International Journal of Biomedical And Advance Research

ISSN: 2229-3809 (Online)
Journal DOI:10.7439/ijbar
CODEN:IJBABN

Review Article

A paradigm shift of the conventional intramedullary devices to new biological osteosynthetic devices: Bone stents

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Abstract

The intramedullary nailing as a fixation device has a long history, which dates back to the 16th century and has evolved in various aspects. Now, it has become a gold standard for the treatment for diaphyseal fractures, with a good success rate, however the technique still has some drawbacks associated with it, but continued research regarding new mechanisms and devices can overcome these drawbacks. New osteosynthetic devices, such as intramedullary bone stents can be superior to current fixation devices, as they have a modulus of elasticity closer to that of bone, cause minimum soft tissue damage and trauma. Moreover, they can overcome complications posed by conventional devices, such as stress shielding and an inadequate blood supply. This review focuses on an evolutionary perspective of intramedullary devices used surgically for the repair of long bone diaphyseal fractures.

Keywords: Intramedullary nailing; Long bone diaphyseal fractures; Reaming; Internal fixator

1. Introduction

Internal fixation methods have showed significant advancement in the treatment of fractures[9]. The advantages of biological internal fixation lower severe risks and complications, on the expense of less important mechanical drawbacks[24]. Over the decades, the internal fixation technique, intramedullary nailing has become a gold standard for the treatment of long bone diaphyseal fractures. IM nailing, compared to conventional methods is more effective and has a number of advantages. IM nailing provides adequate stability, with minimum soft tissue and vascular damage, as a result, revascularization of the fractured bone is enhanced, which in turn stimulates periosteal callus formation[28]. An example of successful treatment by internal fixation techniques is of the tibial fractures, where results are achieved quickly, the cost of treatment is low and few pulmonary complications are encountered[9].

One of the main issues regarding intramedullary nails is whether the nail should be inserted with reaming or without reaming, as both have their advantages and disadvantages. Another variation is of the nail being statically or dynamically locked. Furthermore, nails can either be made of stainless steel or titanium (usually used for pediatrics)[31]. This review not only focuses on the current fixation methods for the treatment of diaphyseal fractures, but it also addresses some fairly new patented devices, known as intramedullary bone stents, which currently are under research.

2. Long-Bone Fractures & Their Complications

Long bones provide support to the body and allow movement, however if a tubular bone is fractured there is complete loss of movement or support, therefore utmost speed of repair is required. Long bone fractures mainly consist of the femur, tibia, humerus, radius and ulna. With advancements and improved internal fixation techniques in the field of fracture treatment, complications, such as malunions and non-unions still exist, for which convincing methods are still not well defined[6]. Especially in the third world, problems of non-union and malunion are not uncommon[26]. There are a number of factors that affect fracture fixation, such as stability, nutrition supply and gaps between the bone fragments. A lack of stability, nutrition or increase in fracture gap can lead to improper fixation, along with malunion or non-unions. Other factors that affect healing time are, age of the patient, preexisting disease, location, pattern of the fracture, soft tissue damage or infection at the fracture site and the age of the fracture at the time of the initial fixation treatment. Therefore, by keeping all these factors in mind, one can conclude that there is no specified time required for fracture healing[10].

When operative or surgical methods are chosen, intramedullary nails are the treatment of choice for tubular, long bone fractures, however the small size of the intramedullary cavity specifically of the radius, ulna and fibula is a limitation in the development of IM devices. Moreover, open fractures need special care and treatment to prevent infection, as it can interfere with fracture fixation methods, therefore all operative methods should be carefully assessed before treatment is begun[6].

2.1. Reaming & Tibial fractures

In literature, comparative studies have been made to evaluate the clinical results, complications and problems of reamed and undreamed IM nailing in the treatment of open tibial fractures. The treatment of open tibial fractures is still quite challenging, as it poses additional surgical complications. In open fractures, unstable blood supply and tissue damage increase the risk of infection, as well as non-union. While unreamed nailing reduces the risk of infection, it may compromise the stability at the fractured site, whereas reamed nailing provides enhanced stability, but can cause infection and non-union, as a result of a disturbed endosteal blood supply[2].

