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Mechanical Strength and Biocompatibility Properties of Materials for Bone Internal Fixation: A Brief Overview

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Abstract

An ideal bone internal fixation material does more than just fracture union. It ensures the preservation of Bone Mineral Density (BMD) and body-bone's integrity. This has been a major fight in osteosynthesis from the ancient time till date. Animal skeletons that were first used as internal fixations though had some desirable mechanical properties comparable to bones, their usage resulted in mild pus formation, difficulty with resorption of sterile bones and non-union. A shift to metallic bone implants resulted in corrosion and bio-incompatibility, stress shielding, imaging and radiotherapy interference, temperature sensitivity, revision surgery with extreme difficulty, growth restriction, metal-in tissue accumulation, bone-metal elastic modulus mismatch to mention but a few. Advances in osteosynthesis have, however, led to great improvement on metallic bone fixations, yet leaving some fundamental issues unresolved. Exploration of biodegradable polymers and their composites is fast solving most of the problems encountered through the use of skeletal and metallic fixations. Their low Young's moduli and excellent biocompatibility, non-carcinogenicity and bioresorbability have made them viable materials for bone fracture healing. This brief overview covers the biomechanical properties of popular biological materials, metallic fixations and polymeric scaffold.

Keywords: Mechanical properties, Osteosynthesis, Internal fixation, Biodegradability, bioresorbability.

1. Introduction

Human bone fracture is a problem that is both age long, global and popular (Agaja and Ehalaiye, 2009; Anyaehie et al., 2015; Anyanwu et al., 2011; Brasileiro and Passeri, 2006; Eze et al., 2013; Nnonyelum et al., 2015; Ogundipe et al., 2012; Singer et al., 1998; Van et al., 2001). About 9 million fractures occur worldwide among the elderly every year (Costa et al., 2013) and a whopping €37 billion is spent annually to care for bone fracture in osteoporotic patients in the European Union (Hernlund et al., 2013). The enormity of this problem has invited the attention of researchers from several fields and there have been several thoughts on how to care for bone fractures. From the time immemorial till date, internal fixations have played a crucial role in the treatment of bone fracture (Allgöwer et al., 1970; Matsumoto et al., 2017; Mehmood et al., 2014; Uhthoff et al., 2006; Zhu et al., 2018). Several materials, ranging from natural to synthetic, have been used. This piece attempts a brief review of the mechanical strength and biocompatibility of common biological materials, metallic fixations and polymeric scaffold used as internal bone fixations. The performance of a human bone internal fixation is strongly dependent on the choice of material (Mehmood et al., 2014). A suitable internal fixation is expected to combine an appropriate value of Young's modulus comparable to the cortical bone with good tissue interaction for proper osseointegration. In addition to this, a gradual transfer of load from the internal fixation to the bone as the bone heals up is also expected.

2. Biological Material

Ivory and bone were in the class of the earliest bone internal fixations (Bartoníček, 2010; Greenhagen et al., 2011; Mehmood et al., 2014). Elephant dentition formula (Figure 1) is $\frac{1.0.0.3}{0.0.0.3}$. Elephants in Africa (Loxodonta africana) have been said to have massive incisors which could be as big as 85 kg and as long as 3.0 m in length. Their other teeth are molars which are incomparable in length and mass to the incisors (Macgregor, 1980) as clearly shown in Figure 1. Considering the stress elephants usually subject their tusks to, mechanical properties were expected to be comparable to bone. Macgregor (1980), however, finds Young's modulus of elephant tusk to be 6.8 GP and 2.6 GP in the longitudinal and transverse sections respectively. The bending strength measured longitudinally and transversely were found to be 155 MP and 72.5 MP respectively. These were the values obtained when the ivory samples were wet (Table 1). Table 1 also gives the mechanical properties, bending strength and Young’s modulus of some other skeletons. It is apparent that, cattle tibia and Deer antler are better options than ivory in terms of the bending strength and Young’s modulus.

