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Bioabsorbable Screws for Anterior Cruciate Ligament Reconstruction Surgery: A Review

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ABSTRACT

One of the popular orthopedic implants is utilizing fixation screws to fix Anterior Cruciate Ligament (ACL) grafts and secure the graft into femur and tibia. Currently, these screws are made of titanium or bioabsorbable materials. In this respect, bioabsorbable screws were generated in order to overcome some of the potential problems caused by metallic screws. Although the bioabsorbable screws are susceptible to some drawbacks includingbone ingrowth features as well as good in vitro and in vivo mechanical properties. The biomechanical results of ACL screws showed that the ultimate failure loads and yield point loads varied from 800-1500 N and 600-1000 N, respectively. Moreover, the evaluations of in vivo degradation behaviorshowed the almost complete or fully complete resorption of ACL screws from 6 month to 2 years. However, it was proved that the addition of bone mineral phases such as Hydroxyapatite (HA), β-Tricalcium Phosphate (β-TCP), and Calcium Carbonate (CC) could enhance this degradation rate. Incorporation of biceramics into pure polymeric ACL screws may contribute to enhancing the osteogenesity of bone after full resoprption of screws,function as buffering agents that decrease the acidity of screw adjacents resulting from degradation of products, andimprovee the mechanical properties of ACL screws. In this paper, the latest bioabsorbable ACL screws which are currently available for graft fixation in orthopedic markets are discussed. A brief review of the literature regarding the physical, biological, and mechanical properties of bioabsorbable ACL screws was made. Besides,the insertion technique, various manufactured sizes, and in vitro and in vivo mechanical properties for each screw were addressed.

1. INTRODUCTION

In orthopedic surgery, biomaterials such as metals, ceramics, polymers, and composites are used as implants which are well compatible with living body tissues [1]. For many years, various metal alloys have been extensively used to fix the fractured bone or soft tissue rupture due to their desired mechanical properties and at the same time, their own proper biocompatibility [2]. Common orthopedic alloys are stainless steel, cobalt-chrome, titanium, and magnesium alloys [3]. Bone is a dynamic and complex live tissue that provides the body with the required mechanical enduranceand has an elastic modulus of 10 to 30 GPa [4]. Among all of orthopedic devices used for fixation and preservation of damaged bone or soft tissues in order to restore their functions, Anterior Cruciate Ligament Reconstruction (ACLR) screws are one of the most popular orthopedic devices. The stability of knee joint is provided by four extremely strong ligaments: ACL and Posterior Cruciate Ligament (PCL) prevent the tibia from slipping in sagittal planes; Medial Collateral Ligament (MCL) and Lateral Collateral Ligament (LCL) prevent the knee from bending in coronal plan. Among them, ACL tearing is one of the most common injuries (11 to 33% in different series) which is prevalent among athletes or patients with high activity. Fixing the graft into bone tunnel is a substantial step during the ACL reconstruction surgery. In this regard, the graft is threaded and compressed into bone pilot drilled hole by interference screws.There are two different types of ACL screws: metallic and degradable polymer-based screws. Use of metallic screws are regarded as the standard graft fixation method [5, 6]. The first ACL interference screws made of titanium alloys with a relatively sharp thread were utilized to provide a good anchorage of BPTB grafts into bone tunnel [7].

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Such screws were first introduced by lambert [8] in 1983 and then, popularized by Kurosaka et al. [9]. However, titanium screws provide high initial strength and well integration into the adjacent bone due to good biocompatibility; in some cases which need to be revised, the screw removal is known as a challenging issue [10,11].The advantages of metallic ACL screws are solid fixation and well toleration on behalf of the body, while some of their drawbacks are their interferences with any applied probable Magnetic Resonance Imaging (MRI) following the surgery [1] and their potential interferences with any future surgeries on the knee such as ACL reconstruction, which may cause the laceration of the graft during insertion [12,13]. Currently, many attempts have been made to replace the retained unneeded foreign body materials into body by biodegradable and bioabsorbable ones. Bioabsorbable ACL screws could disappear when they are no longer needed. These categories of ACL screws are capable of overcoming some of the potential problems prevalent inmetallic ACL screws. However, bioabsorbable ACL screws have their drawbacks including their fragility during insertion or inflammatory reactions [7]. Therefore, preserving the mechanical and biological properties of materials during the graft healing process is a crucial challenge. Bioabsorbable interference screws were first introduced for arthroscopic ACL reconstruction applications in the early 1990s [14]. More recent interference screws are made of biodegradable polymers or polymer/ceramic composites [2]. Different combinations of synthetic materials used as the major components of biodegradable ACL screws are Polylactic Acid (PLA) and its various enantiomers, Poly-l-lactic Acid and Poly-d-lactic Acid, Polyglycolic Acid (PGA), and copolymers of PGA/PLA. While PLA, the mainly used material, is characterized by a longer resorption time (yearly basis), the resorption takes a shorter amount of time for the PGA and PGA/PLA copolymers (monthly basis).Currently, various commercial ACLR screws are characterized by different mechanical and biological properties owing to their different chemical composition contents. These screws are usually fabricated by several companies. While substantial biodegradable polymeric ACL reconstruction screws are commonly made of biodegradable polymeric components such as PLA and its enantiomers, PGA, PLC, and some other screws have a bioceramic osteoconductive and osteoinductive fillers such as HA, BCP, TMC, β-TCP, and bioactive glass. Table 1 presents a list of some of these screws containing different polymers and copolymers formulation and those containing osteoinductive and osteoconductive filler phase.The present study aimsto present awhole series of commercial ACLR screws regarding their material compositions, in vitro and in vivo studies, biodegradation behavior, and mechanical and physical properties. The hypothesis here suggests that this collection can promote scientific research since such an issue has not been previously elaborated in the literature.

2. ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION SCREWS

In orthopedic surgery, ACLR is performed by interference screws to maintain ligament inside the bone until the tissue is remodeled. These screws are fixed into a space between the bone plugs and drilled tunnel walls. These kinds of screws are available in different sizes to meet the patient's requirements. To ensure that the screws are implanted at the appropriate angle and direction, a wire with a proper diameter is used is drawn from the inside of the screw and drill hole (Figure 1) [15]. Currently, several companies manufacture reconstruction screws used in ACL surgeries. While most commercial screws have a similar hollow socket to drive the screws, significant differences in their designs make the distinctions between different companies. For example, some parameters that usually differentiate a company's products are the diameter or length size, screw tapering, threads geometry, thread pitch, and material type. The materials used to make the screws is among those criteria that make the difference. Conventional reconstruction screws are usually made of Titanium due to its biocompatibility and acceptable mechanical and physical features; however, in the past decade, other compounds were also developed. New screws are mainly characterized by their absorbable materials in compositions that are degraded into the body, while the metal ones will remain permanently within the bone [16]. However, the probability of inherent problems caused by the absorbable interference screws for ligaments and tendon reconstructions has not been entirely provenyet.

It should be noted that a harmonic trend of the mechanical properties of loosening due to degradation of screw constructs and tendon healing process is a significant issue. Therefore, if the metal screws are replaced by biodegradable ones, it must show adequate fixation for at least 6–8 weeks until the bone block has been incorporated and biological fixation has been achieved [17,18]. It can be found that the almost whole bioscrews composed of synthetic polymers such as PLA, PGA, etc. have acid-based ingredients. While these screws that are exposed to aqueous medium into the body and reabsorbed by hydrolysis and their products dissolve in water forming liquid acids. In a specific area with good blood supply within the body, the acid is well buffered and metabolized; however, in areas with poor blood supply such as bone, the pH of the screw-adjacent medium can be quite low. A decrease in pH of the adjacent tissue results in an accelerating rate of screw degradation, tissue damaging, and bone destruction.

This is the reason why manufacturers, in some cases of ACL screws, have added bioceramics such as hydroxyapatite and tri-calcium phosphate into the material formulations. These materials could promote the osteoconduction and osteinduction characteristics of screws and neutralize the screw-adjacent acidic medium caused by acidic products of screw degradation resulting from the alkaline ions release.

In addition to screw formulation, various other parameters including component composition, size of acidic crystals, screw geometry, and manufacturing method were identified that would influence the behaviors of screws in implant sites. Thus, all bioscrews are not equal and do not behave the same, even if they have been made from the same materials at different implants [19].

TABLE 1. Current commercial Bioabsorbable screws

Manufacturer	Composition	Bioabsorbable Screws
Inion Ltd.	PDLLA/Tri-methylenecarbonate (TMC)	Inion Hexalon
Smith &Nephew	PGA/Tri-methylenecarbonate (TMC)	EndoFix
	PGA-co-PDLLA/Calciumcarbonate (CC)	Calaxo
DePuyMitek, Inc.	PLLA/β-Tricalciumphosphate (β-TCP)	Bio-IntrafixBiocryl
ArthroCare Corporation		Bilok
DePuyMitek, Inc.	PLGA/ β-Tricalciumphosphate (β-TCP)	Milagro
ConmedLinvatec	PDLLA/ β-Tricalciumphosphate (β-TCP)	Osteo ACL Screw
	SR-PDLLA/ β-Tricalciumphosphate (β-TCP)	Matryx
Smith &Nephew	PLLA/Hydroxyapatite	Biorci-HA
Stryker		Biosteon
Arthrex, Inc.	PDLLA/Biphasic calciumphosphate (BCP)	BioComposite
ConmedLinvatec	SR-PDLLA	SmartScrew
Bioscience, Ltd.	SR-PLLA	Biofix
CenterpulseMedicalAG	PDLLA	Sysorb
Biomet SportsMedicine, Inc.	PLLA-co-PGA	GentleThreadsBioCore
Karl Storz-EndoscopePhusis	PLLA-co-PDLLA	MegaFixPhusiline
Instrument Makar, Inc.	PGA-co-PDLLA	Biologically Quiet
Arthrex, Inc.	PLLA	Delta Tapered Bio-interference Screw
		Round Delta Tapered Bio-interference Screw
		Bio-interference Screw
		Biocortical Screw
		RetroScrew
		Full Thread

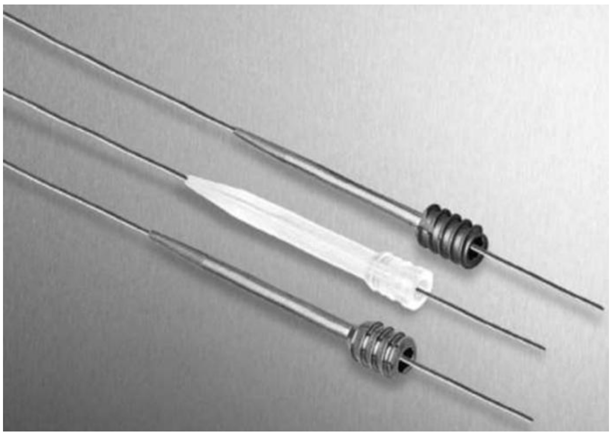

Figure 1. Example of guide wire of ACL reconstruction screws [15]

Of note, it has been reported that the tunnel widening for a poly-levodextro-lactide (PLDLA) and β-tricalcium phosphate composite screw did not occur [20], while this is a common occurrence for other series [21,22].