2.1.1. Malunions

Incorrect alignment or union of bone fragments during healing can lead to malunions and can cause shortening, rotational, angular deformity and degenerative joint disease. Malunions can be caused by early weight bearing after fracture repair or incorrect fixation methods. Moreover, the malunion may be functional or nonfunctional, depending on the location of the fracture, and the configuration in which it has healed[10]. As mentioned before, a minimum gap, adequate stability, and a sufficient nutrient supply are required for proper bone alignment and fixation. According to literature, the treatment of malunions can be classified as femoral malunions and tibial malunions, both of which will be discussed below[6].

2.1.2. Femoral & Tibial Malunions

A femoral malunion includes, shortening, which is more than 2 cm or angular/rotational deformity of more than ten degrees. In addition, if there is a leg length discrepancy (LLD) of more than 2cm, a limp is observed, which can cause some complications, such as back pain. Femoral malunions can be treated by either a shoe-lift or lengthening can be performed, depending on the situation, whereas angular or rotation deformity can be treated by osteotomy. Tibial malunions include shortening of more than 2cm, angular deformity of more than 5 degrees, internal rotation of more than 5 degrees, or external rotation of more than 10 degrees is considered unacceptable. Similar methods to that of femoral malunions can be used to treat tibial malunions[6].

2.1.3. Delayed Union & Non-unions (Atrophic & Hypertrophic)

A delayed union occurs when the fracture fails to heal within the expected time frame. Factors that cause delayed union include instability and an inadequate blood supply. Fracture sites with severe soft tissue damage may have a very limited blood supply. Moreover, the technique used and inappropriate fixation can also lead to fracture instability. A number of different forces act on a fracture and its associated fragments, including shear, tension, torsion, bending and compression. Of these, the rotational and bending forces are the most common causes of instability[10]. A nonunion can be defined as a failure of the fractured fragments to unite[10], or a fracture that permanently fails to heal after repeated surgeries and treatment. Furthermore, non-unions can be divided into two main groups for the ease of treatment, these are atrophic and hypertrophic. Atrophic nonunion occurs when there is a large fracture defect, severe disruption in the blood supply around the fracture site, or infection, whereas, hypertrophic nonunions are caused by insufficient stability[6].

2.2. Complications Associated With Reaming

Reaming has its advantages; for instance, higher rates of union and improved healing have been recorded, however literature studies have also reported a number of negative effects associated with reaming. Complications related to reaming include, higher levels of intramedullary pressure, pulmonary artery pressures, increased fat embolism and pulmonary dysfunction[20,7]. Furthermore, reaming is not recommended for open fractures, as it can cause problems, such as temporary damage to the internal cortical blood supply, which is associated with increased rates of infection [25]. Studies have shown that intramedullary nailing and reaming is linked to the development of fat embolism[18]. Reaming can considerably increase the risk of respiratory distress syndrome (ARDS) in patients who are suffering with thoracic trauma and who are treated within 24 hours of injury, whereas non-reaming does not adversely affect lung function. When femoral nails of titanium were used, they exhibited higher strengths and biocompatibility. Furthermore, it has been suggested that nails with a smaller diameter and increased strength allows them to be inserted without reaming[14].

3. Minor Complications

Minor problems have been reported regarding flexible intramedullary nailing. Pain and skin irritation at the nail insertion site has been encountered, which causes limited movement of the knee, however the problem no longer exists once the nail is removed[13]. One study which consisted of 229 children with 234 diaphyseal fractures of the femur basically showed the most common complication was angulation[16]. Possible IM rod related complications are implant loosening, infection, change in bone length, and hardware fracture[25].