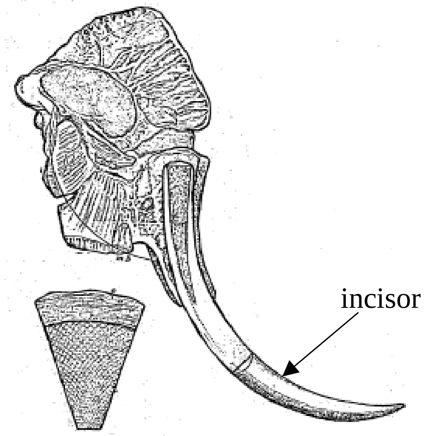


Figure 1: Elephant Dentition (Macgregor, 1980)

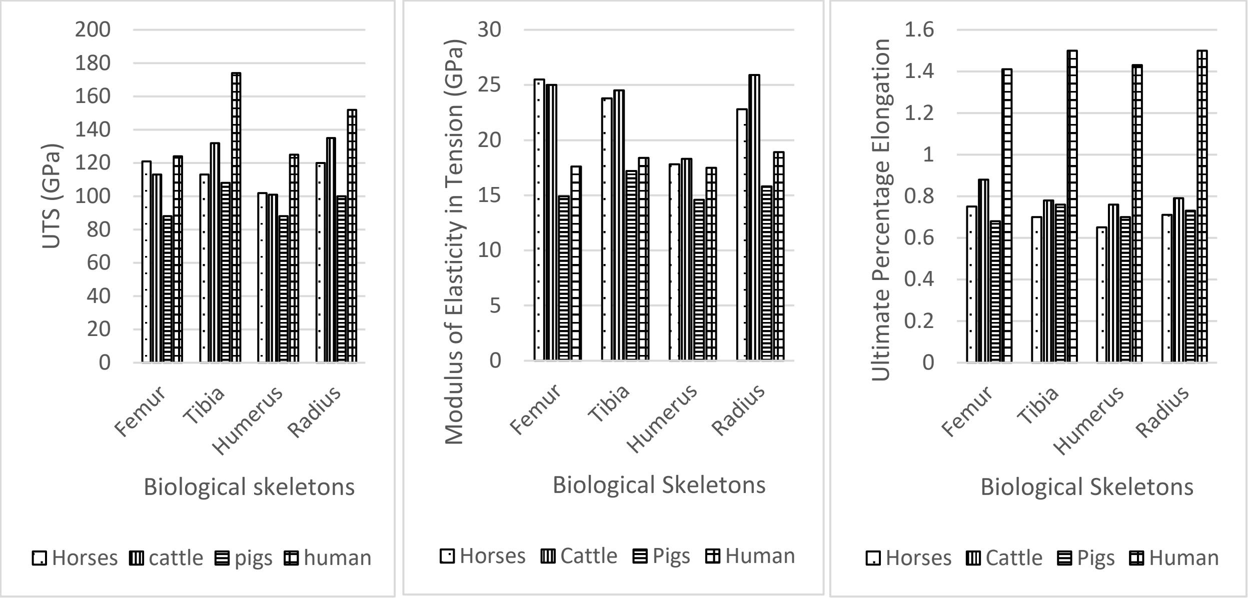
Figure 2 compares the Ultimate Tensile Strength (UTS), the modulus of elasticity and the ultimate percentage elongation of the femur, tibia, humerus and radius of horses, cattle, pigs and human (age 20 – 39 years) (Pal, 2014). The skeleton of cattle shows mechanical properties that are most suited for human bone internal fixation in fracture healing. The tibia, humerus and radius of cattle have the UTS, modulus of elasticity and percentage elongation that are greater than those of horses and pigs.

Figure 2b, for instance, captures the modulus of elasticity of three animal skeletons and compares them with that of human. The modulus of elasticity of cattle tibia is 2.9, 29.8 and 24.9 % more than the tibia of horses, pigs and human respectively. Its radius is 12, 39 and 27 % greater than that of horses, pigs and human respectively when their moduli of elasticity are compared. The percentage of elongation (Figure 2c) of the skeleton of cattle also shows superior values to that of horses and pigs for all the chosen bone sites.

Table 1: The Mechanical Properties of Some Skeletal Materials (Macgregor, 1980; Kajzer, 2013)

Mechanical Property			Skeletal Materials					
			Cattle tibia	Antler	Ivory	Sheep	Ox	Pig
Bending strength (MP)	L	wet	199	178	155	N/A	216 (fresh)	94 (fresh)
		dry	299	343	N/A	N/A	127 (dried for 30 days)	150 (dried for 30 days
	T	wet	98	82	72.5	N/A	N/A	N/A
		dry	96	123	N/A	N/A	N/A	N/A
Young's Modulus (GP)	L	wet	25	21	6.8	3.8	10.992 (fresh)	11.515 (fresh)
		dry	16	13	N/A	N/A	13.287 (dried for 30 days)	9.687 (dried for 30 days)
	T	wet	20	4	2.6	N/A	N/A	N/A
		dry	9	8	N/A	N/A	N/A	N/A

