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Stiffness-Tailored Composites in Lower-Limb Load-Bearing Devices: A Review

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***Abstract*: Mechanical stiffness can be controlled at the device level with composite materials, especially carbon-fiber-reinforced polymers (CFRPs) and polyetheretherketone-based composites, which is a revolution in the design of lower-limb load-bearing devices. This review discusses the engineering of stiffness-tailoring strategies across three types of devices: ankle-foot orthoses (AFOs), prosthetic feet/running blades, and fracture fixation plates; validation of the engineering; and the translation of the engineering to clinical and biomechanical outcomes. In each of the three domains, a design challenge arises: the requirement to optimise the stiffness of the device to the mechanical requirements of the target tissue, loading regime and patient population, while maintaining its structural integrity. For AFOs, stiffness tuning refers to the compromise between maintaining push off power and stabilizing the joints, and an optimal stiffness window has been shown to result in a reduction of the metabolic cost of transport. In prosthetic feet and blades, the qualitative distinction of gait adaptations depends on the degree of regional stiffness difference between the hindfoot and forefoot, and energy-storage-and-return performance is related to walking speed and predictably depends on composite architecture. For the fixation of fractures, intentional stiffness reduction of the plate to the bone (e.g. CFRP, PEEK or functionally graded composites) helps reduce stress shielding and increases callus formation without compromising construct strength as required for clinical use. The review also highlights key gaps: there is no consensus in the stiffness measurement protocols across different stiffness device types, little evidence of longitudinal assessment of device adaptation and durability, and a lack of an evidence base for patient-specific optimization of stiffness. Future work involves computational stiffness-prescription tools, biodegradable composite fixation plates and easily accessible locally produced ESAR prosthetic feet in under-resourced environments.**

***Keywords*: composite materials, stiffness tailoring, ankle-foot orthosis, prosthetic foot, fracture fixation, CFRP, PEEK, biomechanics, lower limb.**

1. Introduction

Among the most complex mechanical requirements in biomedical engineering are those of load-bearing devices in the lower limb. Each device required to meet multiple requirements of being stiff enough to support body weight and control joint motion, compliant enough to dampen the impact forces of walking and allow physiological motion, and durable enough to withstand millions of load cycles. Conventional materials, such as stainless steel, titanium and rigid thermoplastics, meet the strength requirement easily but tend to be overly stiff, which is disruptive of biological function. Bone is protected by mechanical load by metallic fracture plates which prevent the formation of callus. Rigid thermoplastic orthoses have a negative effect on ankle push-off power. Although well designed metallic prosthetic feet can provide some degree of compliance, they cannot mimic the multi-axis graded compliance of the biological ankle-foot complex. One of the key differences between composite materials and monolithic metals and thermoplastics is that mechanical properties can be engineered with composite materials, not just selected. Designers can tailor the stiffness of these composite devices to a targeted clinical goal while maintaining freedom from the limitations of properties of a single material by controlling fiber type, volume fraction, orientation, lay-up sequence, and structural geometry [1], [2]. This design flexibility has resulted in many research efforts in the development of composite ankle-foot orthoses, energy-storing prosthetic feet, carbon-fiber running blades, and CFRP and PEEK fracture fixation plates.

A few reviews have already reviewed the use of composite materials in sports equipment in a general way [3], in the manufacture of prosthetic limbs [4] or in certain categories of sports equipment, such as prosthetic sockets [5] or ankle arthroplasty [6]. However, no one has studied stiffness tailoring as a goal for the entire spectrum of load-bearing devices used in the lower limb, from orthoses, prostheses, to internal fixation. The present review fills this gap. It brings together evidence from materials science, biomechanics, and clinical outcomes research to combine what is known about engineering composite stiffness, measuring stiffness, and how it translates to device performance in three device domains into a single treatment of stiffness as both a material property and a designable clinically relevant engineering parameter.

The review is organised as follows. The scope and literature identification process are described in section 2. The material science aspects of composite stiffness tailoring are laid out in Section 3. AFOs, prosthetic feet and blades are covered in sections 4, 5 and 6, respectively. Section 4 discusses AFOs while section 5 covers prosthetic feet and blades, and section 6 covers fixation plates used for fractures. A critical cross-device

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synthesis is given in Section 7 and Section 8 outlines research gaps and future directions.

2. Scope and Methods

This review will be based on composite materials used in the development of lower-limb, load-bearing devices for which stiffness is a major design consideration. The three categories of devices are: (1) ankle-foot orthosis (AFO) and custom dynamic orthosis (CDO); (2) energy-storing prosthetic feet, running-specific blades and powered ankle-foot prostheses; and (3) fracture fixation plates for the lower-limb skeleton, mostly tibia and its associated structures. Other implants, such as upper-limb implants, dental implants, soft-tissue scaffolds, and powered exoskeletons were excluded because the mechanical loading regimes and design goals are not comparable to the load-bearing function of the lower-limb implants.

