Bioinspired Polymer Composite Implants

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Abstract Long bone fractures are treated with internal fixation prostheses such as screws, pins, intramedullary nails, and bone plates, depending on the type and nature of the fracture. Different prostheses exhibit dissimilar fixation constructs which are vital for callus generation and fracture bridging. Metallic implants have a significant mismatch with bone mechanical properties and create stress concentrations at the plate, which results in stress shielding. This phenomenon impedes load transmission at the fracture site, which can lead to non-union, bone mass loss, delayed healing, refracture, and construct failure. Flexible fiber-reinforced composite prostheses respond to biological friendly healing (secondary healing) and promote callus generation and soft tissue maturation and can provide solutions to problems. These polymer implants promote bioactivity around the implant. Further, the polymer composites biomechanical properties can be tuned easily by adding the functional powders into matrix and changing the type or direction of reinforcement fibers. The performance of these composites from the published work according to different materials is discussed. This chapter concludes that the bioinspired polymer composites have the potential to replace traditional metallic implants for orthopedic applications.

Keywords Orthopedic implants · Biomechanics · Bioactive polymer composites · Mechanical properties · Polymer matrix · Reinforcement fibers

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K. Shaker and A. Hafeez (eds.), *Advanced Functional Polymers*, Engineering Materials,
https://doi.org/10.1007/978-981-99-0787-8_8

1 Introduction

Composites are defined as the materials that consist of two or more fundamentally different components to achieve the target properties superior to those of individual material used [1]. Usually there are two main parts of composites: matrix and reinforcements. Matrix is the base material, which acts as binder for the reinforcement fibers, transfers load, and defines the composite shape along with surface texture. While the reinforcements are used to enhance the mechanical properties of composites along the desired axis by changing the fibers' orientation [2]. Composites majorly can be distinguished into ceramic matric composites (CMCs), polymer matric composites (PMCs), and metal matric composites (MMCs) [3].

Bone fracture occurs when the strain limit of bone exceeds. Fractures mostly occur in the long bones and the causes of such fractures include injuries from vehicle mishaps, falls, sports, and sometimes high muscular forces [4]. Fractures disrupt the blood supply with damage to the external tissues. Depending on these unpredictable forces the nature of fractures varies which may result in the fractured bones pieces to be aligned correctly (stable fracture) or misaligned (displaced fracture). Thus, the fractures could be classified according to

- The position of the fracture (shaft portions: proximal, medial, and distal).
- Shapes of fractures (crack, diagonal, along the length or shaft fractures).
- Open fractures (muscles or skin torn) or closed fractures (no skin rupture).

A perfect implant must provide satisfactory initial healing and permit suitable load transfer to the fractured area. Implants such as bone plates, intramedullary nails, pins, and external fixators are used to fix the broken bones. Conventional implants are made up of metals displacing the poor biomechanical performance including bone resorption, fatigue degradation, implant failure, screw lag, X-ray artifacts, corrosive nature, and re-surgery [5]. Replacing materials should display the unique properties such as corrosion resistant, non-toxic, biocompatible, light weight, improved mechanical properties, and non-allergic as well. Advanced properties of polymer composites using reinforcement materials grabbed the researcher's attention. Recently, bio-composite implants are of great attention to replace these conventional metallic implants as the mechanical and biological properties can largely be altered [6]. Polymers are widely used as matrix and continuous synthetic or natural fibers (e.g., carbon fibers, glass fibers, bamboo fibers, etc.) as reinforcements for these biomedical implants [7]. Moreover, the surrounding tissue growth during their interaction with implants can also be enhanced due to antibacterial and bioactive nature of composite implants. That is why, these materials can be introduced as the replacement of broken bones or damaged parts and are named as biomaterials [8]. Such potential materials are used in dental and orthopedic implants, as their varying properties enable better biomechanical compatibility with bone tissues [9, 10].

Most challenging concerns to attain the required composite implants in medical are their fabrication methods. Various fabrication techniques are being followed by the researchers. The choice of proper fabrication methods to manufacture composites is one of the most challenging issues in medical science to achieve the desired implants. Traditional fabrication techniques including hand layup, gas foaming, phase separation, compression molding, hot extrusion, solvent casting, melt mixing, additive manufacturing, and much more [11]. These techniques have their own advantages and disadvantages but still in the developing phase by the researchers to maximize the performance with reduced drawbacks. This chapter covers the biomechanical aspects of composite implants, their manufacturing techniques, performance, and future aspects.