4. Evolutionary Perspective Of Internal Fracture Fixators

The development of internal fixation devices dates back to the end of the 18th and 19th century[5]. From the earliest recorded devices to the latest techniques today, not only have there been minor changes, but internal fixation methods and devices have evolved in various aspects, such as design, materials, deployment, and results. These advancements have resulted in effective and successful internal fixation techniques[4]. The very first devices to be developed were the cerclage wires, which are known to be unstable. The plate and screw technique is also known to be developed in the year, 1885. The cerclage wire technique involves the usage of at least two wires and is most effective when used for oblique or transverse fractures, however this technique is thought to damage the blood supply, but according to literature, failure is thought to be caused by improper application, inadequate tightening of the wires during application and because of displaced or missing fragments[23]. It was in the early thirties when the Rush brothers in Minnesota and Gerhard in Germany, independently developed an intramedullary nailing technique. Also in the late eighties, some stable bone fixation was achieved, however these caused damage to the vascularisation of the bone and as a result healing was delayed, which further caused the bone to grow weaker with a risk of re-fracture after removal of implant. Techniques used before the 20th century, such as cerclage wires or iron wires for fracture fixation involved open reduction and were almost always unstable, with risks of life threatening infections, muscular degeneration and joint stiffness. Furthermore, the rate of success remained low, whereas the rate of catastrophes was often high. There has been an evolution of internal fixation devices in the twentieth century, with the development of “biological osteosyntheses”, which mainly focuses more on the biological parameters, rather than the physical features of the device[5]. Towards the end of the nineteenth century a number of intramedullary nailing fixation methods were being developed[5]. It was during WWI, it was the first time Hey Groves of England used metallic rods, which were inserted into the intramedullary canal through a very small incision. The true IM fixation technique was developed by the Rush brothers in Minnesota and Gerhard Küntscher in Germany. Gerhart Küntscher, also known as “Father of Intramedullary Nailing” developed the basic principles of IM nailing, material selection and design[22]. In addition, “Marrow Nailing”, a concept developed by Kuntscher’s was practically used for the first time in 1939.[28] This provided a solid foundation for fracture fixation and it was only after this technique; intramedullary nailing devices progressed rapidly over the decades[4].

5. The 1990’s & 21st Century

After the advancement of intramedullary nail design and materials during the 1990’s, another major development was of the unreamed and reamed nailing. Open femoral fractures were previously treated with unreamed nails, which are now being managed by reamed nails. Moreover, there was some progress in the design of IM nails, including new titanium nails and gamma nails. In addition, studies in the 1999 showed that immediate weight bearing in patients with femur fractures, fixed with large diameter nails, with high fatigue strength, promoted mobilization[4]. Finally, the concept of “biological internal fixation”[19] lead to the development of a method known as, Less Invasive Stabilizing System (LISS). This system consists of a plate that functions as an internal fixator and was inserted through a small incision. The technique provided flexible fixation and induced callus formation, which allowed rapid healing, however the technique required precise fixation, as the flexible plate needs to be placed exactly along the bone’s surface. Biological internal fixation is much more effective as compared to older techniques, as it provides easy handling, prompt healing and lower risks of infection[5].

5.1. Evolution of Fixation Strategies

The methods and materials used for internal fixation of long bone fractures have evolved over the past few decades, and there has been a greater emphasis on the biological rather than the physical properties. With time, flexible fixation has evolved from rigid fixation, as it encourages formation of callus, while methods for indirect reduction reduce operative trauma. Conventional methods for internal fixation used plates that aimed at complete stability to avoid even slight movement which could either result in a prolonged healing process or loosening of the implant. In addition, this method can increase necrosis, which is initially initiated by the injury and also enhance the risk of infection and a re-fracture. New methods and techniques involve usage of internal fixators, which have a minimum implant-to-bone contact, fewer screws, and in contrast to the conventional technique require some degree of mobility. Recent flexible fixation techniques aim to reduce trauma and produce minimal biological damage. It does this by avoiding precise reduction methods, (especially of the intermediate fragments), and rather makes use of indirect reduction. Indirect reduction, as the name implies aims only to align the fragments indirectly, by using different methods, such as applying corrective forces. It avoids exposing the fractured site, thereby reducing trauma during treatment. Flexible fixation involves devices which are used for supporting the fractured area, this induces callus formation. In addition, only splinting with compression can be used to achieve flexible fixation. Direct reduction aims to restore fractures by directly manipulating the bone fragments. Overly precise reduction, more invasive implants and extensive implant-to-bone contact leads to surgical and biological complications. Newer internal fixation methods aim to produce better biological conditions, rather than absolute stability of fixation and this approach has given us results of early solid union. Moreover, the main objective is the restoration of function without minimum trauma and complications.

This new evolved approach for internal fixation methods focuses more on the biological properties, rather than the mechanical properties, and is known as the "biological internal fixation". The concept of biological internal fixation is fairly new and is still developing. It focuses on aspects of stability, the blood supply and avoidance of complications, such as necrosis, as well as benefits of new surgical technology[19].