The sources were obtained with the help of Google Scholar, PubMed, Scopus, and Web of Science using the following search terms: Stiffness tailoring, composite, carbon fiber, CFRP, PEEK, ankle-foot orthosis, prosthetic foot, energy storage and return, fracture fixation plate, and tibia. Publication date was not limited, but preference was given to studies published between the years 2014 and 2026 to reflect the state of the evidence. Sources prior to this time were preserved if they contributed conceptually and/or methodologically. A total of approximately 80 sources, including original research articles, systematic and narrative reviews, were identified as relevant to the scope of the review and synthesized.

3. 3. Material Foundations of Composite Stiffness Tailoring

A. Fiber-Reinforced Polymer Composites: Properties and Design Variables

Fiber-reinforced polymer (FRP) composites are composites that are composed of a continuous or discontinuous fiber phase contained in a polymer matrix. The mechanical properties that they bring to bear in designing load-bearing devices are not easily combined in any single class of materials: high strength/weight ratio, designable stiffness, corrosion resistance, fatigue tolerability, and radiolucency for carbon-fiber reinforced systems [1]. Rajak et al. have given extensive classification of all the fibers and matrices available and they have classified fibers as the main reinforcement material and stated that carbon, glass, Kevlar, and natural fibers are the main fibers available which have different stiffness, strength, and failure properties depending on the device application [1]. Carbon fibers have the greatest stiffness and strength per weight and thus are used most in AFOs, prosthetic blades, and fracture plates. Glass fibers, on the other hand, are lower stiffness at a lower cost and can be used in applications where compliance and accessibility are important in addition to structural function.

A composite component's stiffness is not only related to the fiber type but it is also related to the entire design process. One of the most important variables is the fiber orientation: unidirectional lay-ups allow for the greatest stiffness along the fibre axis, but result in highly anisotropic structures, while cross-ply and woven characteristics spread stiffness out isotropically, at the expense of peak fibre axis modulus [7]. Modulus, which is directly proportional to fiber volume fraction, is predicted for the first order by the rule of mixtures, but the quality of the interface between fiber and matrix is also important [8]. The in-plane properties and interlaminar shear strength can also be further optimized, with woven, braided and knitted fabrics each exhibiting distinct dynamic mechanical behaviour which is relevant to cyclic gait loading [7]. Even at the particulate level, stiffness can be modified: Mohammed and colleagues have shown that industrial waste fillers in glass-fiber reinforced epoxy composites can tune the stiffness in a concentration-dependent manner, thus making particulate addition another tool to modify stiffness [9].

All the above is further complicated by the manufacturing method. Additive manufacturing, especially fused deposition modelling (FDM) reinforced with continuous carbon fibre, has become a high-resolution platform for stiffness-tailoring. Ding et al. showed that, the continuous carbon fiber can enhance tensile modulus by about 6 times to that of unreinforced nylon matrix when only a single layer of fiber is used, and the separated multi-layer distribution of carbon fiber can significantly increase flexural modulus to 3.394 GPa, while the concentrated distribution can only reach 0.467 GPa, which is only 1.38 times that of unreinforced nylon matrix [10]. The suggestion is that layer distribution strategy is indeed one of the true stiffness design parameters that is independent of the fiber volume fraction, which has direct implications for 3D printed components of orthotics and prosthetics.

B. Natural and Bio-Based Fiber Composites

Although carbon and glass fibers are the most commonly used in clinical composite devices, natural fiber-reinforced composites (NFRCs) have gained increased attention as an alternative to carbon fiber and glass fibers for their low cost and sustainability, especially in the production of prosthetic sockets for use in resource-poor areas. Nurazzi et al. demonstrated that the combination of natural and natural fiber species or of natural with synthetic fibers could partially compensate the stiffness and strength limitations that natural fibers have, and that the dynamic mechanical performance and free vibration characteristics relevant to gait loading of hybrid composites were improved [11]. Arumugam et al. also showed that fabric architecture (woven, braiding or knitting) gave better structural properties to the natural fiber composites than random or short fibers and hybridisation with synthetic or cellulosic fibers gave better static and dynamic properties of the composites [7]. In a matrix of polylactic acid, a short flax fiber composite material resulted in a 62% higher longitudinal stiffness and 10% higher specific stiffness and the lower anisotropy ratio was due to the presence of flax shives that created more isotropic and predictable mechanical behaviour [12] (Verstraete et al. showed this).

One of the biggest challenges with NFRCs when used for load bearing applications is their variability in fiber properties and durability when subjected to continued dynamic loading. Castro-Franco and colleagues provided a comprehensive

overview of natural fibre composites for the design of lower-limb prostheses, highlighting that stiffness and fatigue life are still the main concerns despite the many benefits of natural fibre composites in terms of their cost and sustainability in the community where CFRP prostheses are not available [13]. The fibre-matrix interface is especially significant: Alsuwait and co. highlighted that the surface treatment optimisation is essential to ensure better bonding without compromising the natural fibers, and that hybridisation with synthetic fibers in an epoxy matrix can lead to creating biocomposites with better mechanical properties compared to natural-natural fibre combinations [8]. The studies of natural fibre composites as a whole provide a useful path for the sustainable use of materials for lower-limb devices, but also help to define the design compromises that restrict the use of these materials for structural applications.