2 Nature of Bone Healing

Once the fracture occurs, all the emergency repairing cells in blood report the injury site and start the repairing procedure. Depending on the fracture's nature, location, and biomechanical environment, the repairing procedure follows the specific healing mechanism [12] as follows:

1. Primary healing (intramembranous ossification).
2. Secondary healing (endochondral ossification).

In primary healing, direct bone formation occurs where the mesenchymal cells directly differentiate into osteoblast cells and blood vessels growth without the callus formation at fracture site. Secondary healing is the common form of bone fracture healing with the process of callus formation as shown in Fig. 1. This type of healing follows the four main stages:

i. Hematoma formation:

   This is an inflammatory action where the blood clots at the fracture site as a result of the local cells' death due to traumatic condition of blood vessels' rupture. This process continues for first week which is the initial stage of calluses formation.

ii. Fibro-cartilaginous callus formation:

   This period continues for second and third week after fracture occurrence. In this preliminary stage, the soft calluses define their shapes wrapping the fracture site to stabilize the broken bones according to the available biomechanical environment. The mesenchymal cells are able to differentiate into fibroblast, chondrocytes, and osteoblasts which are responsible for the production of soft tissues, cartilaginous tissue, and bony tissues, correspondingly. The fibrous and cartilaginous tissues are more prominent with some portions of woven bones in calluses.

iii. Bony callus formation:

   In this step, the woven bone is developed into mature lamellar bone. This process continues from first till fourth month in which almost whole fracture

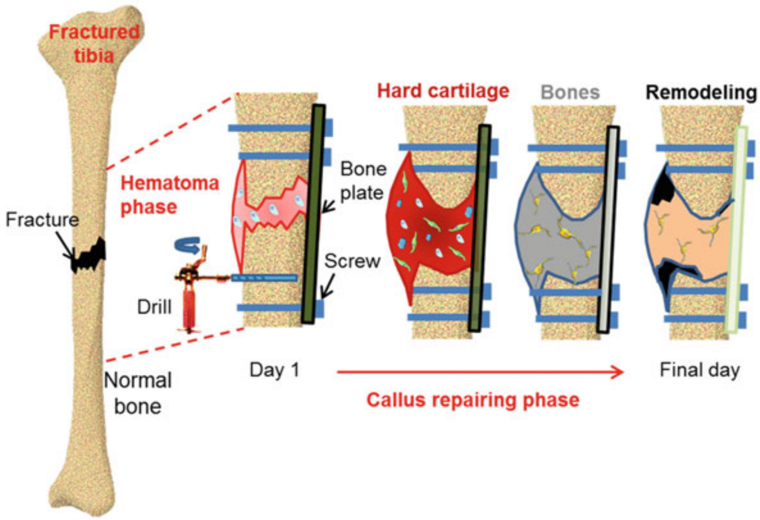

Fig. 1 Callus formation during fracture healing

stabilizes the fractured bones and starts bearing the body weight. The stresses are reduced from the implant assembly and exchanged with the calluses.

iv. Resorption phase:

In this process, the developed bone starts to dissolve itself in the physiological environment and restores its original shape. This process continues for months and years [13].

Depending on these healing mechanisms and fracture's location, the fractures are majorly divided into two types:

(a) Articular fractures:

The fractures occur at the proximal and distal end of the long bones or the bones where trabecular bone is greater than the cortical bone. These fractures are generally minor or hair line fractures. Rigid fixation techniques are used to fix these fractures disgracing any movement. Direct bone formation takes place following the primary healing.

(b) Diaphyseal fractures:

Diaphysis (cylindrical shaft) of the long bones is the main candidate which faces such fractures where the cortical bone is the main runner. For the effecting healing of these fractures, the implant should provide sufficient stability to broken bones while allowing the micro-movement to promote the improved stimulus in calluses. This will allow the gradual sharing of body weight with stress relief at the implant-bones assembly.