Stability is the degree of displacement, caused by a load at a fractured site. A stable fracture is one which does not have any displacement under a load, whereas absolute stability is achieved when there is no micromotion at the fracture site, when induced by a physiological load[21]. The type of healing is determined by the degree of stability and there are two main types of healing mechanisms, namely direct healing and indirect healing. Direct healing, also known as primary bone healing involves stable fixation and no micromotion, which is achieved by compression techniques. This type bypasses the sequential steps of tissue resorption and differentiation and progresses directly to healing without the formation of any callus, whereas in indirect healing the fracture has some degree of movement (relative stability), maintains reduction and allows healing with callus formation. Indirect healing is enhanced by both, micromotion and weight-bearing, however too much movement or load can cause non-union or delayed fixation[15]. In contrast to direct healing, indirect healing does not skip the intermediate steps of tissue differentiation and resorption of bone surfaces of the fracture site, rather it causes bone fragments to unite by callus formation[19]. Primary and secondary bone healing mechanisms show that healing of fractures is directly affected by various mechanical environments[29].

Relative stability in fracture fixation allows the displacement of bone fragments when a load is applied across the fracture. A physiological applied load increases displacement, whereas rigidity decreases the displacement of fragments. A specific amount of required flexibility is not known, but a fixation is considered to be flexible when it allows some degree of controlled movement of the fragments with respect to each other. In addition, all fracture fixation techniques are considered flexible, except the compression method, as all of them provide relative stability[19].

The amount of flexibility of an implant is dependent on a number of factors, such as the method through which the device is applied by surgeon and the type of loading. Furthermore, internal fixation devices allow micromovement, therefore the fracture can heal by callus formation, however if the implant is not applied correctly, it can result in complications, like malunion or non-union of the fractured site. Implants such as intramedullary rods/nails and other internal fixation devices provide relative stability. Intramedullary nails in particular provide stability to fractured bones in two different ways-they can provide axial stability, and rotational stability can also be provided when locking screws are used. In addition, there is always some amount of micro-motion when an intramedullary nail is used; this results in an external callus, which is visible on the radiograph. Stability and mirco-movement should be balanced in such a way that stimulates callus formation and leads to bone regeneration. To conclude, the biomechanical environment greatly affects both stability and healing[30]. Elastic flexible fixation can be achieved without compression, by using more flexible implant materials, such as fibre-reinforced plastic or carbon plates instead or rigid conventional splints. Moreover, the dimensions of an implant and its size affect its flexibility. Usually, a more deformable metal, such as titanium, together with reduced dimensions is used[19].

6. Effect of Mobility on Solid Bone Healing

If a fracture is left untreated, then the broken, mobile fragments are stabilized naturally by contraction of the surrounding muscles, which is usually painful and results in shortening or malunion. Along with these, hematoma formation and tissue inflammation increase, causing the tissue to swell, which has a slight stabilizing effect. Studying bone healing in untreated fractures highlights the effect of initial mobility on solid bone healing.

7. Current Fixation Techniques

There are several causes for fractures of the long bones and the cause can be different in children and the elderly. Fractures are common in children and adults due to accidents caused by falling, sports or trauma, whereas in the elderly fractures can be a result of osteoporosis and falls[30]. The pattern of fracture varies, which gives rise to different types of fractures. These can be classified as, spiral, transverse, oblique segmented fractures and so on[31]. Most of these fractures can simply be treated with a cast or a splint, but more complicated cases require surgery. Some fractures can be treated non-surgically, while a large number of other fractures require surgery. If a fracture is left untreated, the mobile fragments are stabilized naturally by painful contractions of the surrounding muscle, which can result in bone shortening, loss of function and improper alignment. Fracture fixation techniques aim to stabilize the fractured bone, induce healing, allow early mobilization and restore its function. There are two main types of fracture fixation techniques used for long bones: internal fixation and external fixation[25].

This review focuses on internal fixation techniques, devices and other important aspects of internal fixation of diaphyseal fractures. The development of internal fixation devices and techniques has allowed us to overcome the limitations that are caused by other conventional methods, such as skeletal traction or cast immobilization.