C. Stiffness Matching to Bone: The Stress Shielding Imperative

One particular stiffness design problem is encountered with bone-contacting implants. The elastic modulus of the cortical bone range from about 7 to 25 GPa and are significantly lower than the elastic modulus of the traditional metallic implants, which range from 110 GPa (titanium alloys) to 200 GPa (stainless steel). This stiffness mismatch results in stress shielding, that is, the implant takes a larger share of the mechanical load, protecting the other bone from the normal stresses that are necessary to maintain bone density and structure [14], [15]. A severe drawback of the first generation of metallic fracture fixation implants is the clinical consequences: bone resorption, osteoporosis under the plate and, in some cases, revision surgery [14].

The Young's moduli of the Ti-based nanoporous metal-polymer interpenetrating phase composites ranged from 4.4 GPa to 24 GPa (the biomechanical range of cortical bone and cancellous bone, respectively), and the yield strength was as high as 260 MPa, which was higher than the 4.0 GPa of the stiffest conventional composite [14]. Computationally, Ganesh, Ramakrishna and Ghista demonstrated that stiffness-graded plates (plates with planned variations in stiffness along their length) reduces interfacial stress shielding when compared to uniform equivalent stainless-steel plates, but still provides sufficient fixation, thus defining the concept of stiffness-graded plate as a bone-healing principle [15]. In their gait context, Shamaei, Sawicki and Dollar identified three phases of nearly constant quasi-stiffness of the biological ankle joint which they predicted for 216 gait trials over a range of gait speeds (from 0.75 to 2.63 m/s) from known gait excursion and subject anthropometrics, thus defining the quantitative targets for stiffness matching by prosthetic feet and AFOs [16].

4. Stiffness Tailoring in Ankle-Foot Orthoses

The Clinical Rationale for Adjustable Stiffness Ankle-foot orthoses are used in many neurological, vascular and traumatic diseases such as cerebral palsy, stroke, post-polio syndrome, peripheral arterial disease, and military limb trauma. The device will function in both situations as a mechanical support to a compromised ankle-foot complex, while allowing enough motion for functional gait. The driving force in the design of AFOs is the fact that these two goals are competing with each other. Rigid AFOs offer good joint stabilisation but will not be able to generate push-off power at the ankle, which will increase walking metabolic cost. AFOs which store elastic energy when loaded and then release it on push off (spring like AFOs) can either maintain or enhance ankle power and may be enough to provide adequate stabilisation for certain patients. Tailoring the stiffness of the device, selecting or altering it to achieve the best clinical result in a particular patient is therefore not only a design goal but a clinical requirement.

This diversity is reflected in the commercial arena of carbon fiber AFOs. Grunst et al. systematically reviewed 78 articles and found 5 major carbon fiber AFO devices: Intrepid Dynamic Exoskeletal Orthosis (IDEO), ToeOff, WalkOn, Neuro Swing and Chignon, each with a unique patient population and positive outcomes in these patients in terms of walking speed, pain, and balance [17]. Shuman and Esposito measured the mechanical range of a series of commercial nonarticulated carbon composite AFOs, finding that the rotational stiffness of the sagittal plane ranged from 0.58 to 3.66 Nm/deg (a sixfold spread), which is mainly because the current AFOs have a dominant sagittal plane bias. The rotational stiffness of the frontal and transverse planes were much less [18].

A. The Optimal Stiffness Concept

One of the most clinically relevant results from the AFO biomechanics literature is that there exists an optimal AFO stiffness to achieve a specific outcome, which varies by patient. This was shown by Kiss and colleagues both computationally and experimentally in participants with bilateral plantar flexor weakness, wherein metabolic cost of transport was lowest at a certain level of AFO stiffness, but higher than that level. For walking stages below the optimum, there was an inverse relationship between the increment of stiffness and the quadriceps metabolic cost during midstance, while walking stages above the optimum showed an inverted-U relationship between the increment of stiffness and the cost of walking (both quadriceps and hip flexor and hamstring costs). The mechanistic basis was the energy storage/release role of the dorsal leaf spring—the AFO was shown to store elastic energy as the ankle dorsiflexes during stance and release during push-off, effectively replacing the reduced output from the biological plantar flexors [19].

In healthy individuals, Nuckols and Sawicki reported a similar optimal stiffness relationship, where the use of low rotational stiffness (50 Nm/rad) at 1.25 and 1.75 m/s, reduced the metabolic cost by 4.2–4.7%, by lowering biological ankle moment by ~12% and soleus muscle activity by ~10% [20]. Most importantly, no stiffness produced a reduction in metabolic cost at the intermediate walking speed of 1.5 m/s; this finding was confirmed by Hedrick and colleagues, who found that the stiffness-metabolic cost relationship was different across locomotor tasks, and that the best stiffness for minimizing metabolic cost was speed-dependent [21]. Ploeger et al. presented proof-of-concept clinical results in three

individuals with calf muscle weakness after polio, in which they varied the stiffness of AFOs under five different conditions for both dorsal-leaf-spring and spring-hinged AFOs, which led to differences in walking energy cost of 3–15% across conditions, but no changes in walking speed; significant changes in walking energy cost in response to the stiffness change compared to the change in stiffness alone, with a maximum increase of 6–8° upon increased stiffness (and a decrease of 5–7° upon decreased stiffness) in dorsiflexion [22]. Kerkum et al. showed that the stiffness trade-off was population specific when studying children with spastic CP walking with excessive knee flexion: while all stiffness settings improved knee angle and net moment, only the spring-like settings maintained ankle push-off power; and there was no difference in the improvements in energy cost between rigid and spring-like stiffness settings, suggesting that, in this specific population, the prescription of stiffness should focus on knee stabilisation, rather than boosting push-off [23].