L = longitudinal; T = transverse



(a) (b) (c)

Figure 2: UTS (a), Modulus of Elasticity in Tension (b) and Ultimate percentage elongation (c) of select biological skeletons (Pal, 2014)

The use of ivory in form of solid and hollow cylinders, pegs and intramedullary (IM) nail is as old as the nineteenth century. Bartoníček (2010) and Senn (1893), for instance, reported the use of ivory cylinder by Volkmann, Heine and Heinrich Bircher, which was inserted in the medullary cavity of patients. Ivory cylinder, Ivory pegs and ox bone had been used to treat old and young patients (Senn, 1893). One of the rationales behind ivory's usage as internal fixation was due to the fact that its Young's modulus (Table 1) is reasonably low enough as not to cause stress shielding. Stress shielding or "off-loading" is a major problem with the use of metallic fixations (Ya'ish et al., 2013). Another basis for its usage was its high resorbability by the human body. This is due to the fact that it is a skeletal material and can degrade in a bio-environment (Greenhagen et al., 2011; Senn, 1893). However, modern osteosynthesis has since excluded the use of ivory and bones because of some of their drawbacks, namely:

1. there were formations of mild suppuration when it was used. (Senn, 1893).

2. its size (Figure 3) overburdens the absorptive capacity of the tissues, which might lead to revision surgery for its removal. The aseptic ivory would not be easily resorbed into the body (Senn, 1893). The use of hollow ivory cylinder instead of the solid one was proposed to answer the size question (Greenhagen et al., 2011; Senn, 1893).
3. there were complaints about mild infection and outright non-union of fractured bones after treatment (Bartoníček, 2010; Greenhagen et al., 2011; Mehmood et al., 2014).

Unlike the use of ivory and ox bone for internal human bone fixations, noticeable studies have not been done on the use of bone of cattle, antler of deer and skeleton of pig.

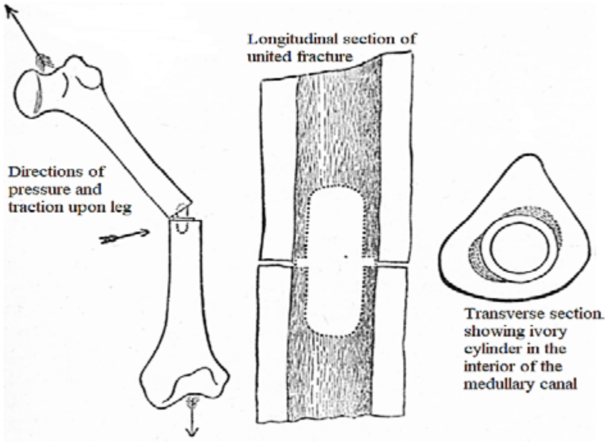


Figure 3: The size of the ivory cylinder and the holding method used by Heinrich Bircher (Senn, 1893)

3. Metals and their Alloys

The failures of skeletal materials, to wit: low Young's modulus of elasticity, non-union, mild infection, resorption with aseptic skeletal fixation, formation of mild suppurations and so forth, have necessitated a shift from the use of biological skeletons to the use of metals as human bone internal fixation in the last two centuries. Metals used include tin, nickel, copper, bronze, gold, lead, nickel, steel, silver, brass, aluminium, vanadium, stainless steel, titanium, vanadium, cobalt, tantalum. These metals were either used in their pure form or alloyed with other metals to enhance their properties and make them suitable for the purpose of osteosynthesis. Eventual discoveries, though, proved some of them unfit and some of the metallic bone fixation devices were outrightly abandoned as a result of corrosion. Figure 4 is the plate used as an internal fixation by Lane in the late nineteenth century, which was abandoned because of the problem of corrosion. Metals, generally, have problem with corrosion. There have been reported cases of the struggle against corrosion of metals even in some other environments other than the human body (Loto, 2017; Loto & Babalola, 2018; Sanni et al., 2018).