Currently, the majority of internal fixation devices are made of stainless steel. In addition to these, elastic titanium implants have gained popularity as they are biologically superior, however they have lower strengths. Moreover, various devices have been developed over the years and are available for internal fixation. These devices can basically be divided into major categories: wires, pins, screws, rods, plates and intramedullary nails[25].

7.1 Screws

Screws are frequently used in combination with nails and rods. Fixation screws can be classified into two major categories, according to the Association for the Study of Internal Fixation [ASIF]: cortical and cancellous. Cortical screws are usually fully threaded, have a small diameter and are designed to be used in the diaphysis. In contrast, cancellous screws have larger diameters, deeper threads and usually have threads at their ends[25,12].

7.1.1. Intramedullary Nails or Rods

Intramedullary nailing has evolved immensely, since it was first developed and is now a standard treatment for the fracture of diaphysis of lone bones. In addition, humeral shaft fractures are being treated with antegrade and retrograde IM nailing, however some complications have been encountered. Intramedullary nailing can either be antegrade or retrograde. Antegrade nailing is used for tibial shaft fractures, whereas both antegrade and retrograde methods can be used for femoral and shaft fractures. The piriformis fossa is the entry site for an antegrade femoral nail, whereas the intercondylar region is the entry site for retrograde; and for the antegrade tibial nail, anteriorly just below the joint line[25]. Retrograde intramedullary nailing is advantageous in many settings, including polytraumatized patients, obese and pregnant patients[17]. In addition, another advantage of retrograde entry point is that fractures in the distal metaphysis region can easily stabilized[1]. Reaming is performed using flexible reamers in order to enlarge the medullary cavity, after which the nails can be introduced using a guide wire[25.] Various types and designs of intramedullary nails and rods are available. IM nails provide adequate stability against bending forces; however they are unable to control rotation and compressive forces. This is where screws are used in combinations with rods and nails. Distal interlocking screws are usually located at the distal/proximal ends of the nail and provide fixation stability. Femoral nails can have one or two proximal interlocking screws and two distal ones, whereas tibial nails have three. The interlocking screws are usually placed perpendicular to the distal and proximal femoral shaft, which provide stability and prevent collapse or shortening of the fracture[25].

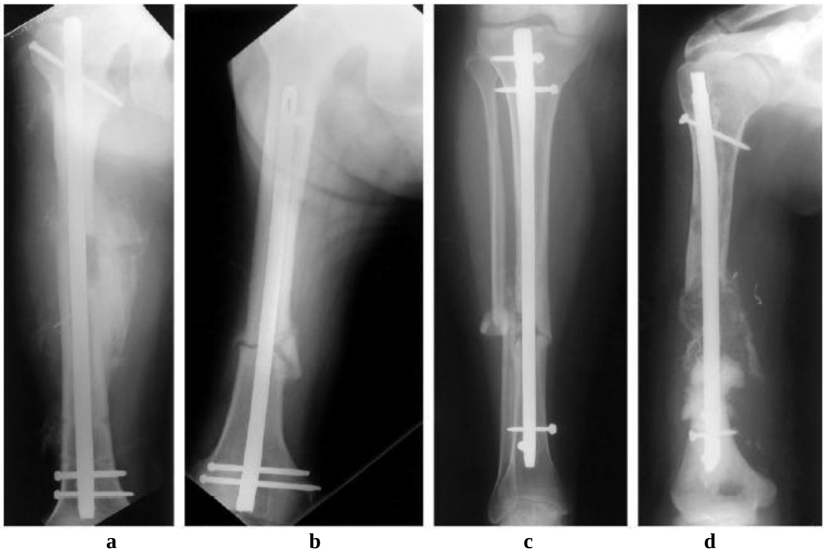


Figure 1: **(a)** Antegrade IM nail with one proximal and two distal interlocking screws. **(b)** Retrograde IM nail with one proximal and two distal interlocking screws. **(c)** Antegrade IM nail with two proximal and two distal interlocking screws.
(d) Antegrade intramedullary nail with one proximal and three distal screws (poorly visualized on this single projection) Also, multiple metallic embolization coils and polymethylmethacrylate cement are present at the fracture site[25].