B. Stiffness Effects Across Patient Populations

The different stiffness reactions observed among patients highlight the non-universality of stiffness prescriptions for AFOs. In post-stroke patients with severe ankle impairment, Tsuchiyama et al. showed that AFOs were effective in reducing the CV of SW, and increasing the MOS, with no significant effects and potentially increased variability of step length for patients with mild ankle impairment, and improvements in toe clearance at all levels [24]. Fallahtafti et al. demonstrated that in patients with peripheral arterial disease, carbon fibre AFOs were able to normalize the kinematics of the ankle and knee joints, bringing them closer to healthy levels, by decreasing plantar flexion and knee extension during push-off [25]. Raijmakers and colleagues showed that continued use of custom knee-ankle-foot orthoses in everyday life was predicted by perceived limitation in walking without orthoses and perceived effectiveness, and not by objective biomechanical measures, highlighting the need for patient-reported outcomes in addition to measures of kinematics to define orthosis success [26].

In post-stroke gait, Kobayashi and coworkers showed that using articulated joints with Triple Action technology to independently tune the plantarflexion and dorsiflexion resistance led to separate tuning of the ankle ($p<0.001$) and knee ($p<0.05$) angles at initial contact, demonstrating that the directionality of the tuning (plantarflexion or dorsiflexion) is a more precise stiffness-tuning approach than fixed-stiffness leaf spring designs [27]. Odanye et al. demonstrated this in a further study in which they found that soleus activity was significantly lower in loading response and tibialis anterior activity throughout gait phases for stroke survivors when the AFO was increased at higher plantarflexion resistances, further validating the AFO resistance as a partial mechanical substitute for paretic muscle output at the EMG level [28].

C. Stiffness Measurement, Computational Design, and Additive Manufacturing

One drawback in the stiffness literature is the lack of a standard testing procedure, making it difficult to compare stiffness values between studies. Shuman et al. evaluated five different test fixtures applied to the same 13 carbon composite AFOs and found that the median absolute difference in stiffness between the test fixtures was 1.03 Nm/deg, and the median relative percent difference between test fixtures was 62%, which is a difference that could affect clinical prescription decisions [29]. After excluding the least constrained method (hanging weights), the four methods based on fixtures also gave 27% median relative difference, which shows that even instrumented approaches give widely different stiffness values. This methodological fragmentation hinders the practical use of the published stiffness data in the clinic and it is one of the key technical gaps highlighted during this review.

A partial solution to costly iterative prototyping is provided by computational approaches. Zou and colleagues created and validated finite element analysis models of carbon fiber AFOs with less than 3% relative error in energy return ratio and showed that multiple fabrication cycles could be saved by using FEA to optimize patient-specific CF AFO design [30]. In a clinical pilot study Anderson and colleagues showed that three different CDOs (Compliant, Moderate, Stiff) generated significant and distinct foot loading distribution and ankle motion changes, and that targeting a specific stiffness for a given patient for each of these outcomes was not always consistent thus supporting the clinical need for patient-specific computational stiffness selection [31]. Sharma et al. also demonstrated that monolithic and modular carbon fiber orthoses with different architectural properties result in different biomechanical effects on the lower extremity (LE) for similar clinical uses, indicating that the biomechanical effects are dependent on the architecture and not just the stiffness of the orthoses [32].

In a systematic review of 3D printed AFOs, Wojciechowski et al. concluded that in most temporal-spatial AFO outcomes, the biomechanical properties and stiffness of 3D printed AFOs were similar to carbon fiber prefabricated AFOs, and that the major opportunity for 3D printing AFOs was in optimising stiffness and weight of AFOs, though the sample sizes of the studies included were very small (n=1-8) and the quality of the included studies was generally low [33]. Abdelgawad et al. went on to show that by adding 0.5% multi-walled carbon nanotubes (MWCNTs) to the Orthocryl matrix they could increase flexural strength by 59.3% and decrease the deformation by 12.6% compared to that of pure Orthocryl, with the highest safety factor (3.2) and lowest deformation under gaits simulating FEA loading demonstrating that the addition of nanofillers can provide targeted stiffness-strength profiles, which cannot be achieved by pure geometric design [34].

5. Stiffness Tailoring in Prosthetic Feet and Running Blades

A. Energy Storage and Return: The Core Design Objective

Energy storage and return (ESAR) is the dominant design paradigm of composite prosthetic feet. Carbon fiber blades store elastic strain energy as they bend during early and mid

stance when the body weight is applied and they give back a portion of that energy when they straighten out during push off, aiding to offset the lack of biological ankle plantar flexor mechanism. The energy return ratio, or what percentage of energy is returned, is very dependant on the stiffness of the composite material, the geometry of the blade, and the kinematics of the user's gait. In the first systematic review in which the effects of prosthetic foot type and walking speed on push-off power were combined, Müller and colleagues have shown that ESAR feet improve push-off power relative to SACH (Solid Ankle Cushion Heel) feet, especially at higher walking speeds, and that push-off power increases with walking speed across all foot types, implying that the prescription of stiffness should be related to the intended activity level of the patient [35].