3 Why Composites?

Metallic implants highly mismatch the material properties as that of bones resulting in the aforementioned complications, especially erosion during long-term remains [14]. An ideal implant should provide reasonable initial micro-movement at fracture site to stimulate healing and permit suitable load transfer to the fractured area. The metallurgical composition of metallic implants was enhanced with improved corrosion resistance and edges design were presented in 1909 and afterward in 1912; these bone plates because of poor fatigue properties were abandoned. The following improvement was made in 1948, when a plate with sliding vertical pockets was created for the screws assembly to prevent stress concentration [15]. Due to insufficient structural stability, improvement in this plate design was also required. In 1965, a new plate design was presented with a fixing tensioner that permitted the interfragmentary development of broken bones. This development process continued along with the introduction of locking compression plate and dynamic compression plate but still there are many controversial theories about the satisfactory performance of metallic implants. Composite materials grabbed the attention of research due to their enhanced features as shown in Fig. 2. The preferred mechanical properties for special fracture cases can be achieved by altering the stacking sequence of the fibrous composites, while keeping the basic structure the same [16]. Elastic composite implants provide proper stability along with the favorable biomechanical environment to promote the secondary healing process and reduce the stress shielding phenomenon. This process increases the callus volume which envelops the fractured area causing the bony bridging to facilitate bone-implant stability and decrease the risk of implant failure [17]. In the last decade, one of the extensively studied areas is bio-composite materials for medical applications. Therefore, biodegradable, bioactive, antibacterial, and nanomaterial FRP composites are strong candidates to meet the biomechanical requirements in the biomedical surgery as orthopedic implants (for knee, jaw, elbow, hip, leg, ribs, and dental) to collaborate with the biomechanics of bones [18, 19].

4 Materials for Composite Implants

Large range of materials are used these days to achieve the target properties of implants for desired applications. The implant materials should be biocompatible means the material which acts as an appropriate host with minimum disturbance in the body function. These materials include metals, ceramics, powders, polymers, fibers, and their composites [20, 21] while their existence period and decomposition behavior define if they are non-degradable, partially degradable, fully degradable, biocompatible, or bioactive. These properties tend to differ in mechanical properties of these materials which are listed in Table. 1. The industry has grown over 150

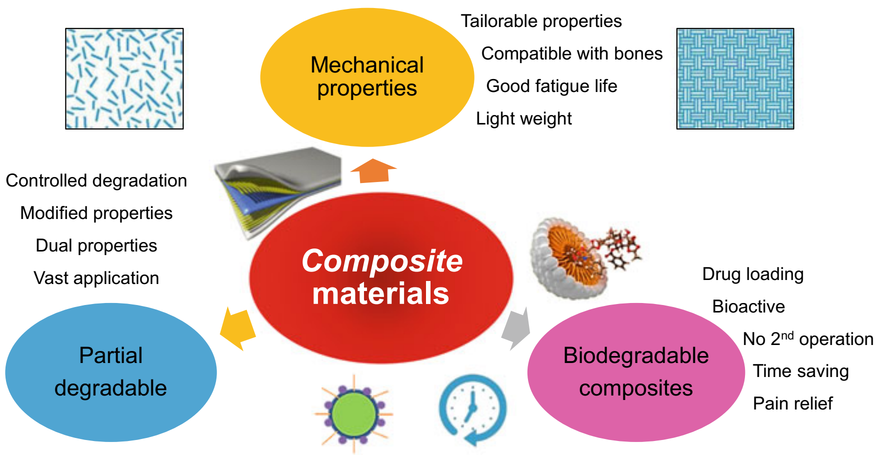

Fig. 2. Composites for implants application

billion US dollars [22], serving the quality life to millions of patients by treating their fractured bones.

4.1 *Non-degradable Materials*

Non-degradable materials are those which maintain their integrity both mechanically and physically. Traditionally non-degradable metallic materials were massively used for the implants manufacturing. Advancement in artificial polymers technologies in recent years resulted in various medical devices and were effectively used for the treatment of patients around the world. These

materials include stainless steel (SS), titanium (Ti), cobalt (Co), chromium (Cr), silver (Ag), and platinum (Pt) [23] while synthetic polymers include poly(ethylene), poly(propylene), poly(methyl methacrylate), poly(dimethyl siloxane), poly(ether ketone), and polyurethane [24].

Manufacturing of implants began with pure metals which displayed reduced strength and high corrosion. Improved mechanical- and corrosion-resistant properties of stainless steel brought an innovation in market as they are stiff, ductile, and dense. But release of metal ions and other chemical compounds caused material deterioration with pitting and stress corrosion resulting in irritation and allergic reaction in the body [25, 26]. Titanium is light weight, higher torque, and fatigue resistant as compared to stainless steel [27]. Moreover, titanium implants are better corrosion resistant as oxide layer regenerates quickly. The high metal mechanical properties cause stress shielding along the bone resulting in bone resorption and mass loss. Various methods were introduced to reduce the structural stiffness of implant like in bone plate the higher density was maintained around the fracture and reduced