The intramedullary nail can either be "dynamically locked" or "statically locked". When the nail is locked at both, distal and proximal ends, it is statically locked[25]. This is achieved by inserting screws at both ends of the nail in round holes[27]. In contrast, dynamic locking refers to the placement of screws at one end of the nail only, which allows compression at the fracture site[25].

Different methods are used for treating long bone fractures in adults and children, as there is a difference between their bones, which is of the epiphyseal plates (growth plates). These plates allow growth and are composed of cartilage; however these are the weakest parts of the long bones[3] and therefore must be avoided in children. The epiphyseal plates are localized near the joints. These are located at the proximal and distal ends of the bones, whereas in adults who don't have any growth, the plate is replaced by the epiphyseal line. Damage to the growth plates can cause cause uneven growth of the legs, therefore, currently, two different methods are practiced, depending whether the patient is an adult or a child: ***IM nailing for adults*** and ***flexible elastic nails for children***. A study shows that fractures of the femur are quite common in children and a number of different methods can be used for fracture fixation, depending on the type of fracture and age of the child. Titanium elastic nailing is a common technique used to treat femoral fractures in children, which has been used for nearly two decades in Europe and more recently it has effectively replaced external fixation, traction and spica casting in the United States[26].

8. Flexible IM Nails in Pediatrics

Flexible intramedullary rods have smaller diameters and have enhanced flexibility, which allows them to be used for different long bone anatomy. The entry point of flexible nails is the metaphysis and they are mainly used for paediatric shaft fractures, to avoid damage to the growth plates. In addition, flexible nails allow micromovement[13] and are associated with a lower risk of infection[25]. Previously, this technique was considered to be the appropriate treatment for femoral shaft fractures in patients of age of 6-16 years, but literature suggests that the technique works well for preschool children too, and has also produced exceptional union results. Furthermore, timing of nail removal is another factor which can affect fracture fixation; however there are no standard guidelines in literature for the time of removal. Generally, the time recommended for nail removal ranges from 6 months to a year after surgery. Moreover, results produced by stainless steel and titanium nails are somewhat similar; however stainless steel is considerably cheap, as compared to titanium[13].

9. Intramedullary Bone Stents

Recently, improved and newer fracture fixation devices with superior properties, to those of IM nails and rods, have been the focus of research. One such patented device, known as osteosynthetic shape memory material intramedullary bone stent used for treating bone fractures will be discussed below.

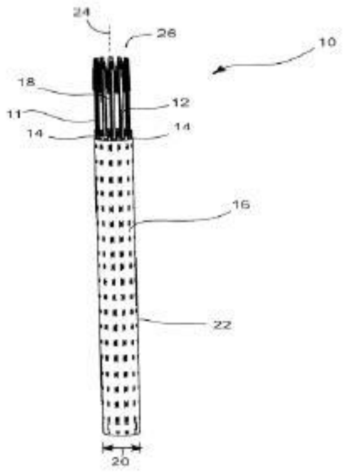
Intramedullary bone stents can either be prepared from alloys, such as stainless steel or Shape Memory Alloys (e.g Nitinol). The IM bone stent is inserted into the intramedullary bone cavity to reduce the fracture and cause proper alignment of bone fragments. Radial expansion exerts circumferential stress at the fracture site, whereas longitudinal contraction restores the fracture and holds the bone in the correct alignment. Intramedullary bone stents can be superior to current fixation techniques in a number of ways: the bone stent has a modulus of elasticity closer to that of the bone, stress shielding does not occur and it does not cause osteonecrosis. While rods, screws and nails can cause damage to the growth plates in skeletally immature individuals, stents do not interfere with growth at the epiphyseal plates. In addition, there are a number of other advantages of using intramedullary bone stents, as fracture fixation devices. Nitinol intramedullary bone stents of the present invention provide compression for longer periods of time compared to conventional fixation devices and methods. In order for a fracture to heal, it requires an adequate blood supply. While conventional devices, such as plates, rods and nails can cause vascular damage and necrosis, the IM bone stent does not disrupt the blood supply or cause vascular damage. The patent basically describes two preferred methods for stabilization and compression of the fracture. The first method consists of an intramedullary implant, with a porous structure between the distal and proximal ends. The first technique includes two states, in the first state there is longitudinal expansion and radial contraction, whereas in the second state the device is first longitudinally contracted and then radially expanded. This creates a desired bone-implant contact at the fracture site, which provides both, stability and compression. The second preferred form of invention consists of a device, which when deployed into the IM cavity of the bone, restores the fracture, by expanding radially and contracting longitudinally. As the device expands radially it applies hoop stress to the fracture, and when it shortens, fracture fragments of the bone are drawn closer. The material used to develop the intramedullary bone stent is a shape memory material, known as Nitinol. Nitinol, an alloy of Nickel and titanium has been used as arch wires in orthodontic applications, and with time it has become a key component of many medical devices, including stents and filters. Its unique and superelastic properties have made it the material of choice for a vast range of medical devices. In addition, it can experience much greater strains, as compared to conventional materials. The superelastic property of nitinol allows it to be deployed in a compressed state, which can then easily expand, and drastically transform its shape and configuration. Moreover, the NiTi has a titanium based oxide layer, which provides corrosion resistance and creates an effective barrier against the release of nickel ions. Therefore, these properties make Nitinol a biocompatible material. The current device makes use of the mechanical behavior of the stent, which is foreshortening, to repair and reduce the fracture. The radial expansion and axial compression during foreshortening allow bone fusion and reduction. Another important aspect of the bone stent is its ability to be osteoconductive, due to the piezoelectric effects on osteoblasts. Along with the stent's ability to apply compressive forces, the stent's structure is "spring-like", which to some extent can cause vibrations. Therefore, both the osteoconductive behavior and oscillations due to "spring-like" behavior can positively affect, bone density, remodeling, healing and therefore stimulate rapid bone regeneration. In addition, osseointegration is preferred between the struts of the stent. Often, implants stimulate the formation of soft connective tissue, which can cause adverse effects, such as improper fixation, loosening and eventual failure. However, for successful implants hard bony tissue fills the gaps between the bone and implant, allowing the bone to be firmly attached to the implant.