To establish that the effects of prosthetic foot stiffness and energy return are not just ankle-related, but whole-body phenomena, Childers and Takahashi correlated whole-body consequences of the latter with novel, more movable and higher energy return prostheses; they found that the greater the energy return of the novel foot, the higher the centre-of-mass propulsion from the prosthetic limb ($p=0.012$), and the lower the collision energy on the sound limb ($p<0.001$) [36]. The same was found by Pröbsting and colleagues for transfemoral amputees, where powered feet with optimal settings and ESR feet showed significant decreases in knee adduction moment, knee flexion moment, and vertical ground reaction forces on the contralateral side of the body when compared to SACH feet, suggesting that the prosthetic energy return component is not sufficient to prevent the sound limb from taking up the excess load, thereby raising the risk of injury over time [37].

B. Regional Stiffness: Hindfoot vs. Forefoot

A major clinical implication of the prosthetic foot biomechanics research is that the stiffness of the hindfoot and forefoot have different, qualitatively distinct and separable effects on gait. In transtibial amputees, Adamczyk and Roland and Hahn independently adjusted the stiffness of the forefoot and hindfoot, respectively, in 15 N/mm increments and tested them at various walking speeds ranging from 0.7 to 1.5 m/s. The stiffer hindfoot resulted in decreased energy return of the prosthesis, higher loading rate of the ground reaction forces and higher knee flexion and extension moments during stance phase. In contrast, a stiffer forefoot decreased prosthetic side ankle push-off and the COP work, and increased knee extension and knee flexor moment in late stance [38]. The two regions are thus independent stiffness-tuning channels, with consequences for the prescription of prostheses where the stiffness of one region influences the outcomes of the other, but not the reverse.

These effects were confirmed and quantified by Nichols and Adamczyk who performed the same three tests on a Variable Stiffness Foot (VSF) at three stiffness settings with seven transtibial amputees showing that lower ankle dorsiflexion angles ($r2=0.90$), higher plantarflexor moments, higher knee extension moments and knee flexor moment, and lower prosthetic energy storage ($r2=0.90$), energy return ($r2=0.67$), and power ($r2=0.74$) occurred with the stiffer settings. Compliant settings resulted in lesser moments at ankle, knee, and hip with increased ROM at the ankle, which is more desirable for walking in the community. Forefoot stiffness is one of the most strong single design variable in prosthetic foot prescription, as indicated by the high r^2 values for a variety of biomechanical outcomes.

C. Composite Architecture and Geometry in Prosthetic Blade Design

In addition to material choice, another major variable of stiffness design for composite prosthetic blades is the structural geometry of the blades. Akkaş and Alsancak identified a geometry of a running prosthetic foot that is composed of an optimised aluminium honeycomb core with carbon fiber skins that reduced the distal mass by 63.9% compared to a solid carbon-epoxy laminate foot, and produced a 57.4% increase in strain energy storage simultaneously enhancing energy return and reducing mass without compromising structural integrity, with a safety factor of 1.95 above the recommended 1.5 by ISO 10328 [40]. The counterintuitive finding that reducing the structural density by sandwiching enhances the energy storage capacity, but not the energy loss capacity, shows that the properties of energy storage and energy loss can be decoupled through geometric design in the case of solid composite laminates.

Martulli and colleagues tackled the design problem from the additive manufacturing side, demonstrating that numerical simulation can aid in redesign of a laminated prosthetic foot component using continuous fibre-reinforced 3D printing, with stiffness within 5% of the reference laminated component, at around 83% thicker with glass-fiber skins [41]. Ray, Wurdeman and Takahashi added a temporal element to this design challenge: the energy return of the prosthetic foot improved greatly over a 3-week adaptation period as the user learned to load the foot so as to optimally use the elastic storage mechanism of the blade, this indicated that the prosthetic foot's stiffness, measured at initial fitting, systematically underestimated long-term performance, and that the duration of adaptation periods required to be included in both research protocols and clinical fitting schedules [42].

Li and colleagues built an intelligent ankle-foot prosthesis with a carbon fiber foot designed to mimic the human foot shape, and showed through a series of calculations that the energy storage capability of the elastic foot increased as a function of CF thickness, thus demonstrating computationally that the thickness of the CF foot is a direct stiffness-by-geometry tuning parameter [43]. Petrone and colleagues filled an important gap in validation by designing instrumented running prosthetic feet equipped with strain gauge bridges that measure actual ground reaction forces on the track during sprint and long jump in the Paralympic environment, finding that the loading conditions experienced in the field during elite Paralympic performance diverge from laboratory assumptions, highlighting the need for in-field stiffness characterisation in addition to laboratory testing [44].

