Some of the commercially well-established techniques are fused deposition modelling (FDM), stereo lithography (SLA), selective laser sintering (SLS), and 3D printing (3DP). Presently, in different manufacturing sectors including electronics, computers, automotive, aerospace and the medical field, the manufacturers are adopting and harnessing the built-in advantages of the additive manufacturing techniques (Bolugoddu et al. 2021). In medical sector, there are various successful examples of applications of additive manufacturing techniques for fabrication of be-spoke and custom-made aids and implants and devices (Saeideh et al. 2020; Junqi li et al. 2022; Andrysek and Ramdial 2023). These techniques have shown the benefits in the fabrication of individual anatomical parts, custom-made devices and products with increased fit and accuracy and overall improved product quality. In the Fig 1, show the examples of

successful commercial scale production of custom-made medical devices (a) in-the-ear hearing aid device (b) dental aligner braces and (c) lower limb prosthetic socket (Jumani. 2013 and Hopkinson et al. 2016).

(a) (b) (c)

Figure 1. Additive manufacturing-based custom-made medical devices

In clinical practices of prosthetics and orthotics, foot orthosis is prescribed as the externally supported device/aid for the treatment of foot related problems including by birth foot defects, injuries occurred in sports, biomechanical disorders and different diseases affecting the foot such as rheumatoid arthritis and diabetes. Foot orthosis model (a) and (b) fabricated orthosis to support the foot arch shown in the Figure. 2.

(a) (b)

Figure 2. Foot orthosis model and Foot orthosis for arch support.

1.1 Conventional foot orthosis fabrication methods (Literature)

In the provision of the foot orthoses, the manufacturing process involve handcraft art and individual expertise in the design and manufacture of supportive and comfortable orthosis in order to support foot and provide the comfort, prevent disability, improve foot function and overall gait stability in the users. The conventional methods for design and manufacture of foot orthoses are based on trial and hit method involving manual activities and individual expertise and craft-based activities and processes (Junqi li et al. 2022; Zheng et al. 2021). These methods are highly labor intensive and based on manual work involving increased time in manufacturing activities. The conventional manufacture process has three main stages (i) Geometry capture of the foot. (ii) Incorporation of orthosis features in the developed foot mold (iii) Manufacture of the orthosis. Conventional design and fabrication starts by taking the geometrical measurements of the foot using plaster of Paris or foam impression box. After the geometry of the foot obtained a positive mold is developed in which the required orthosis features and controls such as wedging angles, heel cupping and different other required features are incorporated. After that, the orthosis shell is developed around the positive mold.

In another traditional foot orthosis manufacturing method, the thermoplastic sheet that is larger in measurements than the anticipated orthosis is placed in pre-heated oven at controlled temperature so that the plastic sheet become pliable. In the next step, the heated plastic sheet is then draped over the positive mold developed. The pliable sheet pressed and smoothed over the mold until the sheet gets in full contact with the positive mold. After that, the cutting lines are marked on the draped plastic sheet on the mold. The last step is cutting of the draped plastic sheet according to drawn lines. Finally, the orthosis shell of plastic sheet is smoothed with grinder for finishing of the orthosis (Doxey 1995 and Pratt 1995).

Another method of design and fabrication of the custom-made orthoses is utilization of vacuum press or vacuum former. Many authors have recognized that manufacture of the orthoses using vacuum press shell resulted in more uniform and given better results than heated plastic draping method (Brown and Smith 1976). The manufacturing process starts with (a) Wood orthosis developed mold is placed in the vacuum press and then heated plastic sheet draped over the wooden mold (b) The heated plastic sheet get the mold shape (c) next step involve cooling with air and spray mist and finally release and trimming of the developed shell is done.