A study on a comparison of different combinations of absorbable interference screws showed that Poly L-Lactide (PLLA) wasnot completely degraded after 20 months of implantation. However, poly(DL-Lactide-co-glycolide) (PDLLA-co-PGA) undergoes complete degradation during this period of time. Although no damage has been reported for poly(DL-Lactide-Acid) (PDLLA) up to 6 weeks, it would be completely degraded within 10 months [23]. The degradation rate of ACL screws should be in agreement with the biological tissue growth. Bach et al. [24] evaluated the tissue growth surrounding the surgical site in ACLR with the screws made of 32.5% tri-methylene carbonate and 67.5% polyglycolide. This study conducted experiments on 20, 10, and 8 patients over 6, 12, and 24 months, respectively. The clinical and MR imaging results indicated that according to Figure 2(a-b), the screws were partially resorbed within6 months and completelyresorbed within12 months; besides, according to Figure 2(c), these screws enlarged the bone tunnel as a result of screw replacement [24]. Another potential problem of absorbable interference screws is caused by their degradation. As the biodegradable screws breakdown, their moleculesand components will be released, causing inflammatory reactions through the foreign body responses. These reactions may be either minor, releasinga small non-bacterial sinus, or significant which requires immediate attention. Although screws with along degradation time duration will cause fewer foreign body reactions, they will simultaneously require a longer period of time to complete the bone regeneration. However, it was observed in most cases that the body did not completely repel the screw until the emergence of foreign body reactions, hence the cysts formation and osteolysis [25]. Moreover, as reported in several studies, late inflammatory reactions appeared after ACL surgery. Morgan et al. [26] elaboratedon the advantages of explants made of screw remnants, fibrous connective tissue, cortical-like bone, and cancellous bone due to PLLA interference screws after 30 months. Similarly, Park and Tibone [27] observed the persistence of tibial PLA interference screws 4 years past the ACL surgery, which was approved by MRI. However, under irrigation, no screw was found, probably due to late inflammatory reaction.

However, the new bone formation through replacement of ACL screws is only observed for bioscrews independent of its formulation with a slow rate of degradation manner in excess of 5 years [19, 28].

Several studies compared the biodegradable and metallic screws and suggested that bioabsorbable screws would provide good fixation like metal screws; therefore, these screws could be a rational alternative to metallic ones [29-35].

For example, on the comparison of bioabsorbable and metallic ACL reconstruction screws for graft fixation, a number of researchers have found no significant difference in the final patient outcomes in terms of clinical scores, clinical evaluation, and imaging assessments [32]. Moreover, in terms of the range of motions, the obtained comparative results of bioabsorbable and metallic screws for different fixations of grafts confirmed that there was no significant difference between the two groups in the long term, as seen in studies [29,33,36]. Concerning the functional outcomes, Rocco Papalia et al. [37] found no differences between the two types of screws.

3. ACL RECONSTRUCTION SURGERY

ACL injuries are very common, with around more than 4 million reconstruction and healing surgery every year all over the world [38]. This type of injury may occur due to severe knee blowing, sudden stopping, sudden turning, or severe stretching. Individuals who play sports like skiing, football, and basketball are more prone to ACL ligament injury than any other groups [39]. When an ACL injury occurs, the injured usually hear a pop sound, followed by a mild pain that causes swelling in the affected area [15]. The diagnosis of quick ACL tearing is performed by asking the patient to relax his/her legs and the doctor pulls the patient's legs forward to see if the bone is limited to moving in the anterior direction or not; this test is called the Lachman displacement test [15]. Now, if the bone has no limitation in displacement, it can be concluded that the ligament is torn. In this case, MRI can easily determine the ACL rupture. Reconstruction of the ACL involves the replacement of the old ligament by a tissue graft and is usually harvested from the hamstring tendon or patellar tendon [15]. Harvesting of the graft is the first part of the ACL surgery. In the case of patellar, the surgeon creates an incision on the patellar which is of less importance. In the following, the central part, the attached and cylindrical portions of the tendon are removed outside the femoral and tibia head, so-called bone plugs. The end of the remaining tendon is sutured to regrow and continue to perform its duties. After the graft harvesting, sutures are added to the bone part of graft used in placing the tendon. Then, the remains of ACL are removed from the knee and pierces of the inter condylar notch burred away so that the surgeon will have a chance to reach the correct placement of the tendon. To complete the perforation, the surgeon creates two holes in the upper part of tibia and the lower part of the femur near the knee (Figure 3) [15]. To create each of these holes, a small hole is initially created by a small diameter drill to increase the accuracy of perforation and then, by a drill with a diameter similar to the cylindrical bone plug. After the holes are smoothed, the sutured end of the graft is inserted to the knee through tibia head, while the other end is pulled out from the femoral head [15]. The graft is tightened using the interference screws. The biodegradable interference screws keep the tendon firm within the bone (Figure. 4) [15]. After the surgery, the patient will have a fairly moderate painand difficulty bending and extending the knee. In addition, postoperative activities are limited and a hard rehab program must be tolerated to be restored. Since the graft is gradually becoming a tendon, the postoperative activities should be limited to be well applied. During this process, the graft is very weak and the knee is partially unstable. The emergence of a tear is possible in case such activities are intense and uncontrolled. Setting a limit on these activities is absolutely necessary because the graft is only kept by an interference screw. Therefore, as the graft is being pulled by the tibia and femoral bone, the screw will be pulled out of the hole. This scenario may also lead to another reconstruction.

4. BIOABSORBABLE POLYMERIC ACL SCREWS

4.1. PLLA-BASED ACL SCREWS

Among the biopolymers that belong to poly (α-hydroxy acids) family, PLA is extremely well known and widely studied. PLLA is a kind of PLA enantiomer that is a common biodegradable polymer used in the compositions of ACL fixation screws. They go through a degradation process mainly due to the hydrolysis mechanism. Throughout the degradation, water diffuses into the structure which leads to a break in the long chains and changes them to small oligomers that can diffuse inside and outside of the polymeric matrix. These degradation products can be eliminated from the human's body through the Krebs cycle (using urination or CO_2 gas during breathing) [40].

Figure 2. a) Magnetic Resonance Images (MRI) of partial resorption of interference ACL screws at 6 month following implantation, b) total resorption at 12 month following implantation, and c) implantation tunnel after total resorption. New tissue formed around the bone plug (open arrow) determined fibrous tissue (long skinny arrow) with fatty tissue surrounding it (thick short solid arrow) [24]

PLLA molecular weight varies due to its manufacturing technique; for instance, PLLA with high molecular weight (>100 kDa) has a melting point around 137 °C to 178 °C and T_g temperature of 58 °C. Although PLLA is totally semicrystalline, its injection molding also makes nanocrystalline products, leading to a biomaterial whose modulus drops above the glass transition temperature [41]. In order to enhance the PLLA mechanical properties, an alternative strategy called self-reinforced polymer composites can be implemented. The fiber reinforcement in these materials is a highly orientated version of the same polymer from which the matrix is made [42]. For example, a PLLA matrix is reinforced with highly orientated PLA fibers.