D. Clinical Mobility Outcomes and the Accessibility Challenge

In the real world, the choice of prosthetic foot stiffness needs to be translated to functional mobility outcomes for individual users. Rakbangboon et al. demonstrated that a locally designed ESAR foot (sPace) was comparable to a commercial Össur Vari-Flex for mobility outcomes in 10- and 20-metre walk tests, two-minute walk test and Comprehensive High-Level Activity Mobility Predictor scores, with no significant differences found in mobility outcomes, thereby suggesting that locally produced ESAR feet can be as performant as commercial feet and make affordable CFRP prosthetic options available to patients [45]. From a Paralympic performance perspective Fletcher, Gallinger and Prince made a strong argument for the use of patient-specific stiffness and for the stiffness of running and jumping specific prostheses to be tuned to the demands of the specific event [46].

Elgamsy and his team directly focused on the global access aspect in their work where they identified ESAR composite feet as the most suitable category for local production in scenarios where import expenses are high, and developed a manufacturing chain prototype to produce resin impregnated CF composite feet which were tested according to the ISO 22675 [47] standard. Nagarajan et al. showed PET-fiber reinforced prosthetic sockets produced via VARTM had higher stiffness resistance and load-bearing capacity compared to PP and HDPE monolithic socket under the ISO 10328 static test, and were comparable to GFRP, thus proving that the manufacturing methods available in lower resource areas can be used to produce composite sockets that are clinically viable [48].

6. Stiffness Tailoring in Lower-Limb Fracture Fixation Plates

A. Stress Shielding and the Stiffness Mismatch Problem

The major biomechanical challenge of metallic fracture fixation plates is the mismatching of stiffness. The stiffness of conventional stainless steel and titanium locking plates is 10-100 times larger than that of the normal cortical bone and results in stress shielding that affects callus formation and can lead to osteoporosis of the bone under the plate [14], [15]. When a diaphyseal fracture is to be healed by secondary bone healing (callus formation), the healing rate depends on the amount of interfragmentary micromotion at the fracture site, which is limited by excessive stiffness of the plate. The computational study by Ganesh et al. showed that stiffness-graded plates (plates deliberately made stiffer in one part, and weaker in another, using composite design, to reduce stress shielding) performed better in compressive and tensile stress shielding than the respective stainless-steel plates, while still being structurally adequate to be constructed [15].

In a systematic biomechanical review of 52 papers on proximal tibia fracture plates, Zdero, Brzozowski and Schemitsch reported the wide variety of outcomes reported in existing research on plates in the literature: construct stiffness ranged from 22 to 24,869 N/mm, interfragmentary motion from 0 to 22.53 mm, and failure strength from 259 to 14,387 N [49]. The review revealed that biomechanical variables such as plate geometry, plate material, number and type of holes in the plate, and screw variables were the main factors. This review also explicitly indicated that the use of alternative and composite plate materials is an under-researched variable that would benefit from additional study [49].

B. CFR-PEEK Plates: Biomechanical and Clinical Evidence

The composite CFR-PEEK has become the most commonly used material for fracture fixation plates as an alternative to the metallic plates. Many of the properties of PEEK are closer to the properties of cortical bone than those of titanium and steel, with the intrinsic elastic modulus of PEEK being around 3–4 GPa compared to 110 GPa for titanium and 200 GPa for steel, and reinforcing PEEK with carbon fibres raises these to clinically useful structural values without compromising the stiffness advantage over metals. Senra, Marques and Monteiro present a thorough review of the biocompatibility profile of PEEK and its mechanical similarity to bone, as well as the principal limitation that propels the research on PEEK – the bioinert surface, impeding osseointegration – and the methods currently under investigation for its surface modification and bioactive composite formulation to overcome such limitation [50].

Zhou and colleagues compared the biomechanical properties of CF-PEEK with titanium locking plates in a model of tibial diaphyseal comminuted fracture; they found that CF-PEEK was significantly less stiff than titanium (6.8–30.8% lower in axial compression, 64.9% lower in torsion, and 48.9% lower in bending), but that strength of the constructs was only marginally reduced (2.6–7.8% lower) and these differences were not statistically significant [51]. This dissociation is the most clinically relevant property of CFR-PEEK – it will transmit enough of the load to encourage healing, but it will allow for the controlled micromotion at the fracture site that is necessary for callus formation. CF-PEEK's radiolucency was noted as an extra clinical benefit for allow artefact-free imaging after the surgery [51].

These biomechanical predictions have more recently been substantiated by clinical evidence. A Cochrane methodology systematic review was performed by Chloros et al. that included 9 studies (n=361 patients) that compared CFR-PEEK plates to conventional metal plates for fixation of extremity fractures, revealing similar clinical and radiological results and no significant difference in complication rates [52]. This was independently confirmed by Rijs et al in a systematic review which complied with the PRISMA guidelines, which found that the complication rates and outcomes of CF plates matched that of metallic plates [53]. Giannoudis et al. included the patient perspective by asking patients who underwent fracture surgery with CFR-PEEK plates for their patient-reported outcomes; the findings were acceptable [54].