Table 1 Material properties of biomaterial implants

	Material	Material properties	Degradation properties	Medical applications
		Young's modulus (GPa)	Time (months)	
Lower limb long bones	Cortical bone (longitudinal dir.)	15–20	–	–
	Cortical bone (transverse dir.)	8.5	–	–
	Cortical bone (hoop dir.)	6.9	–	–
	Trabecular bone	1.1	–	–
Tissue phenotype in bone healing process	Granulation tissue	0.00002	–	–
	Fibrous tissue	0.001	–	–
	Cartilage	0.005–0.5	–	–
	Immature bone	0.5–1.0	–	–
	Intermediate bone	1.0–2.0	–	–
	Mature bone	2.0–6.0	–	–
Metals	Stainless steel	190	Years	Bone plates, IM rods, screws, joint replacements, tissue engineering, dental implants, heart valves, stent spinal implants
	Co-Cr alloys	210–235	Years	
	Titanium	110	Years	
	Titanium alloy (Ti-6Al-4V)	116	Years	
	Magnesium alloys (AZ91, AZ31, WE43, Mg-Ca, LAE442, Mg-Mn-Zn)	45	Months ~ Years	
Ceramics	Alumina	380	–	Orthopedic prosthesis, bone fillers, dental implants, jawbone reconstructions, facial surgery, ear, nose and throat repair
	Zirconia	150–220	–	
	Calcium phosphate (HA, TCP)	35–110	–	
Bioglass	45S5	35	0.6–1	–
	13–93	60	0.6–1	–
Polymers	UHMWPE (ultra-high molecular weight polyethylene)	12~4	–	Bone plates, IM rods, screws, disks, dental implants, prosthesis, spine cage, suture anchors, meniscus repair
	PEEK (Polyether ether ketone)	3.6	–	
	Polysulfones (PS)	2.6	–	
	Polyethylene terephthalate (PET)	2.8	–	
	Polylactic acid (PLA)	0.3–2	18~12	

(continued)

Table 1 (continued)

	Material	Material properties	Degradation properties	Medical applications
	Polyglycolic acid (PGA)	0.7–5	0.4–3	
	Poly(lactic-co-glycolic acid) (PLGA)	1.4–2.8	0.6–2	
	Polycaprolactone (PCL)	0.4–0.6	>24	
Polymer composites	CF/PEEK, GF/PEEK, CF/epoxy	10–70	Months ~ Years	–
	BG/polylactide, polyglycolide and its copolymers			–
	CF/PS, BG/PU, BG/PS, CF/UHMWPE			–

moving toward the edges [28]. Attention was drawn for the further improvement using metallic alloys like Co-Cr (cobalt, chromium, and traces of molybdenum) and Ti-Co. Cr promotes oxide formation on the surface which decreases corrosion while molybdenum discourages bulk corrosion [29]. In artificial hip implants, Co-based alloys are used due to better ductility with improved wearing resistance during physiological loading conditions where high-strength applications are required [30]. Titanium was then introduced as implant material with biocompatible, light weight, and mechanical properties closer to bone making it better option over others. It forms titanium oxide as corrosion-resistant layer on the surface.

Polymer-based composites have more fatigue resistance compared to other materials with high strength and low stiffness. Carbon fiber-reinforced polymer (CFRP) composites are potential candidates for orthopedic applications [31]. Monitoring the implant designing factors in vivo and in vitro is a time-taking process with involvement of various ethical issues. Thus, introducing the computer models to check the effect of implants' performance is made much easier to tune the various designing parameters and their effect on fracture healing. It was concluded that these CFRP composites can effectively reduce the stress concentration in the bone [32, 33, 16, 34]. Improvement in structure was done by sandwiching the flax/epoxy between glass/epoxy composite. This hybrid composite provided flexible inner surrounded with stiffer shell providing more ideal conditions for fixing bone fractures [35]. Only the mechanical performance of the implants was investigated while the biological response was not considered. In vivo tests need to be done for their biomechanical performance validation as a safe implant.

Moving toward the synthetic polymers, chemical linkages made them resistant to degradation in the human body and were assessed broadly for medical applications but few displayed satisfactory results as implants. Major interest of using polymers was its altering mechanical properties by changing the reinforcement orientation. Ultra-high molecular weight poly(ethylene) (UHMWPE) being a tough material, resistant to wear, chemically stable, less friction, and reduced moisture permeability made them to dominate over four decades starting from 1962 as joint replacement material [36]. Large number of 1.4 million patients were treated during this period. However, long-term biological exposure reduced their mechanical performance which led to re-surgery. Investigation of this failure exposed the requirement of altering the fabrication process like mixing with additional materials, changing cross-linkage which improved the performance including surface properties [37]. Polypropylene (PP) was used as woven mesh to reinforce the implants but showed inflammatory response leading to pain [38]. Introduction of foreign materials during surgery is critical and the complete healing process can take 12 weeks. Thus, various materials were used as coatings or blends to improve the biomechanical response of the implants facilitating the bone repair.