With the applications of computer in manufacturing, in the design and manufacture of the orthoses milling machines were introduced in the manufacturing process. These systems are known as computer-aided design and computer-aided manufacturing (CAD/CAM) orthosis fabrication systems (Lasurdi and Nielson 2000). Currently, the custom-made foot orthoses design and manufacture process involve (i) digital scanning equipment for foot geometry capture (ii) orthoses design using CAD systems (iii) Milling machine for milling the block of EVA material. This systems use the digital technology for foot geometry capture using 3D scanning of the foot (b) orthosis designing software (c) milling machine for milling of EVA block of material (d) Manual trimming and smoothing of the orthosis shell. The CAD/CAM based applications in the fabrication process using milling machines currently considered as the closest solution to fully customized-on site manufacture of the custom-made foot orthoses (Jumani 2013). However, the milling machines have limitations in the fabrication and incorporation of the complex orthoses design and required functional features minimize the product design range using the CAD/CAM techniques (Pallari et al. 2010). Additionally, the experts in the prosthetics and orthotics industry have raised significant training issues for the applications and use of CAD/CAM techniques in the prosthetics and orthotics manufacturing industry (Otto 2008).

2. Applications of additive manufacturing techniques in foot orthosis fabrication

In the fabrication of foot orthosis, six of the commercially well-established additive manufacturing techniques were used. The CAD based designed model of the orthosis in the stl. file format was used. The model of the orthosis was designed in order to support, prevent foot deformity, improve the biomechanical movements and overall foot functions for the treatment of rheumatoid arthritis patients. Table 1. Shows the measurements and dimensions of the CAD based deigned model of the orthosis shell.

Table 1. Measurements of the CAD-based orthosis model

Specifications and measurements of orthosis model	
CAD based orthosis model	Width 179.52, depth: 79.81 mm height 50.82 mm

Figure 3. Shows the volume of 83596.162 mm³, surface area of 32145.781 mm² and bounding box of 179.52 x 79.81 x 50.82 mm of the designed orthosis model. The orthosis model was fabricated and using the default proprietary machine software. Six of the well-established AM systems were used with default software parameters having different slice thicknesses. There are good physical reasons to use a particular slice thickness in different AM manufacturing systems. This is related to physics and chemistry of the layer consolidation method during the fabrication process in different AM manufacturing systems. All the AM systems were optimized with standard operating parameters of the machines. Moving away from these parameters often invalidates the warranties and can deliver a poor quality product (Jumani 2013).

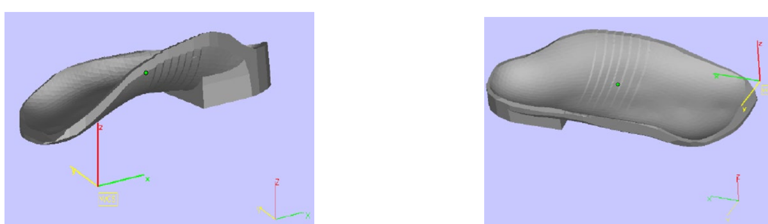

Figure. 3. CAD based designed orthosis model used in AM manufacturing techniques \

The build-time for orthosis model is presented in the table 2. Six of the commercially established additive manufacturing techniques were used in the fabrication of CAD based designed orthosis model. The AM systems were (i) Fused deposition modelling (FDM) technique using Dimension SST 768 system (ii) uPrint system by Stratasys, Inc, USA, (iii) 3D PolyJet; Connex^{TM} 500 system by Objet Geometries, Israel, (iv) Stereolithography, *ipro* 8000 SLA system, (v) V-Flash 3D system and (vi) Selective laser sintering *spro* SD 60 SLS system by 3D systems Inc, USA.

Table 2. Build-time for CAD-based designed orthosis model.

Additive manufacturing (AM) systems	Build volume. mm	Approx. resolution mm	Build Volume cm^3
Dimension SST 768 FDM	203 x 203 x 305	0.245 mm	19677.38
Dimension uPrint FDM	203 x 152 x 152	0.245 mm	4719.47
Polyjet Connex 3DP 500	500 × 400 × 200	0.1 - 0.3 mm	40000.00
ipro 8000 SLA	650 x 350 x 300	0.05 mm	68250.00
3DP V-Flash	178 x 229 x 203	0.22 mm	8259.08
spro 60 SD SLS	381 x 330 x 457	0.08 mm	57458.61