Several studies reported the in-vitro results of PLLA-based screw degradation rate as well as body responses. In most of these screws, foreign body reaction during 20 to 30 months after the implantation indicated little or no evidence of inflammatory reaction within the implant environs. In some cases, body responses to screws offer little evidence of adverse inflammatory reaction which is related to the degradation of cartilage or loosening of knee joint envious especially in cases with retardation of screw degradation. Fixation strength of a biodegradable PLLA interference screw (Arthrex, Naples, FL) was compared with press-fit fixation and a titanium interference screw in ACLR using a Bone-Patellar Tendon-Bone (BPTB) graft. The results showed that there was no significant difference between the ultimate failure load of PLLA (805.2 N; range680 to 995 N) and titanium interference screws (768.6 N; range 544 to 1094 N) [43]. The mechanical behavior of delta tapered bio-interference screws (PLLA nanocrystalline, Arthrex) as quadriceps hamstring tendon fixator was dynamically tested. It was found that the ultimate failure load and displacement at the break point of screws were 647±200 and 10.91±4.4 mm, respectively. The screws obtained their toughness of 64.54±22.1 N/mm [44]. The biomechanical properties of Retro screws (Arthrex, PLLA) for tibial called anterior graft-tibial tunnel fixation were also obtained. The Retro screw displays superior toughness (114.1±23.3 N/mm) and displacement (18±0.5 mm) during cyclic testing. During load-failure testing, the maximum load of Retro screw failure was 787±177.5 N. The displacement and toughness of bioscrew resulting from the pull-out test were 5.3±2 mm and 204.4±52.9 N/mm, respectively [45]. In another study on BPTB fixation Bioscrews (PLLA, Conmed Linvatec, Largo, FL) implanted into a cadaver , the results illustrated that the mean load to failure was 189±118 N [46]. The fixation strength of BioFix screws (Self-reinforced (SR)-PLLA, Bio Science, Ltd, Tempere, Finland) in a BPTB graft within the bovine knee is 1211±362 N and its elastic moduli in upper (>500 N) and lower (<500 N) range loads are 304±71.8 N and 189±47.4 N, respectively [47]. There is no significant difference between these biodegradable screws and metal screws in the BPTB graft fixation in the bovine knee; therefore, they can be recommended regarding ACL reconstruction using this type of graft.

The mechanical properties of BIORCI screws (PLLA, Smith & Nephew, Andover, MA) for hybrid femoral fixation were investigated. The Ultimate Tensile Strength (UTS) of these screws was 643.5±148.4 N and their toughness was reported as 315.7±38.9 N/mm [48]. The initial fixation strength of two types of biodegradable screws consisted of Poly-L-Lactide/Tri-Calcium Phosphate (PLLA/TCP); one suspension screw (Bilok ST) with a diameter of 9 mm and length of 35 mm and the other interference screw (Bilok TS) with a diameter of 9 mm and length of 30 mm, determined in the hamstring reconstruction of ACL using bovine knees. The single-cycle test results showed that the maximum failure load, yield load, and stiffness were 1475.8(±315.3) N, 998.5 (±122.56) N, and 248.1 (±76.1) N/mm, respectively, in suspension screws group. For interference screws, the maximum failure load, yield load, and stiffness were measured 651.1 (±155.4) N, 537.8 (± 86.7) N, and 199.5 (±82.9) N/mm, respectively [49].

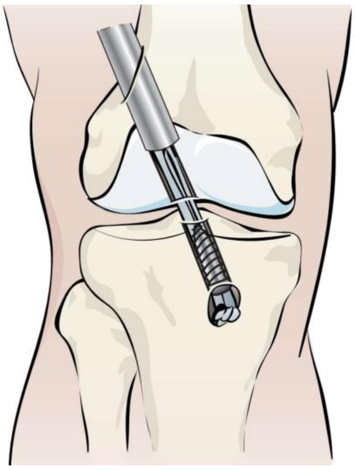

Figure 3. Creation of implantation holes at tibia and femur [15]

4.2. PDLLA-BASED ACL SCREWS

PDLLA is a copolymerization product of PLLA and PDLA as two enantiomers of PLA. Different mechanical properties of PDLLA are related to the composition percentage of each enantiomer. PDLLA is usually amorphous and has a glass transition temperature of about 56°C. In vivo results of PDLLA screws demonstrated that these screws would not be degraded at least for 6weeks, but they would be completely absorbed by the body in 10 months [50]. All PDLLA, PLLA, and PGA copolymers could provide different mechanical properties together and none of them has this capability by itself. For example, the glass transition temperature of PDLLA/PGA blend with 50:50

portions isabout 30℃ and increasing the PDLLA: PGA ratio from 65:35 to 75:25 leads to an increase in theT_g temperature from 33.3℃ to 38℃ [51]. A blend of PDLLA and PGA with the ratio of 82:18 (Lactosorb, Biomet sport medicine, Inc., wasaw, In) can provide a nanocrystalline copolymer with atemperature of 55.3℃ T_g. It was found that a 2℃ increase in T_g temperature would significantly increase the hydrolysis degradation rate of lactosorb from 20% to 25% [52]. Moreover, blending PDLLA with 10, 20, and 30% wt of PCL phase decreased T_g PDLLA from 67.3℃ to 66.2, 65.1, and 63.5 ℃, respectively [53].

Figure 4. Creation of secure fit by holding of screw between the graft bone plug and the wall of the drilled hole [15]

PDLLA/PCL blends reinforced with Bioactive Glass nanoparticles (BGn) showed that the addition of BGn improved the initial mechanical properties as well as biological activity [54].

Phusilin biodegradable interference screws (poly-D(2%), L(98%)-lactide, Phusis, Saint-Ismier, France)are used in patella tendon autograft fixation. The results of an average follow-up of 24 months showed that screws were degraded while bone in-grows earlier than an individual PLLA screw. Clinical tests and MRI results showed no adverse complications during screw insertion thanks to its degradation [52]. The tin octoate is commonly used as an initiator of PDLLA polymerization; however, in order to decrease body immune response to implant screws in phusilin screws, polymerization process is applied to ring-opening procedure using zinc catalyst, which consists of less toxic material. Ring-opening polymerization that uses zinc as a polymerization initiator creates a combination of stereoisomers by means of ionic reactions. In this case, the resulting screws are more hydrophilic than the PLA screws derived from tin and can create interference screws with quicker degradation [52].