4.2 Partially Degradable Materials

Partially degradable materials are those which display two behaviors at the same time, one is non-degradable part and the other is degradable. Non-degradable part maintains its physical, mechanical, and chemical integrity throughout its stay while degradable portion initially helps in the improvement of mechanical properties and then starts to degrade as time progress. The target of the implant is to provide the initial stability, but their mechanical properties should cooperate with bones. As the material starts to degrade, the bioactivity starts which enables the cell adhesion, stimulus to embryonic tissues, and antibacterial properties as well. These materials could be applied as coatings on the implant surfaces, blend during fabrication process, or fillers in the porous structures. Materials for surface coatings of implants include hydroxyapatite, calcium phosphate, polylactic acid (PLA), polylactic-co-glycolide acid (PLGA), silver, MXene, magnesium, zinc oxide nanoparticles, and iodine [35, 39–41]. These coatings start to dissolve as they encounter the body fluid and perform their duties by releasing ions and nutrients. Further, to decrease the structural modulus of the solid implants for target application, various techniques were introduced like 3D printing (additive manufacturing) of porous structure [42–44]. These structures can be tuned by changing their cellular structure (cubic, honeycomb, diamond, circular, and body-centered cubic) along with the pore size, shape, and strut thickness simply by modeling software [45]. These porous structures manufactured using metallic biomaterials can be filled using degradable polymers which are safe and broadly used in medical industry [46]. Recently, titanium bone plates with varying porosities of cubic cellular structures were prepared and the cavities were filled with polyglycolic acid (PGA). Titanium is responsible of the elastic–plastic properties as a major load carrier while PGA degraded till seventh week losing its maximum properties [47]. Thus, the partially degradable materials are multifunctional with better performance as of non-degradable materials.

4.3 Fully Degradable Materials

These are the materials that are completely resorbable with the passage of time into the body. The concept of these implants came due to the various complications with the materials discussed previously. Once the calluses heal properly, we go for the second surgery to remove the conventional metallic implants which will cause pain, disruption of soft tissues, blood loss, and sometimes infection. As the fracture heals, the calluses start sharing the load with the implant used to fix the broken bones. With the passage of time, the calluses are mature enough to withstand the body weight. Here is the point when implant should start losing its strength during the healing process with the load-sharing mechanism. This was the motivation of developing the biodegradable composites which will dissolve in the physiological environment once the fracture heals. It will diminish all conventional problems of metallic implants. Majorly, under clinical applications, the biodegradable materials are categorized into three groups, (a) metals, (b) bioceramics, and (c) polymers, and combinations of these materials as composites.

(a) Recently, unidirectional magnesium alloy wires have been used to reinforce PLA for in vitro tests [48]. Magnesium alloys [49] were not invented for medical use but their biocompatible attitude and excellent mechanical properties made them a suitable candidate to be used as fixation devices which are comparable with those of human cortical bone. Thus, various alloys were developed for these applications such as Mg-Ca, Mg-Zn, and Mg-Al. Magnesium devices were introduced as bars and rods [50] at 5–20% volume content, and wires in uni-directional or braided form at 6–10% fraction at different angles.
(b) Ceramics are well known because of their biocompatibility, bioactivity, and corrosion resistance behavior. But the drawbacks are their brittleness, complex shapes, high modulus, and poor fatigue. Thus, the ceramics are used as reinforcement materials in polymers as they alone are not feasible for medical devices. Calcium phosphate, tri-calcium phosphate, and hydroxyapatite are well known bioceramics.
(c) The origin of the natural polymers is starch, collagen, silk, alginate, and chitosan and synthetic polymers are polylactic acid, polyglycolic acid, poly-l-lactic acid (PLLA), polycaprolactone (PCL), polydioxanone (PDS), and polylactic co-glycolic acid (PLGA). The use of these polymers alone cannot be used because of their low strength.

Thus, polylactic acid (PLA) has been studied mostly because of its excellent biocompatible and biodegradable properties. To make the PLA compatible with the requirement of load-bearing bone fractures, various reinforcements are required. Its modulus and tensile strength have been described to be approximately 3.5 GPa and 59 MPa, correspondingly, which are much lower to bear the body weight [51]. As the reinforcement materials, Mehboob et al. [52] used unidirectional plasma-treated bioactive glass (BG) fibers as they offer excellent biomechanical properties. 30-second plasma treated displayed the elastic modulus of around 27 GPa with 118

MPa strength. But the BGF/PLA showed fast degradation when exposed to body fluid and thus magnesium (AZ31) alloy wires were used for reinforcement in PLA. The mechanical tests were carried out with varying volume content of 20–50%. These wires showed better sustainability in the human body [6]. Composite with 50 % volume content of Mg wires was selected for surface treatment of Mg wires for improved sustainability and stifled mass loss, stable pH, and encouraged the deposition of Ca and P compounds with better mechanical properties [6]. Further, research is going on to improve the biomechanical properties of these fully biodegradable composite implants to make them bioactive and antibacterial.