3. Materials selection for foot orthosis.

In medical sector, there are many 3D printing materials are available with different properties used for fabrication of custom-made implants, anatomical models for surgical preparation, medical tools, equipment and rehabilitation aids and devices in prosthetics and orthotics (Qian et al. 2018; Mallikarjuna et al. 2020; Amit et al. 2021). The AM based materials used for medical applications must have the characteristics and properties including, biocompatibility, sterilizability, bio usability and temperature sensitivity along with good mechanical properties including strength, durability and stiffness. Currently most of the materials used in prosthetics and orthotics for fabrication of foot orthoses are rigid to semi rigid materials, as the primary aim of foot orthoses is to improve foot functionality, provide support and improve gait of the patients. The soft materials have the tendency to "bottom out" quick wear and tear and break down rapidly under the operational phase of activities that significantly reduces the orthoses service life and support and durability (Goodman 2004; Caselli 2004). The material used for foot orthoses must combine the physical and mechanical properties and characteristics including elasticity, density, durability, flexibility, compressibility, strength and stiffness, ease of fabrication and availability (Rome 1990; Nicolopoulos et al. 2000). Stiffness and strength are the main two important characteristics in orthoses materials along with other mechanical and physical properties; as the orthoses shell during the utilization phase have to carry out and withstand the whole body weight of the patient in parallel with serving and addressing specific treatment requirements of the patients.

- **Requirements of the material for foot orthosis.**
- Hard and stiff, enough to be able to realign the foot when most of the body weight is going through it during the service phase.
- Impact resistant as the orthoses should be able to withstand rough handling.
- Should be able to withstand extended use with patients without any change in the material properties, ease of fabrication, and ease of use and availability of the materials.

4. AM based materials used in orthosis model fabrication

The AM based materials used in fabrication of orthosis model is presented in table.4.

Acrylonitrile butadiene styrene (ABS) is a common thermoplastic polymer material used in fused deposition modeling (FDM) technique. The material results in high surface finish products, cost effective and complex shapes can easily fabricated. ABS provides favorable mechanical properties that includes impact resistance, toughness and rigidity when compared with other common polymers. The materials have also properties of lightweight, impact resistant, toughness.

1. **"VeroWhite"** a rigid polymer that have the functionally graded material properties, which helps designers in fabrication of complex deigned products using 3D printing additive manufacturing technique. The Objet geometries Inc. is marketing the verowhite FullCure 830 material that is specifically developed for fabrication of custom-made hearing devices and other medical aids. The material reflects in the products the combination of dimensional stability and high-detail visualization, produce smooth and accurate prototype and surgical models and tools.
2. **Accura 55** stereolithographic material is rigid, strong, functional assemblies and is suitable for short-run production parts. The material have the high surface finish whereas the complicated parts can easily fabricated. The material also have the high accuracy and properties of high thermal durability.
3. **FTI-GN** material is strong, durable and printed parts using the materials comes with excellent surface quality and detailed product features.

4. **Duraform** polyamide nylon is tough, durable and having the properties of biocompatible material used in selective laser sintering technique. The material is durable, good mechanical properties, excellent surface finish and used in production medical parts.

Table 3. Materials used in different additive manufacturing techniques

Additive manufacturing (AM) systems	Build volume. mm	Approx. resolution mm	Material used
Dimension SST 768 FDM	203 x 203 x 305	0.245 mm	ABS P400
Dimension uPrint FDM	203 x 152 x 152	0.245 mm	ABS P430
Polyjet Connex 3DP 500	500 × 400 × 200	0.1 - 0.3 mm	Verowhite 830
ipro 8000 SLA	650 x 350 x 300	0.05 mm	Accura 55
3DP V-Flash	178 x 229 x 203	0.22 mm	FTI GN
spro 60 SD SLS	381 x 330 x 457	0.08 mm	Duraform

Table 4 shows the different mechanical properties of the traditional materials from semi rigid to rigid materials for orthoses fabrication. In rigid and semi-rigid custom orthoses, the thickness of orthoses shell commonly ranges from 2 mm to 4 mm (Mcpoil and Brocao 1985; Lockard, 1998; Steven 2002).As the custom foot orthoses are prescribed for provision of comfort, improvements in the foot function and overall increased gait stability. The implications of bending stiffness are to improve foot function and comfort. The value of bending stiffness depends on the specific intended function and comfort in the prescribed orthoses. The orthoses prescribed in order to primarily provision of, pain relief require a quite low stiffness in order to be comfortable. The orthoses prescribed in order to improve the foot function typically require higher stiffness.