Bioabsorbable interference screws (Sysorb; Sulzer Orthopedics, Baar, Switzerland) are used for autologous BPTB fixation throughthe press-fit technique and distal bone block in 25 patients. The results showed that no replacement of sysorb screws in tibial tunnel took place by osseous neo-formation up to 8 months after ACLR surgery, excluding one performed on tibial bone tunnel enlargement and tibial subcutaneous cyst [55]. Mechanical evaluations of Sysorb screws used for BPTB graft fixation in cadaver indicated that the maximum pull-out force and toughness were 544±109 N and 162±27 N/mm, respectively. Cyclical loading elongation also showed that during the first five cycles, 5^{th}-20^{th},and 20^{th}-1500^{th} loading cycles, the amounts of elongations reached 1.4 mm, 0.14 mm, and 4.1mm, respectively [56].

Biological ACLR screws (85/15 PDLLA/PGA, Instrument Maker, Inc., Okemos, MI) revealed some pieces of evidence of total screw degradation, bone remodeling, and new bone formation in femoral and tibial bone tunnel throughout a two-year follow-up. Moreover, MRI results showed no cystic or osteolytic changes associated with minimum swelling at the implant site [57]. Studies of biodegradable screws megfix (70/30 PLLA-PDLLA, Storz-Endoscope Tuttlingen , Germany) withthree different diameters of 6, 7, and 8 mm implanted in porcine kneeshowed thatnone of 6mm screws, 3 of 7 mm screws, and all the 8 mm screws were able to tolerate cyclical loading protocol. Elongations after 1000 cyclic load achieved 8.36 and 4.26 mm for 7 mm and 8 mm screws, respectively. The maximum load, yield strength, and toughness for 7 mm screws were 245 N, 199.1 N, and 98.6 N/mm, respectively. These values for 8 mm screws were 567 N, 456.9 N, and 151 N/mm, respectively [58].

4.3. POLYMER/TRI-METHYL CARBONATE (TMC) ACL SCREWS

TMCs with elastic properties similar to rubbery polymers are not appropriate for biomedical application, because they are characterized by poor dimensional stability, tackiness, and inadequate mechanical properties [59]. However, the combination of TMC andother polymers like PGA, PLLA, and PDLLA could create interesting biomechanical properties that will be favorable for particular applications. As an example, Polyglyconate is ablock copolymer of glycolic acidand TMC linked together by covalent bonding. Copolymers of PGA and TMC have more flexibility than PGA alone. In vitro studies have shown that the molecular weight of unirradiated PGA cultured in PBS solution decreased from 124 KDa to 18.6 KDa for 31 days. The ultimate tensile strength of unirradiated PGA falls down from 51.7 MPa to 5.7 MPa after 3 weeks [60]. However, results ofin vivo studies of polyglyconate implants revealed that their mechanical properties and integrity disappeared within 6 weeks and the full resorption of implant took place within 6 to 12 months [61]. Comparative in vivo studies were performed on 20 patients who had femoral bone block fixation with a bioabsorbable interference screw (EndoFix absorbable interference screw; Smith & Nephew Endoscopy, Andover, MA) and tibial bone block fixation with a titanium screw. The follow-up results of 3, 6, 12, and 24 months indicated no problem and complications related to graft fixation took place for bioabsorbable as well as titanium screws. Upon the point of 12 months, degradation of the implant was complete, whereas there was no radiological evidence of bony replacement up to 3 years postoperation [30]. ACL hexagon Inion screws (PDLLA- TMC, Inion Ltd., Tampere, Finland) illustrated that they preserved 70% to 90% of their initial strength during 12 weeks and considerable degradation during 18 to 36 weeks, whereas complete degradation took place up to 2 years, post operation [62]. MRI results of 2 follow-up years indicated that the screw degraded bone tunnels replaced by fibrosis like tissues. Initial fixation strength of Hexalon Inion screws was evaluated atthree separate levels in comparison to (i) interference metallic screws for fixation of soft tissue graft, (ii) smart self-reinforced screws for fixation of soft tissue grafts, and (iii) PLLA bioscrews used for fixation of bone-tendon-bone grafts. Yield loads of Hexalon Inion screws in each experiment were obtained as 491 N, 501 N, and 901 N, respectively [63,64]. Hence, researchers found that the strength of Hexalon Inion screws was similar to that of other polymeric and metallic screws .

5. BIOACTIVE AND BIOABSORBABLE COMPOSITE ACL SCREWS

5.1. EFFECTS OF BONE MINERAL PHASES IN ACLR SCREWS

Incorporation of various inorganic phases such as calcium carbonate (CC), β- tricalcium phosphate (β-TCP), and hydroxyapatite (HA) into ACLR screws compositions couldovercomesome shortcomingsof other polymeric ACLR screws. Addition of these phases to ACLR screw compositions could enhance the absorption rates of bioabsorbable screws, treat osteogenesis after absorption, reduce oxidation, and act as buffering agents to reduce the acidity of screw adjacent resulting from the decomposition products of screws based on polymers with the acidic origin.

A comparative clinical and radiological study was conducted on 349 patients between 2 different tibial fixations performed using bioabsorbable poly-L-lactide (PLLA) and PLLA-HA ACL screws. The results showed that the PLLA-HA screw groups would induce a significant reduction in the tibial tunnel widening and foreign body reactions, improving the osteointegration and significantly increasing screw resorption compared to the pure PLLA group [65]. The proximal tibial tunnel widening effects of PLLA groups revealed a positive correlation with knee laxity. Hunt and Callaghan carried out an in vitro animal study to compare a composite (PLLA-HA) with PLLA screw. They concluded that the composite screw significantly increased new bone formation and decreased inflammatory reactions in comparison with the PLLA screw [66]. The Computed Tomography (CT) evaluations demonstrated that the pure PLLA screws were completely degraded after 5 years with no evidence of osteoconductivity behavior, leaving bone void after degradation [67]. In the meantime, biocomposites screws made of PLLA (70%)/β-TCP (25%) (Bilok, ArthroCare, Sunnyvale, CA) and copolymer of 70 % PLLA/PGA with 30% β-TCP (Milagro, DePuy Mitek) showed complete degradation and osteoconductivity at 75% and 81% of the screw sites and complete filling of screw voidin 10% and 19% of tests, respectively [68].