5 Implant Types and Their Applications

Treatment of broken bones is concerned not only with the repair of the bone anatomy but to consider the complete bone union with full recovery and increased callus volume. Callus is the soft tissue that envelops the fracture during early stabilization and converts into bone as time progresses. Enhanced callus volume ensures the better quality of healing. Various implants are used during operation to stabilize with minimum additional reduced injury to bone and surrounding soft tissues. These implants are majorly categorized into external (traction and pins) and internal devices (pins, screws, intramedullary nails, rods, and bone plates) for the treatment of orthopedic and dentistry fractures (see Fig. 3). Further the implants could be static or dynamic. Static implants are stiff and tightly screwed with bone without any relative motion while the dynamic implants are flexible around the assembly or with less stiff material providing the micro-movement at the fracture site. These devices are used according to the fracture location and its nature which decides the quality of bone union. Internal fixation devices are of main concern which are discussed in detail.

5.1 Screws

Orthopedic screws (OS) are usually used as fixation devices to fix the bone plates, intramedullary nails, and treat the minor bone fractures independently. The screws geometry has four parts: head, thread, shaft, and tip. For tightening the screw, screwdriver is attached to the head. This head could be hexagonal, circular, slotted, and straight. Head produces counterforce when compression is generated during fastening any implant to the bone. The shaft is the smooth surface between the threaded area and the head. The threads consist of the core diameter, thread diameter, pitch, and the lead with which screw advances during single complete turn into the bone. Thread core determines the contact area of the bone and screw resistance during pullout force. The screw tip is either fluted or round depending upon the way of insertion during tightening. Types of screws vary according to the length, its thread diameter, the distance between threads, and the design of their head and tip.

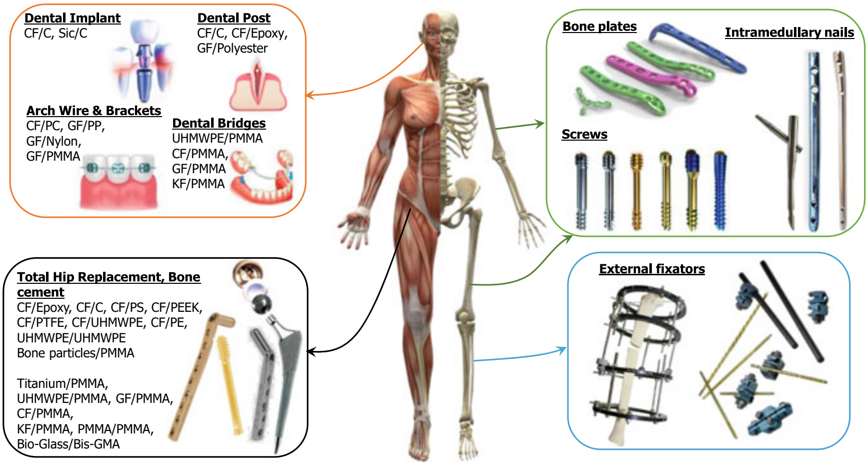

Fig. 3 Implants for fracture treatment

Based on these parameters and application, they are divided for the use of cortical and trabecular bone. For cortical screws, if the length of screw is very small and able to be tightened only in single cortical wall called as uni-cortical while the screws which hold both cortical walls when tightened are bi-cortical screws. These screws have dull ends with close spaced shallow threads overall the length [53, 54]. Mostly the holes are drilled before the insertion of these screws. The packing like the washer is placed if there is no bone plate between the screw head and the cortical bone to prevent any bone damage due to stress concentration. For trabecular bone, the screw threads are wide with large area to improve screw grip into the bone. Cannulated screws are hollow fixed using guide wire for better alignment to hold the multiple fracture segments instead of drilling. These are the basic types of screws used to repair small fractures.