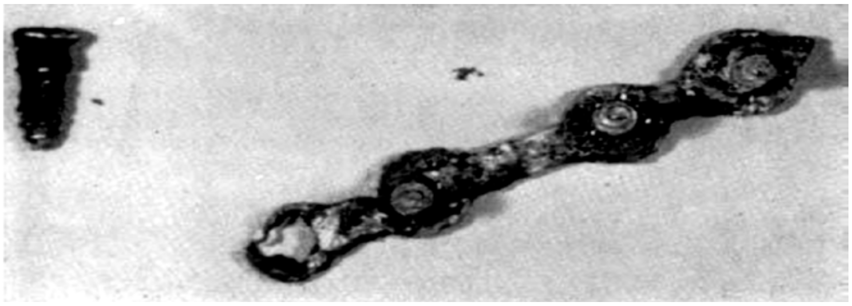


Figure 4: Relinquished Lane's plate due to corrosion (Mehmood et al., 2014)

Stainless steel is one of the prominent metals (tantalum, cobalt-chromium alloys and titanium and its alloys being others) still in use in the orthopaedics industry in this century (Augat and von Rüden, 2018; Manam et al., 2017; Marcomini et al., 2014; Shi et al., 2017; Simpson and Tsang, 2018; Vangapally et al., 2017; Saini et al., 2015). This is partly because of its amazing biocompatibility from its good corrosion resistance point of view (Balamurugan et al., 2008). Its elastic modulus of 200 GPa is, however, too high for human bone and has a problem with "off-loading". In addition to the problem of high modulus of elasticity, stainless steel has been reported to have a propensity to release toxin if it reacts with ions like reduced sulphur compound and chloride which are the normal ions in the body (Minnath, 2018). Besides, the failure case of stainless steel in an aged patient has been reported (Marcomini et al., 2014). Aside this, metals like titanium can preserve BMD more than stainless steel (Uhthoff et al., 1981).

In an attempt to bring the mechanical properties of metallic scaffold close to that of the human cortical bone and thereby reduce bone loss as a result of internal fixation materials, Chen et al., (2017) manufactured porous titanium and got samples with 30%, 40% and 50% porosity. The cell adhesion property was very reasonable and Young's modulus, E (±0.6 to ±2.5); compressive yield strength, σ_{cy} (±6.0 to ±17.5); strain at fracture, ε_f (±0.6 to ±2.1); density, ρ (±0.1 to ±0.14) are as shown in table 2.

Table 2: Mechanical properties of porous titanium (Chen et al., 2017).

Sample (% porosity)	Physical and Mechanical Properties			
	E (GPa)	σ_{cy} (MPa)	ε_f	ρ (g/cm^3)
30	44.2	405	41	3.01
40	24.7	221.7	6.6	2.64
50	15.4	117	5.4	2.25

The Young's moduli of this porous metal with 40% and 50% porosity are very much in the neighbourhood of the Young's modulus of bone (Harrison et al., 2010; Liu et al., 2017; Ramírez et al., 2011; Tan et al., 2013) and so does the biocompatibility of the porous titanium. However, one major and established problem with titanium is the human allergic reaction to it. This is aside from the fact that metals are generally not bioresorbable and may, therefore, result in deposition and accumulation of metal particles in tissues: a case not favourable to the human body.

Tantalum is yet another viable metal, which has been copiously used in osteosynthesis. It has been said to have an exceptional Young's modulus of elasticity (Harrison et al., 2010). Table 3 gives the modulus of elasticity of tantalum sheet produced by powder-metallurgy at high temperatures.

Table 3: Mechanical Properties of Tantalum Sheet (Schmidt and Ogden, 1963)

Temp, F	Tensile Strength, 10^3 psi	Yield Strength (0.2% Offset), 10^3 psi	Modulus of Elasticity, 10^6 psi	Load Rate, psi/sec	Elongation, per cent
3420	6.16	3.2	3.6	2.67	39
3670	5.11	2.55	0.6	197	46
3955	3.025	1.51	0.7	63	34
3955	2.74	1.85	0.2	16	32
4380	2.46	1.24	1.1	63	44
4470	2.29	1.32	0.4	64	37
4525	2.65	1.35	1.5	54	34
4525	2.06	1.27	0.4	57	38
4985	1.87	1.14	0.4	67	25
5010	1.24	0.86	0.3	10	11
5100	0.977	0.8	0.1	7.5	13

From table 3, Young's modulus of tantalum produced at 3955 F and tested at the load rate of 63 psi/sec and that produced at 5100 F at 7.5 psi/sec testing load rate bear semblance with the modulus of elasticity of the one used by Harrison et al., (2010) to study the effect of porous tantalum on BMD in the treatment of knee osteoarthritis via Total

Knee Arthroplasty (TKA). Interestingly, the production of tantalum at 3420 F and a testing load rate of 2.67 psi/sec gives the value of Young's modulus of elasticity that is well comparable to that of the bone.