It was found that the content of mineral bone phase could also affect the degradation rate of screws and osteoconductivity behaviors. Research on two different amounts (30% and 60%)of β-TCP evaluated using CT scans over 29 to 45 months showed that the biocomposite of PLLA/30 % β-TCP (Ligafix; SBM, Lourdes, France) exhibited more dominant osteoconductivity behavior than other screws containing 60 % β-TCP [69]. This is due to at least two reasons: (a) the screws with greater β-TCP content were absorbed more rapidly; (b) the screws with 30 % β-TCP could be completely surrounded by bone plug or tibial bone rather than screws containing 60% β-TCP [70]. The other theory in this respect depictsthe greater release of phosphate ions into the adjacent screw during degradation by screws with high β-TCP, resulting in a greater pH which may play an inhibitory role in the osteoconductivity manners [70].

5.2. POLYLACTIDE CARBONATE ACL SCREWS

Calcium Carbonate (CC) is a bone mineral phase that forms other bone calcium salts. A combination of CC and other polymeric materials would create an osteoconductive interface that may provide enhanced degradation properties and stimulate its replacement by new bone formation [71]. The presence of calcium carbonate into implants could also provide pH value between 7.4 and 6.3 throughout the degradation process; help avoid local acidity formation [72]. An interference screw madefrom a novel bioabsorbable material, polylactide carbonate (PLC) (Calaxo Screw; Smith & Nephew Endoscopy, Andover, MA) is composed of PGA and PDLLA (65%) copolymers at ratio of 85:15 and 35% calcium carbonate. The combination of PDLLA-co-PGA and calcium carbonate is an appropriate composite material for ACLR screws. In vitro studies and molecular weight (M_w) changes surveying of calaxo screws into phosphate buffer saline (PBS, pH=7.36) for following up to 12 weeks was performed. The results suggested that the calaxo screws lost 85% of its molecular weight, whereas pH of PBS also decreased to 6.86 [73]. Researchers found that the buffering effect of CC may lead to rapid degradation of screws. The in vivo studies of calaxo screws carried out by insertion of ACLR screws into 41 sheep. No inflammatory reaction was realized with a mean follow-up of 6, 12, 26, and 52 weeks after implantation into sheep body. Within 26 weeks after insertion, screws partially were replaced bynew bone; however, in 52 weeks after implantation, they were resorbed completely, whereas they were simultaneously replaced with a new bone. The ultimate load to failure of these screws was identified 70 N and 225 N for 6 and 12 weeks after implantation, respectively [71].

5.3. POLYMERIC COMPOSITES ACL SCREWS WITH ß-TRICALCIUM PHOSPHATE

Various companies designed the ACL screws made of polymer-based composites reinforced by osteoconductive and osteoinductive phases. For example, biodegradable screws contain PDLLA, PLLA, and PLGA as polymeric and β-tricalcium phosphate (β-TCP) as osteoinductive materials. β -TCP has brittle origin with low toughness, this means that the susceptibility of cracks formation throughout the brittle materials restrict the capability of these materials for load-bearing applications. These materials presented good osteoconductive properties and hydrolytic dissolution products of materials that contain calcium and phosphate ions [74]. Adding β-TCP to PLLA screws improved the mechanical properties and also observed that β-TCP caused an increase in both the degradation kinetics of the composite material, accelerating the remodeling and healing of bone. Moreover, β-TCP is alkaline in solution and may neutralize the acidic by-product resulting from PLLA degradation. A PLGA screw has more rapid degradation than PLLA one that can, in combination with β-TCP, provide a proper degradation profile as well as osteoconductive and osteoinductive properties due to the presence of TCP phase. There are some ACL screws composed of TCP phase. For example, Bio-intrafix screws made of 30% β-TCP and 70% PLLA [75]. In vivo studies of Bio-intrafix screws administered to the body of patients illustrated that no post-surgery adverse inflammatory reaction occurred up to 2 years. In addition, the ultimate tensile strength of Bio-intrafix screws indicated about 700 N [76]. In this respect, another screw is composed of 30% β-TCP and 70% PLGA (Biocryl, Rapide TM). Preclinical in vivo studies illustrated that the composite-based screws inserted into cortical femoral bone defect were completely degraded throughout 24 months and simultaneously replaced with a new bone [77]. Another in vitro studies on Biocryl screws were carried out in PBS solution with pH=7.36. The results showed that the dimensional variations of the screw occurred to some extent after 12 weeks from culturing into PBS solution [73]. Throughout this time, molecular weight decreased to 66.9%, whereas pH almost unchanged. These results proved that TCP might increase the degradation rate of Biocryl screws. This may be due to the alkaline origin of TCP materials, which could make a buffering circumstance for acidic by-products resulting from screw degradation. These screws in another study were used as ACL screws in tibial bone tunnel enlargement. Tibial fixation was performed using 2 bioresorbable interference screws. Magnetic Resonance Imaging (MRI) was performed onall patients after 1 year post operation. The results determined an increase in bone tunnel enlargement up to 43% by digitally measuring the widths of the bone tunnel perpendicular to the long axis of the tunnels on anoblique coronal and axial planes. However, there is no report about the degradation profile of screws [78]. Another study investigated the biodegradable β-TCP-PLGA screws for fixation of ACL autograft patellar tendon inserted into 41 patients. During the follow-up 3 years, the post operative results illustrated that complete degradation accompanied by new bone formation occurred. The degradation rate of β-TCP-PLGA based screws was more than that of the β-TCP-PLLA screw [73].