5.2 Bone Plates

Bone plates are used to stabilize the broken bones by fixing them on the outer surface of the bone. These plates are available in different sizes, length, width, and shapes depending on the area of application. When fracture occurs, two different forces are produced on both sides of fractured bone: tensile and compressive forces. Pauwels defined the way of fracture fixation using tension band procedure for first time. During this principle, the bone plate is applied on the tension side of the fractured bone which neutralizes these tensile forces and translate them into compression forces. If the plate is directly applied on the compression side, it will bend or break due to fatigue. Plates help the primary function of muscles and joints by fixing the broken bones but early weight bearing is not recommended. Plates promote the risk of refracture after removal due to irritation, mass loss, and osteoporosis below the plate [55]. A rigid compression plate (CP) was first used in 1970 to fix the fractures and bone union was observed without callus formation promoting primary healing [56]. This fixation requires the plate compression against the bone relying on the tightening torque by the screw heads. CPs demonstrate disadvantages including: bending the plate before insertion to sit on the bone surface, damage of the one-third of vascular tissues, increased bone porosity around assembly, and mainly the stress shielding effect between the bone–bone plate [57]. To reduce the soft tissue injury, researcher tried to improve the plating technique by limiting the contact area of the bone plate–bone. Locking plate provides stability with locked screw heads into the plate maintaining the distance between bone plate–bone instead of compression with bone. To enhance the performance, flexible plates were prepared using vitallium alloys [58]. Still the controversies exist in using the completely rigid or flexible plates. It is believed that the micro-movement at the fracture site encourages fast fracture union due to the enlarged callus wrapping with combined primary and secondary healing process [59]. Bone plate rigidity depends on the material properties and cross-sectional area of the bone plate. That is why biomaterials with reduced stiffness and improved biomechanical performance implants are ruling the orthopedic industry by replacing the metallic implants [60]. Depending upon the fixation method and fracture's nature, plates are broadly grouped into four types: compression plates, buttress plates, bridge plate, and neutralization plates.

Compression plates as explained above are designed to fix fractures using compression. These compression plates are commonly referred to as the dynamic compression plates (DCPs). The holes in DCPs have tapered edges and the screw tights the plate against the bone without leaving any play.

Buttress plates are used to hold the fractures in place rigidly mostly at the proximal and distal ends of the long bones like at the ankle or knee where the fracture faces large forces. These plates are mostly wide to increase the strength. As these plates are used around complex surfaces, thus designed into L-shaped, T-shaped, or rounded ends.

Bridge plates as clear by the name are used to stabilize the comminuted fractures or large bone defects. Alone the function of this plate is very hard to stabilize the fracture and therefore scaffold-type artificial structure or bone grafts need to be placed between the fragments to relief the bone plate.

Neutralization plates are general plates where neutralization indicates that how the plate works during fracture fixation. This plate reduces the loading phenomenon on the fracture site by caring the loads and transferring them across the plate instead of the fracture site. Neutralization plates are fixed with screws to neutralize the torsional force, bending force, and shear forces. Wedge- or butterfly-type fractures are commonly fixed using these plates.

5.3 Intramedullary Nails

Intramedullary (IM) nails have gained attention and accepted universally over more than past 50 years. The nails are inserted into the medullary canals of the long bones following the hammering (HP) or reaming procedures (RP) assembled with screws at the proximal and distal ends of bone. During hammering, the nail press fits with the bone into the canal by the frictional forces and secures the movement of separated bone fragments. This fixation method is preferred for the mid-shaft diaphyseal long bone fractures especially in lower limb. The advantage is that the insertion method of IM nails requires small incision without extensive surgical procedure. They are in contact at multiple points of longitudinal bone interface while during reaming, a reamer is used to drill a coaxial hole along the bone length into the medullary canal. Gap is created around 1mm between the IM nail and bone interface promoting the flexible fixation. HP is more stable during axial and rotational distortion of fracture while more damage is done to the bone marrow and trabecular bone with RP. An ideal intramedullary nail is still under development with improvement in design and material although the varying bone anatomy makes it impossible. Better implant should have the following conditions:

It should provide enough stability by maintaining the alignment and position with reduced rotational movement as the axial compression is recommended.
It should provide the needed biomechanical stimulus for bone union.
It should be positioned in a way that its removal is facilitated after bone union.

Fracture stability with torsional and bending stiffness in nailing mainly depends on the material properties, diameter of the medullary canal, number and types of screws, and the diameter of the nail.

6 Fabrication Techniques

Numerous fabrication methods are used to prepare bioactive composites for fracture fixations. Commonly used fabrication processes include hot pressing, additive manufacturing, melt extrusion, injection molding, and compression molding. Various forms of implants with desired shapes can be fabricated including scaffolds, films, disks, screws, intramedullary nails, and bone plates.