C. Functionally Graded and Lattice Composite Plates

In addition to uniform CFR-PEEK construction, computational research has focused on functionally graded and

lattice composite constructions that have variable stiffness throughout the implant, such as the CFR-PEEK stiffness gradient from cortical to cancellous bone or varying the stiffness at various regions in order to meet the varying loading demands. In a study by Zhang and co-workers, finite element analysis of chopped carbon-fiber reinforced PEEK, FGM bone plates under static and dynamic loading conditions revealed that the stress shielding effect was reduced when the CF content was graded across the thickness of the plate with respect to uniform CF metal plates, but this did not compromise the structural integrity [55]. In a FEA optimisation of a functionally graded Ti/HA plate for the stabilisation of tibial fractures, Szymkiewicz showed that the graded composition minimized bone stress compared to both Ti and steel plate; he explained that this gradient in stiffness, and not just material substitution, was the main difference [56].

Daniel and his colleagues implemented lattice architectures for metamaterials into bone plate design, and tested four types of lattice structures (tetrachiral, re-entrant, rotating square and hexagonal) made from CF-PLA under cyclic compressive loading within the range of 20-80% yield strain. Rotating square and hexagonal structures resulted in stiffness loss after 50,000 cycles upon application of moderate strains, with the square geometry showing stiffness loss earlier, while the re-entrant geometry showed the highest number of cycles sustained (100,000) with minimal stiffness loss, indicating that lattice geometry is as significant as material composition in influencing fatigue life, under physiological loading, with the re-entrant geometry having the highest fatigue life [57]. Namvar et al. demonstrated computationally that fully lattice implants were well suited to allow bone ingrowth and decreased implant stiffness without compromising implant structural integrity under maximum compression and torsion in femoral bone reconstruction, advocating the clinical translation of porous composite implant architecture [58].

D. Emerging Materials and Critical Limitations

Bioresorbable composite plates are the natural culmination of stress-shielding reduction - a plate that becomes less rigid over time until the fracture is healed, thus gradually transferring more of the load to the bone, and eliminating the need for plate removal surgery. Plyusnin et al. invented PLAMA (polylactide functionalised with dimethacrylate), which has excellent biocompatibility and acceptable mechanical properties and provides a controlled bioresorbability in simulated body fluid, and which can be used for in-situ curable bioresorbable load-bearing composite plates [59]. Park and their collaborators demonstrated that the formulations of stereocomplex PLA offer better strain resistance compared to pure PLLA at the same modulus, with near-infrared transparency as another benefit in monitoring [60]. These materials are still in the early stages of development compared to CF-PEEK and long-term in vivo performance data is not available.

The evidence base supporting CF-PEEK fracture fixation has some limitations which the composite should recognize. A systematic literature review by Doodkorte, Kuske and Arts revealed that there was limited evidence for carbon fibre fragments around CFR-PEEK implants and one study indicated that inflammatory response to CF-PEEK explants was higher than with metallic implants, but no clear causality was confirmed and wear-related complications were rare in validated implant designs, with CF-PEEK [61]. The case report of Sardar and Jarzem that used a composite implant to achieve CFRP cage failure at the L5-S1 level in a patient with rheumatoid arthritis and non-union is instructive: composite implants may fail under mechanical instability or failure of healing, which leads to loading conditions beyond the design's assumptions [62]. The end of the day, CFR-PEEK is not dangerous; it will never be as successful as a metallic plate will be unless it has the same biomechanical properties (stable construct mechanics and attainable union), which do not replace surgical technique.

7. Cross-Device Synthesis: Shared Design Principles and Conflicts

For the three device categories analyzed in this review, a number of design principles are evident in every device, and, with sufficient consistency, are summarized here as general principles of composite stiffness tailoring for lower limb load bearing applications.

First, there is an optimum stiffness for each combination of device and population and it is not at either extreme. The inverted-U relationship between stiffness and metabolic cost has been shown both computationally and experimentally for a variety of patient cohorts in AFOs [19, 20, 22]. For patients wearing prosthetic feet, a combination of too rigid and too flexible affect push off power and gait economy [38, 39]. For fracture fixation, a stiff plate leads to stress shielding and delayed union and a compliant plate allows too much interfragmentary motion that affects callus formation [15, 51]. In every case, the clinical challenge is to find the individual patient's optimum, which depends on the pathology, walking speed, BMI and activity.

Secondly, stiffness and strength can be separated in the design of composite materials, which cannot be done in metallic materials. The combination of properties (stiffness and strength) obtained by the Zhou et al. CF-PEEK plate finding is illustrative of a combination of properties that the strength-stiffness scaling of conventional materials cannot achieve [51]. The mass saving and improved energy storage through the use of a honeycomb sandwich prosthetic blade [40] is another example of how the same principle—composite architecture, which controls structure at multiple length scales—can yield mechanical properties that solid metallic structures cannot.

Thirdly, geometric design is as crucial as a material choice. Stiffness design variables of a composite device are of the same order of magnitude as the fiber type and volume fraction, and include the lay-up sequence, blade geometry, lattice architecture, and structural configuration. This is seen in the Ding et al. study, where they have demonstrated the influence of layer distribution strategy on the stiffness of 3D printed CF composites, without making any changes to the fibre volume [10]; the Adamczyk et al. study, which showed that stiffness of hindfoot and forefoot produces separable biomechanical effects

[38]; and the Daniel et al. study, in which they were able to show that lattice geometry determines fatigue life of CF-PLA bone plates without changing the fibre volume [57].