5.4. POLYMERIC COMPOSITE SCREWS WITH HYDROXYAPATITE

Hydroxyapatite (HA) similar to β-TCP is a bioceramic inorganic material and a major constituent of bone whose high biocompatibility has been widely used for bone remodeling [79]. Besides, HA can act as a buffering factor against acidic products resulting from PLLA degradation. Similar to β-TCP, HA suffers from low fracture toughness and also high brittlement. Elastic modulus of HA varied from 80 to 100 Gpa and its compressive strength ranged from 500 to 1000 MPa [75]. In vitro studies of PLLA/HA composite material in PBS solution with pH= 7.36 were introduced such that no significant changes occurred throughout the 12 weeks; however, the molecular weight of screws decreased by about 22.9% and pH also slightly decreased from 7.36 to 7.32 [73]. Two biodegradable ACL screws, i.e., PLLA-HA composite screws and no composite PLLA screws, were compared. The results of evaluation studies showed that the remaining strength of HA-PLLA composite after 24 weeks is higher than PLLA screws. Modulus of composite screw was also more similar to that of natural bone tissue. This similarity between composite screws and natural bone tissue modulus causesa substantial decrease in stress shielding during the bone healing [80]. A study was performed on BIORCI-HA screws made of HA-PLLA composite for fixation of patellar tendon graft into 20 patients. Based on MRI images of screws inserted into the body, no complication during the 2-year follow-up and inflammatory reaction at patellar tendon graft were observed. Although the degradation rate of screws and bone integration were slow based on MRI, it should be noted that in this study, screw failure during insertion was just reported in one patient [81].

6. MAGNESIUM AND MAGNESIUM ALLOYS AS POTENTIAL BIODEGRADABLE ACL SCREWS

Non-degradable titanium interference screws may impair the tendon or ligament graft throughout the screw insertion. This may be due to high mechanical strength. Besides, these screws need a second surgery for removal. In the case of bioabsorbable ACLR screws as a well-established practice, there also are some complications. As an example, due to inadequate mechanical strength, the screw may fail upon insertion. In addition, during the degradation process, some adverse reactions such as synovitis, granuloma, and tunnel enlargement may occur, retarding the healing of tendon grafts by fibrous scar tissue layer formation at the tendon-bone interface [82,83]. In this respect, biodegradable metallic screws with modulus resembling the natural bone can be a proper choice. Recently, magnesium (Mg) and Mg alloys represented an interesting potential for biomedical application and may be suitable for tendon graft fixation in ACL reconstruction as a new generation of bioactive implants [38,84-85]. These screws could stimulate fibrocartilage regeneration. Additionally, these types of screws possess a good mechanical behavior owing to their similarity in modulus between Mg (41-45 GPa) and natural bone (15-25 GPa) [86], which could meet strength requirements throughout the insertion into bone. Mg metal could be degraded when exposed to the aqueous solution. Its degradation is initiated by chemical reaction with body fluid and release of the Mg ions and equivalent mole of hydrogen gas.

Generally, Mg is firstly oxidized throughout the anodic reactions to formcations and then, throughout a cathodic reaction, the water of body fluid is reduced by the generated electrons during the last levels. Furthermore, $Mg(OH)_2$ is formed as the overall products. Dissolution of passive $Mg(OH)_2$ layers in the presence of destructive biological ions such as Cl^- ions occurs according to Equation 4. Furthermore, the degradation of Mg implants into body environments including Cl^- ions is dominant because the degradation rate of the passive layer is higher than that of degrading products on the surface [87].

$$Mg \rightarrow Mg^{2+} + 2e^- \quad \text{(anodic reaction)} \tag{1}$$

$$2H_2O + 2e^- \rightarrow 2OH^- + H_2 \quad \text{(cathodic reaction)} \tag{2}$$

$$Mg + H_2O \rightarrow Mg(OH)_2 + H_2 \quad \text{(overall product formation)} \tag{3}$$

$$Mg(OH)_2 + Cl^- \rightarrow MgCl_2 + 2OH^- \tag{4}$$

Since the Mg ions have a stimulating role in osteogenic differentiation of stem cells, it could promote the osseous ingrowth into graft as well as the incorporation of tendon graft into the surrounding bone tissue enhancement [88]. Most recently, Cheng et al. introduced the high purity Mg as promising materials for use of interference ACL screws [23]. They also expressed that Mg interference screws could effectively inhibit the degeneration of the tendon graft by reducing the expression level of MMP-13, while the remodeling phase occurred. This fact indicates that more collagen fibers in the tendon graft were preserved to connect the surrounding bone tissue for higher knee stability [89]. However, it has not been yet reported if Mg-based implants could also promote graft healing in tendon-bone healing in a bone tunnel [25]. Besides, there is no sufficient information about the bone tunnel after surgery to determine the potential application of Mg implants. Therefore, it seems that the investigation of graft healing quality into bone tunnel in ACL reconstruction model is crucial. Herein, it was hypothesized that Mg-based interference screw could significantly enhance the incorporation of tendon graft within a bone tunnel when compared to conventional Ti interference screws.

7. MECHANICAL PROPERTIES OF ACLR SCREWS

The ACLR screws intend to fix ligament into tibial or femoral bones that must have sufficient mechanical strength when either inserted into the bone tunnel during surgery or fixed the ligament into the bone for a certain time until rehabilitation of damaged ligament is completed. Regarding the initial fixation strength of ACLR screws, many factors such as bone quality and its diameter and screw features such as length, diameter, design, and material compositions are affected. Moreover, the age of patients and surgery techniques affect the mechanical properties of implanted ACLR screws. In terms of screw geometry, there are many controversies with respect to the appropriate diameter and length of screws on mechanical strength. It wasfound that an increase in screw diameter could increase the fixation strength [90]. There is also hypothesized over the screw length effects on biomechanical properties. In one study, it was found that the significant improvement ofthe mechanical properties of BPTB units was made when they were fixed with a custom-designed 9 mm interference screw rather than a 6.5 mm cancellous screw [47]. Moreover, use of fully-threaded ACL screws has remarkably increased the fixation strength rather than partially-threaded screws [47].