Two types of stents can be used for the present invention, these are: expandable and non-expandable meshes. Expandable meshes are further grouped into two categories, namely, self-expanding and non-self expanding meshes, which are usually constructed from plastics or polymers. The self-expanding type can be made from materials, such as Nitinol. These exhibit super-elastic behavior, and can change their configuration due to the temperature change, i.e. heating to surrounding temperature, once deployed in the body. A different mechanism is used for non-self expanding meshes, where an inflatable balloon is placed inside the stent's cavity and is then inflated in order to expand the mesh to the desired diameter configuration. Once the stent is positioned at the right location, the balloon can be deflated and removed. Furthermore, the expandable intramedullary bone stents can be made with a number of different configurations, such as zig-zag patterns (e.g "Z" stents), coiled spring and braided filaments. Also, the stent's collapsible structure can consist of external hooks, which can easily and effectively grip bone tissue. Moreover, the struts can have teeth like structures, which can dig into the bone during longitudinal compression, and cause the reduction of the bone fracture. Intramedullary bone stents can be used for all types of long bone fractures, including Carpals, Matatarsals, Humerus, Radius, Ulna, Femur, Tibia and Fibula, however, it must be noted that stents have still not been used in practical orthopedic applications as fracture fixation devices[8].

9.1. Thermo-chemically Activated Intramedullary Bone Stent

Another patented device, known as Thermo-chemically Activated Intramedullary Bone Stent is a deformable device that conforms to the shape of the intramedullary canal. The invention is basically a composite device, which consists of two components: a support structure and a thermo-chemically activated thermoplastic matrix. As seen in Figure 2, the support structure (labeled as 11) consists of a cage (labeled as 12). It also has stiffening rods, (labeled as 14). The stent is of a tubular shape, with a hollow central core, which extends through the stent's length. In addition, the rods and cage is embedded in the thermoplastic matrix.

Figure 2: IM bone stent consisting of two components: a support structure (11) and a thermochemically activated matrix[11].