Fourth, adaptation and time-dependence are important. Ray and coworkers demonstrated that the energy return gained from the prosthetic foot improved with adaptation over 3 weeks [42] and Kobayashi and coworkers found that the impact of the change in resistance on stroke gait at one session needs to be subjected to a longitudinal study to draw longer-term conclusions [27]. The stiffness that is optimal at first use of a device might not be optimal after weeks or months of use, and research designs that evaluate outcomes at a single measure time systemically misrepresent device performance. Be aware of one major point, stiffness modification is not a performance improvement for everyone. In 15 runners, however, the addition of carbon-fiber plates to shoe soles (to increase bending stiffness) did not change muscle activity or active muscle volume of the soleus muscle, nor did it affect aerobic power, according to Beck, Golyski and Sawicki's results, so that there is no consistent prediction of biomechanical reaction to stiffness modification [63]. However, this is only a footwear finding, but a blanket warning not to assume that stiffness tailoring results in any benefits to a population without characterizing individuals first.

8. Research Gaps and Future Directions

This review highlights four priority areas in which the evidence base is lacking and where future research could have important clinical impact.

The first and most obvious gap is the lack of a standard method to measure stiffness. Shuman and her colleagues showed that the median relative difference in stiffness from the five different methods of stiffness testing was 62% for the same 13 devices [29]. Prosthesis stiffness is also not standardized, with no equivalent to ISO 10328 for stiffness testing of the structural properties; furthermore, the articles in the fracture fixation literature define stiffness in different ways and in different testing setups that prevent a direct comparison of the results of the 52 articles reviewed by Zdero et al. [49]. There is the need for standardised (reproducible) stiffness measurement methods for different types of devices, similar to the standardised biomechanical testing used to approve implants.The translation of lab findings would be significantly enhanced if there were agreement on shared, reproducible methods to measure stiffness, just like there is for biomechanical testing used when approving implants.

The second gap is about the longitudinal data on device adaptation and durability. Most studies of the composite AFOs, prosthetic feet and fracture plates are cross-sectional or acute studies. The literature reviewed by Doodkorte et al. [61] suggests that there is no long-term wear data available for most composite orthotic and prosthetic devices compared to that of fracture plates; the finding by Ray et al. [42] that there is a systematic underestimation of energy return at initial fitting and the finding by Raijmakers et al. [26] that orthosis discontinuations are predictable based on perceived rather than objective outcomes, lend support to the literature that can explain immediate biomechanical effects but cannot answer whether the effects are sustained or whether the stiffness properties of the device are maintained over time or if patient adaptation improves or degrades the performance of the device over time.

The third gap is the need for more evidence to support the patient-specific stiffness optimization. While the concept of an optimum stiffness has a strong theoretical basis and is supported by many empirical studies in small patient populations, clinical methods to determine an optimum stiffness prior to device fabrication are rudimentary. While computational modelling with musculoskeletal simulation (as in Kiss et al.) and FEA-based AFO design (as in Zou et al.) have proved concepts, prospective clinical trials are still needed to validate these concepts. Prescribed tools to calculate stiffness for individual patients that are validated and computationally efficient are a high-value engineering and clinical research target, particularly when considering body mass, gait speed, pathology severity and activity goals.

The fourth gap is on the issue of access to composite prosthetics and orthotics. The evidence provided in this review is mainly from high income countries and the global burden of lower-limb amputation and orthotic need is heavily skewed toward LMICs where either advanced composite devices are missing or too expensive for access. Elgamsy et al. showed that composite prosthetic feet that are locally produced can adhere to the ISO 22675 mechanical requirements [47], and Rakbangboon et al. found no differences in mobility between a locally designed and commercial ESAR foot [45]. This expanding body of evidence would be a global health research priority with direct implications for millions of people around the world who are currently unable to access stiffness tailored composite devices, such as the composite AFO, prosthetic sockets, and eventually fracture implants.

9. Conclusion

Stiffness tailoring, the deliberate engineering of composite device stiffness toward a clinically defined mechanical target is a unifying principle across ankle-foot orthoses, prosthetic feet and blades, and lower-limb fracture fixation plates. In each domain, carbon-fiber reinforced polymers and PEEK-based composites enable mechanical property combinations inaccessible to metallic or thermoplastic alternatives: reduced stiffness without proportional strength loss, regional stiffness differentiation within a single component, and structural compliance matched to bone. The clinical consequences improved gait economy, preserved push-off power, reduced stress shielding, and promoted fracture healing are supported by a growing body of biomechanical, computational, and clinical evidence.

The evidence also identifies clear limits to the current state of knowledge. Optimal stiffness is patient- and task-specific, measurement methodologies are not standardized, longitudinal data are scarce, and most advanced composite solutions remain inaccessible to patients in under-resourced settings. Addressing these gaps through standardized testing protocols, prospective longitudinal trials, computational prescription tools, and

accessible manufacturing approaches will determine whether the biomechanical promise of stiffness-tailored composites is fully realized in clinical practice for the populations who need them most.

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