In terms of material compositions, several attempts have been made to develop biodegradable ACLR screws with sufficient strength for the fixation of ligament or tendon into bone tunnel. The weakness of graft fixation immediately and during the first six to eight weeks after surgery will limit early intensive rehabilitation [91]. In a study where the fixation strength of PLLA biodegradable screws compared with two metal screws, the results show that there is no significant difference among thethree groups. Therefore, the mean forces to failures in the three groups of metal interference (n=11), an AO cancellous screw (n=11), and PLLA screws (n=11) were 1358±348 N, 1081±331 N, and 1211±362 N, respectively [47].

Regarding screw insertion during operation, since the screw was submitted to torsional and axial loads owing to the application of compression and longitudinal shear forces [92], it has been reported that the biodegradable screws may be subjected to break during operation [93]. The technical standard ASTM F2502 (Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants) provides a standard test method for measuring the mechanical properties of polymer screws in torsion [94]. According to this standard, the fully threaded screw was equipped with the holding device so that five threads under the head of the screw were exposed outside the holding device. A large enough portion of the screw thread should be gripped firmly to secure the screw so that it does not rotate when exposed to torsion loads. The torque is applied by inserting the screw driver (bit) into the screw head. However, unlike solid core osteosynthesis screws, cannulated interference bioabsorbable screws have a cylindrical orifice along almost their entire length to the screw driver connection [95].

Torsion test results of PLDLA 70/30 screws during hydrolysis circumstance identify that the mechanical behavior of screws switched from ductile to fragile as a function of degradation time up to 240 days. The results demonstrated that the maximum torque varied from 1168 N.mm to 349 N.mm after 240 days, whereas the maximum torque angle varied from 85.42 to 8.28 degrees. Moreover, the torsional stiffness of screws decreased from 70 Nmm/deg to 54 Nmm/deg [94].

A novel hydroxyapatite ACL screw with a novel geometry presented by schumacher et al. showed that the applicationof multiple threads with a large thread pitch to screw design facilitated the insertion of the screws into the bone without the application of screw driver or an external torque. Besides, the ex vivo studies of screws with rigid polyurethane (PU) foam and sheep ankle showed the pull-out forces of 486±60 N and 387±160 N, respectively, and these values are comparable to commercially BioComposite interference screws (Arthrex Inc., Germany) tested in PU foam, i.e., 435±120 N [96].

Another research group performed a comparison between bioabsorbable screws (self-reinforced L-lactide/D-lactide, PLA 96/4, Bionx Implant Ltd., Tampere Finland) and titanium interference (Softsilk, Acufex Microsurgical Inc., Mansfield, Massachusetts) ones in ACL reconstruction using matched pairs of porcine knees. For this reason, two groups of screws were used in single and cyclic loading conditions [97]. The results showed that the mean ultimate failure loads for the single-cycle failure loading test were 837 ± 260 N and 863 ± 192 N for the bioabsorbable and titanium interference screws, respectively (no significant difference). Moreover, the yield loads were obtained as 605 ± 142 N and 585 ± 103 N for the bioabsorbable and titanium interference screws, respectively (no significant difference) [97].

For the sake of comparison, the characteristics of biomechanical properties for the ACL screws studied in the current review paper and other commercial screws aresummarized in Table 2.

8. CONCLUSION

There are two different categories of ACL screws, namely metallic and bioabsorbable. The mechanical, physical, chemical composition, insertion technique, and various manufacturers as well as in vivo behaviors of different biodegradable commercial ACL screws were investigated in this research. The findings illustrated that the bioabsorbable screws showed similar behaviors tothe metallic ones in several cases. However, the bioabsorbable screws suffer from some drawbacks, especially in bone ingrowth that prevents them from leaving a void after disappearing. Generally, the commercial bioabsorbable ACL screws are currently composed of polymers such as PLA and the enantiomers, PGA, PCL, and in some cases, composites of these polymers with inorganic filler phases such as Ca-P based products. Incorporation of bone mineral phases into ACLR screws may enhance the absorption rates of bioabsorbable screws, lessen the chances of osteogenesis, help neutralize the environs of bone site, and improve the mechanical properties.

The potential new generation of these screws may be magnesium screws and they have not reached their commercial production objective.

Given the literature reviews, the authors hold the belief that the biocomposite ACL screws rather than polymeric and metallic ones possess interesting features in terms of biological, physical, and mechanical properties. However, there are some challenges such as the optimum contents of bioceramics on osteogenesis and mechanical properties.

TABLE 2. Comparison of mechanical properties of commercial ACLR screws

Screws Compositions	**Manufacturer**	**Screws Dimensions**	**Ultimate Failure Load (N)**	**Yield Point Load (N)**	**Ref.**
30% β-TCP/70% PLLGA	DePuy	10 × 35 mm	1113 ± 362.2	845.1 ± 243.7	[95]
30% BCP/70% PDLA	Arthrex	10 × 35 mm	1051 ± 244.5	792.2 ± 157.5	[95]
70% PLGA/30% β-TCP	Milagro(DePuy)	10 mm	877 ± 8	728	[98]
25% HA/75% PLLA	Smith & Nephew	10 × 35 mm	920.3 ± 283.5	684.1 ± 163.9	[95]
70% PLDLA/30% BCP	BioComposite (Arthrex)	10 mm	1206 ± 248	1053 ± 378	[98]
Self-Reinforced L-lactide/D-lactide (PLA 96/4)	Bionx Implant Ltd., Tampere, Finland	7 × 25 mm	837 ± 260	621 ± 139	[99]
25% HA/75% PLLA	Srtyker	10 × 35 mm	1073.8 ± 378.7	797.6 ± 293.3	[95]
PLLA/TCP	Suspension screw (Bilok ST screw, Biocomposites Ltd, Etruria, UK)	9 × 35 mm	1475	998.5	[49]
PLLA/TCP	Interference Screw (Bilok TS; Biocomposites Ltd)	9 × 30 mm	652	538	[49]
PLLA	Arthrex, Naples, FL	7 × 23 mm	995	689	[43]
PLLA 70/30	Linvatec, Largo, Florida- USA	9 × 20 mm	607.11 ± 97.49	509.98 ± 94.03	[100]

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