Table 4. Mechanical properties of the traditional materials (Edupac 2011)

Mechanical properties	**Units**	
Ethylene vinyl acetate EVA		
Young's modulus	10 - 40	MPa
Yield strength	12-18	MPa
Tensile strength	16 - 20	MPa
Fracture toughness	0.5 – 0.7	MPa
Polypropylene PP		
Young's modulus	89 - 1500	MPa
Yield strength	20.27 - 37.2	MPa
Tensile strength	27.6 - 41.4	MPa
Fracture toughness	3 – 4.5	MPa
Acrylonitrile butadiene styrene ABS		
Young's modulus	1100 - 2900	MPa
Yield strength	18.5 - 51	MPa
Tensile strength	27.6 – 55.2	MPa
Fracture toughness	1.19 – 4.29	MPa
Polycarbonate PC		
Young's modulus	2000 - 2400	MPa
Yield strength	59 - 70	MPa
Tensile strength	60 - 72	MPa
Fracture toughness	2.1 – 4.6	MPa
Poly methylmethacrylate (PMMA)		
Young's modulus	2240 - 3800	MPa
Yield strength	53.8 – 72.4	MPa
Tensile strength	48.3 – 79.6	MPa
Fracture toughness	0.7 – 1.6	MPa
Polyamides PA		
Young's modulus	2620 - 3200	MPa
Yield strength	50 -94.8	MPa
Tensile strength	90 - 165	MPa

Table 5. Relative bending stiffness in conventional materials (2 to 4 mm thicknesses)

Traditional materials	Dimension (mm)			E (MPa)	Relative Bending Stiffness (N.mm)
	Length (l)	Width (w)	Thickness (d)		
1. Ethylene vinyl acetate EVA	80	10	4	10	640
			3.5		428.75
			3		270
			2.5		156.25
			2		80
2. Polypropylene PP	80	10	4	89	5696
			3.5		3815.875
			3		2403
			2.5		1390.625
			2		712
3. Acrylonitrile butadiene styrene ABS	80	10	4	1100	70400
			3.5		47162.5
			3		29700
			2.5		17187.5
			2		8800
4. Polycarbonate PC	80	10	4	2000	128000
			3.5		85750
			3		54000
			2.5		31250
			2		16000
5. Poly methyl methacrylate (PMMA)	80	10	4	2240	143360
			3.5		96040
			3		60480
			2.5		35000
			2		17920
6. Polyamides PA	80	10	4	2620	167680
			3.5		112332.5
			3		70740
			2.5		40937.5
			2		20960

Table 6. Relative bending stiffness in AM materials (2 mm to 4 mm thicnesses).

RM Materials	Dimensions (mm)			E (MPa)	Relative Bending Stiffness (N.mm)
	Length (l)	Width (w)	Thickness (d)		
1. ABS 400	**80**	**10**	**4**	**1834**	**117376**
			3.5		78632.75
			3		49518
			2.5		28656.25
			2		14672
2. ABS 430	**80**	**10**	**4**	**2204**	**141056**
			3.5		94496.5
			3		59508
			2.5		34437.5
			2		17632
3. ACCURA 55	**80**	**10**	**4**	**2690**	**172160**
			3.5		115333.75
			3		72630
			2.5		42031.25
			2		21520
4. Duraform PA	**80**	**10**	**4**	**1387**	**88768**
			3.5		59467.625
			3		37449
			2.5		21671.875
			2		11096
5. FTI-GN	**80**	**10**	**4**	**1700**	**108800**
			3.5		72887.5
			3		45900
			2.5		26562.5
			2		13600
6. VeroWhite fullcure 830	**80**	**10**	**4**	**2137**	**136768**
			3.5		91623.875
			3		57699
			2.5		33390.625
			2		17096

4. Results and Discussions

As earlier mentioned, in rigid and semi-rigid orthoses fabricated from nylon or propylene material the thickness of orthoses shell ranges from 2 mm to 4 mm, so there is not an ideal value of bending stiffness in custom-made orthoses. However, there is a useful range of values of bending stiffness according to thickness size of the orthoses shell prescribed for specific purposes (pain relief or foot function). Table. 6 shows the range of relative bending stiffness of conventional materials and Table. 7 shows the relative bending stiffness of additive manufacturing based materials with varying thicknesses from 2 mm to 4 mm for the orthosis shell.