The composite device can transition from a contracted, flexible orientation to an expanded and rigid state, when deployed into the IM canal. The expanded and firm configuration provides support and correct alignment to the fracture site. Moreover, the thermoplastic nature of the matrix allows the stent to conform to the shape of the IM canal in its first state, whereas the second state provides torsional and bending reinforcement of the broken bone fragments during healing. The cage is tubular and can be braided or woven, a laser cut tubing cage, or a chemically etched tubing cage. In addition, it can be made from different materials, such as Nitinol, stainless steel, Titanium alloys, polymers or other biocompatible materials. The stiffening rods can either be made from biocompatible or non-metal biocompatible materials. The biocompatible materials include, stainless steel, cobalt-chromium alloys, zirconium alloys, titanium or titanium alloys and particularly beta titanium alloys, whereas the non-metal biocompatible includes ceramics, bioabsorbable materials and biocomposites. Once the device is deployed, the stiff rods run parallel to the longitudinal axis of the bone and line the inner surface of the IM canal. As mentioned above, the thermoplastic matrix, which has an embedded support structure, can be thermo-chemically activated. The change from one state to another can be accomplished by changing factors, such as the molecular structure of chemical components of the matrix. Techniques to change the structure include, changing the temperature of the material, exposing the material to gamma or ultraviolet radiation and others. Furthermore, the matrix can consist of a thermoplastic biocompatible polymer or polymer blend. A wide range of polymers can be used, such as polylactic acid (PLA), trimethylene carbonate (TMC), polyglycolic acid (PGA), poly l-lactic acid (PLLA) or other biocompatible polymers. These polymers have a glass transition temperature. When the temperature of a specific polymer rises above a glass transition temperature, the polymer becomes flexible and deformable, whereas when the temperature falls below its glass transition temperature, the polymer structure transforms and becomes rigid. Energy is required for the first thermo-chemical state, whereas for the second thermo-chemical state there is dissipation of energy. Moreover, the thermoplastic matrix can also consist of a bioactive material, which can stimulate bone and accelerate the healing process. The device is inserted into the intramedullary canal through an opening, which is usually in the proximal or distal metaphyseal region of the bone and is not parallel to the intramedullary canal. The deployment of the stent can be achieved by using a delivery tube, which can be inserted into the opening. Also, the device can be heated right before implantation, so it can be flexible and in a deformable shape. Alternatively, the IM stent can also be inserted directly through the opening, without the use of a delivery tube. When placed inside the IM canal, the stent expands radially causing the rods, cage and the matrix to move radially outwards towards the walls of the IM canal. Once the device is allowed to cool below the low glass transition temperature, it transforms and attains the second thermo-chemical state, which allows the matrix to become rigid and crystallize. As the matrix hardens, it takes up the shape of the intramedullary canal, allowing the rods and the cage to be embedded/fixed in the thermoplastic matrix.

As the device conforms to the shape and irregularities of the intramedullary canal, it begins to provide torsional support and stability to the fractured bone. In order to deploy the IM bone stent, radial expansion is required. This can be achieved by using a deformation apparatus. The deformation apparatus expands and allows the device to expand, until it conforms to the IM canal's shape. After the implantation, the device can be removed if desired. Different methods can be used for the removal, as it depends on the decomposition of the biocompatible thermoplastic matrix. A heating element or heatable expansion apparatus is inserted into the intramedullary cavity, and the device is heated above the glass transition temperature until the matrix is flexible and deformable. The heat source is then removed and the device can be easily be removed by pulling the structure in the longitudinally direction, whereas no heating is required when thermoplastic matrix has been absorbed and it can be directly removed. It must be noted that a number of alternative embodiments of an intramedullary bone fixation composite device have also been included in this patent, which have similar deployment methods and components[11].

10. Conclusion

The fixation technique, intramedullary nailing has a long history, which dates back to the 16th century and has evolved in various aspects. Now, it has become a gold standard for the treatment for diaphyseal fractures, with a good success rate, however the technique still has some drawbacks associated with it, but continued research regarding new mechanisms and devices can overcome these drawbacks. New Osteosynthetic devices, such as intramedullary bone stents can be superior to current fixation devices, as they have a modulus of elasticity closer to that of bone, cause minimum soft tissue damage and trauma. Moreover, they can overcome complications posed by conventional devices, such as stress shielding and an inadequate blood supply. While nails can interfere with bone growth in children and infants, stents might prove to be beneficial for the treatments for pediatric patients. Bone stents can also be made biologically active by using bioactive materials, as these stimulate bone growth and accelerate the healing process. However, the combination of bioactive materials with new osteosynthetic devices, such as bone stents and their practical application in the field of orthopedics is yet to be determined.

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