6.1 Melt Extrusion

Melt extrusion in early 1930s was introduced in manufacturing industries. This technique was then used for the fabrication of orthopedic composite implants. During melt extrusion, raw material is melted and forced into a die of the desired shape.

Various steps include: (1) heating the material until it melts, (2) mixing of desired materials to obtain the homogeneous composite blend, and (3) applying pressure using piston or screw to the prepared material into the die for desired composite shape. These advantages include the following:

Cost-effective procedure.
Various material combination.
Solvent absence reduced toxicity.
Elimination of time taking drying process.
Complex shapes achievable.

While melt extrusion also reveal some disadvantages. High energy systems are required for heating chambers, push drives and only 2D shapes can be achieved. Degradable materials including ceramics, metals, polymers, and glasses in powder form can be easily processed with polymer pellets or fibers to enhance the biomechanical properties of composite implants.

6.2 Hot Compression Molding

In this technique, various composite materials including several combinations of the long and short fibers, aligned and random-oriented fibers, powders, and ceramics can be fabricated. Films of the pure polymers or in combination with powders are prepared using hot compression into the mold. Then the reinforcements prepared in the form of mats, weaved or random-oriented fibers, are placed in between the polymer films during staking sequence. Once the staked layers are placed in the mold, the mold is preheated up to the glass-transition temperature and the pressure is applied to the upper moveable surface of the mold to compress the stacked layer for even distribution of matrix into the reinforcement materials removing all possible trapped air. Then the mold is left at room temperature to cool down the fabricated composite. Different shapes with varying volume fraction and fibers orientation can be achieved using this fabrication technique.

6.3 Injection Molding

This process is same as that of melt extrusion process. The main difference is the addition of mold in which the melted material is injected to the cavity of the enclosed mold with desired shape. The material is then allowed to cool by rapid heat removal for composite solidification. This process is automatic and the even distribution of matric cannot be controlled.

6.4 Additive Manufacturing

Additive manufacturing (AM) is a technique that is grabbing much attention in recent years for three-dimensional (3D) printing of material. This technique was brought to the medical industry for biomaterial printing. This technique includes various methods like the fused deposition modeling (FDM), selective laser sintering (SLS), bioprinting, direct metal laser sintering (DMLS), and stereolithography (SL).

Fused deposition modeling is widely used for 3D printing mainly for the polymer materials along with their composites reinforced with chopped and continuous fiber. The materials used for FDM include thermoplastics including PLA or PLLA along with their blends such as carbon fibers, Kevlar, glass fibers, and onyx. The part is prepared using melted filament of thermoplastic extruded from the printer heated nozzle in semi-solid form to lay up the layer-by-layer structure. This technique aims high resolution with brilliant accuracy compared to other AM techniques.

Selective laser sintering is another 3D printing technology which was first introduced in 1980s. The high performance of SLS includes superior accuracy, resolution with smooth surface finish compared to other 3D plastic printing technologies. Any kind of shape can be produced using high power laser beam by fusing the small powder or polymer particles. The remaining unfused powder supports the printed structure without any additional structure attached. These printed parts have good mechanical properties compared to other 3D printing technologies along with low production cost with fast manufacturing making it trendy in AM.

7 Future Directions; Challenges and Opportunities

Degradable implants should meet two biomechanical criteria: one is initial integrity with degraded mechanical compatibility during healing period and second is the biocompatibility and bioactivity between the implant and the host bone fracture. Therefore, these two criteria should be considered while designing a biodegradable implant. The first objective is to provide the adequate initial mechanical support to the fractured bones followed by optimal gradual degradation. During this period of bone healing, the biodegradable implant provides temporary structural support for tissue differentiation process and completely degrades in a certain time frame, which depend on the severity of fracture, fracture site, fracture geometry, age, and weight. Generally, an orthopedic implant should provide the mechanical stability from 1 to 6 months in lower limb long bone fractures. However, it remains a challenge to set the balance between implant mechanical properties and healing rate of fractured bones. Therefore, careful considerations should be given to the material of implant and fracture-related parameters influence the healing of bone fractures. Moreover, a reliable in vivo or in vitro degradation study should be conducted according to the FDA recommendations following ISO-10993 standard if biodegradable implant is designed. Therefore, a biodegradable implant and the clinical implications such as healing of bone fractures should be critically investigated. Additional functions such as bioactive materials, drug delivery mechanism, and bone healing monitoring via smart biosensors should be integrated into the biodegradable implants. Appropriate bioactivity, optimal amount of drug release, and the biosensors for real-time monitoring of healing status need more advancements and extensive investigations are required to design the next-generation biodegradable orthopedic implants.

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