The orthoses prescribed for improving the foot function and correct the walking behavior is fabricated from rigid materials such as Polypropylene (PP) in different thickness sizes ranging from 2 mm to 4 mm according to conditions and requirements of the patients. Table. 6 shows the calculated values for relative bending stiffness in Polypropylene (PP) material ranging from 712 to 5696 N.mm. The values of relative bending stiffness in additive manufacturing based materials shown in Table 6 qualify the range of values in traditional materials used for orthoses shell of varying shell thickness sizes. Figure 4 shows the relative bending stiffness of traditional materials with comparison to relative bending stiffness of rapid manufacturing materials, shown in the Figure 5. The comparison shows that the additive manufacturing based materials offer potential to be used as material for custom-made orthoses for end use product material.

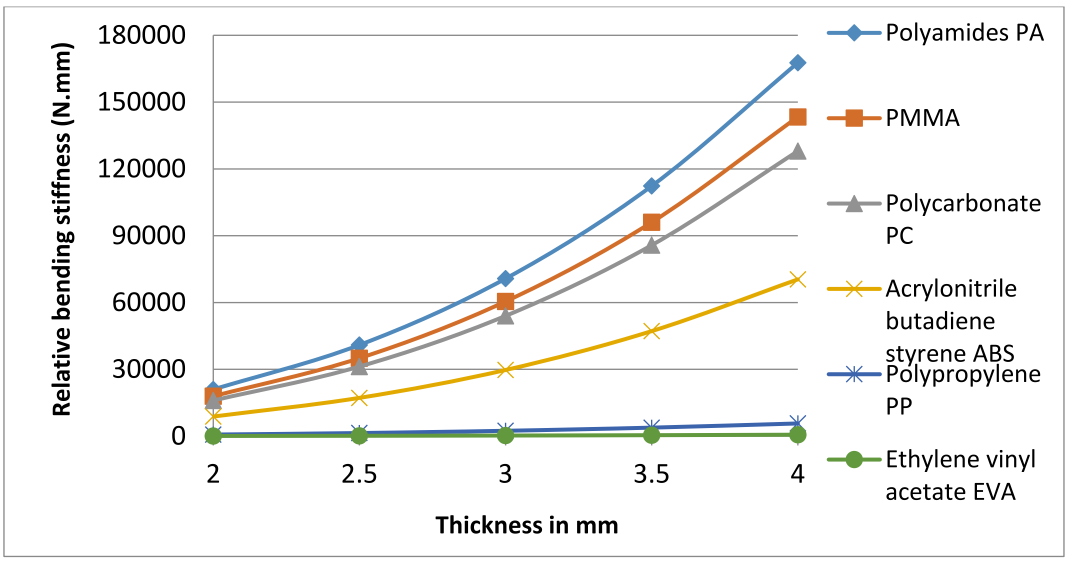

Figure 4. Relative bending stiffness in traditional materials

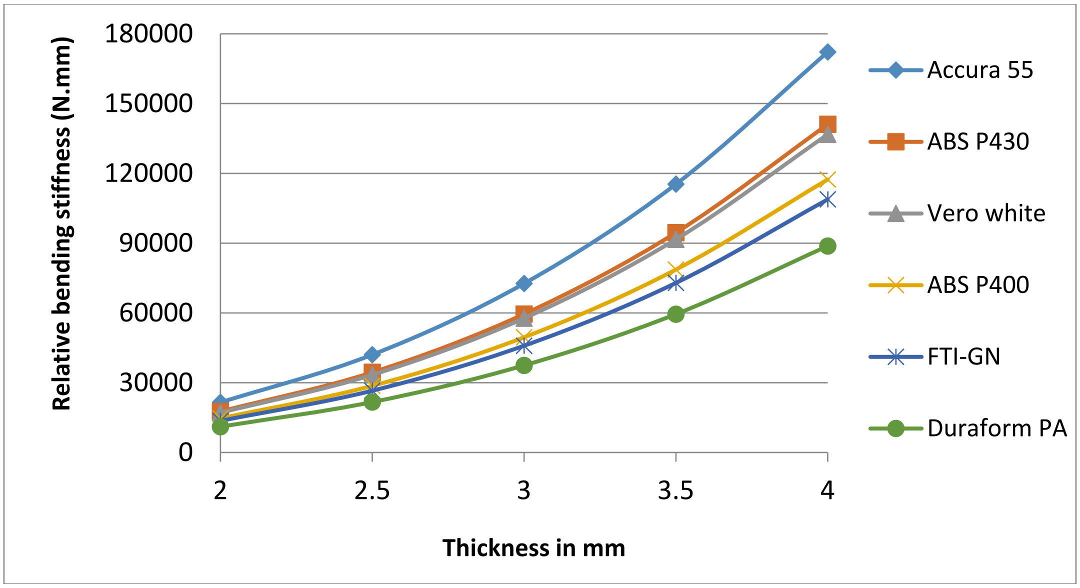

Figure 5. Relative bending stiffness in AM based materials

5. Conclusion

The analysis and comparison of the mechanical properties of the traditional orthosis materials used in the fabrication of custom foot orthoses with the additive manufacturing-based materials showed that currently commercially available additive manufacturing materials could be used in the orthoses fabrication as an end-use product material. However, for the durability and reliability of the parts and devices fabricated and prescribed in the prosthetics and orthotics field, fatigue behavior of the different AM based materials need to be further investigated as the materials gets degradation under loads and unloads during service life phase of the devices. Further research is ongoing in terms of influence of build parameters and effects of the part orientations in different additive manufacturing techniques. Further in medical devices and aids fabrication the most important is that regulatory framework developed by the Governments regarding the AM based materials; manufacturer must fulfills the regulatory requirements in terms of balancing the safety, care and innovation; as the AM techniques have revolutionized the medical field, where at the health and care facility become manufacturer. For sustainability, the AM techniques have the advantage of reduced waste during fabrication, replacing the waste full manufacturing processes as in milling and machining, higher energy efficiency and capability of fabrication of product on demand and on-site product manufacturing particularly in health care sector.

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Biographies

Dr. Muhammad Saleh Jumani working as Professor in the Department of Industrial Engineering and Management, Mehran University of Engineering and Technology, Jamshoro holds a PhD in the field of Additive manufacturing and applications of AM in advanced orthotics and prosthetics and material engineering from a Newcastle University United Kingdom. Specializing in the commercialization and business aspects of prosthetics and orthotics research, Professor Jumani focuses on 3D printing applications, developing innovative digital design and manufacturing systems in prosthetics and orthotics. His work bridges the gap between cutting-edge academic research and market-ready custom-made medical devices, fostering collaborations between academia and industry. By advising companies on new material and technology applications, market trends and regulatory requirements, Professor Jumani suggest that new AM based orthotics design and fabrication technologies meet the need of customers in health care systems. A published author and sought-after speaker, he play a crucial role in advancing both the scientific field and new trends in prosthetic and orthotics industry.

Asif Wassan, is enrolled as PhD student in Department of Industrial Engineering and Management. Currently he is engaged in development of system of commercialization and business aspects of prosthetics and orthotic research. His work bridges academic innovation and practical application, focusing on developing affordable, advanced prosthetics designs and fabrication process. By fostering industry-academia partnerships, Mr. Wassan is working on facilitating the transition of lab prototypes to market-ready products. He is engaged in strategic consulting for companies entering the prosthetics market; ensuring innovations meet regulatory and consumer needs.

Irfan Ahmed is a Ph.D. scholar in the School of Economics and Management at Nanjing University of Science and Technology, Chiana. His primary research interests focus on multi criteria decision-making, healthcare device industry and emerging technologies. Publications on these topics appear in Medical Devices, Mathematical problems in Engineering, and materials today: proceedings, among others.

Athar Khoso is an independent research scholar with thirty years of experience in Clinical Prosthetics and Orthotics. He is a Board Certified Prosthetist and Orthotist, holding a diverse educational background that includes prosthetics and orthotics, along with advanced degrees in computer science, Mechanical Engineering, and Technology Management. Khoso has dedicated his career to the advancement of prosthetics and orthotics care, blending his extensive clinical expertise with cutting-edge technology and engineering principles. His keen interest in research and design drives his commitment to developing next-generation prosthetics and orthotics solutions that enhance patient outcomes and quality of life. Through his innovative approach, Khoso continues to contribute significantly to the field, pushing the boundaries of what is possible in medical technology.