Tantalum, therefore, is such a very promising fixation and has found application in the medical field, especially, because of its excellent compatibility with body fluid (Buckman, 2000). However, Harrison et al., (2010) observed that there was a significant decrease in BMD of the bone next to and supporting the implant used in TKA treatment. BMD was found to decrease by 6.7% ± 18.0%, 8.4% ± 25.3% and 6.6% ± 21.5% after 2, 12 and 24 months respectively. This is bad for human bone as it can lead to osteoporosis.

Cases of a combination of different materials, titanium screw and PLA insert for example, have also been investigated as shown in Figure 5. PLA inserts were used as cushions. The intention was to allow for a gradual transfer of load to the bone as the biodegradable PLA degrades. This was done to combat the problem of stress shielding and loss in BMD. Uhthoff et al., (2006), however, reported that the PLA insert degraded faster than it was hypothesised and the aim of the materials combination was defeated.

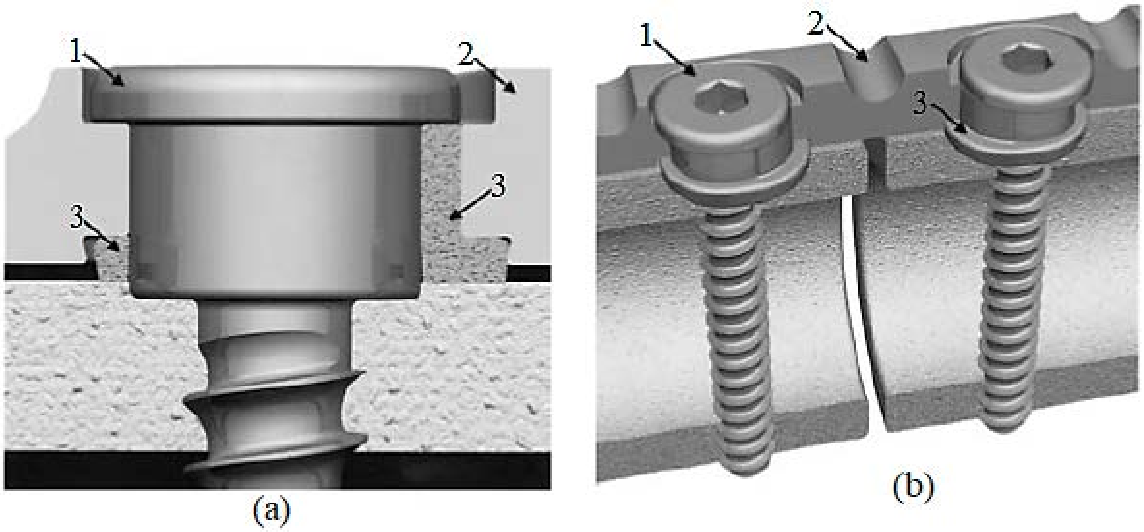


Figure 5: Titanium Screws and PLA - 1 is the screw; 2 is the outer shell; 3 is the insert; 1 and 2 are made of titanium, while the parts labelled 3 are made of Polylactic acid (PLA) (Uhthoff et al., 2006).

In summary, metals were considered good implantable devices and are about the most prominent of internal fixations, because of their high mechanical strength. However, corrosion and bio-incompatibility (Mehmood et al., 2014), stress shielding or 'off-loading' (Ya'ish et al., 2013), pain (Schmidt et al., 1998), implant migration (Cohen et al., 2001), hypersensitivity to titanium (Katou et al., 1996), imaging and radiotherapy interference (Dias, 2001), temperature sensitivity (Orringer J., 1998), revision surgery with extreme difficulty (Ya'ish et al., 2013), growth restriction (Yaremchuk et al., 1994), accumulation of metal in the tissue (Daniel et al., 1997), bone-metal elastic modulus mismatch (Daniels et al., 1990), amongst others remain their peculiar problems. On if the alloyed metals were better off, Gu et al., (2009) stated that the release of Mg^{2+} ions, hydrogen bubbles, alloying element metal ions, alkalization of the solution by the OH^{+} ions and peeling off particulates are the major drawbacks in magnesium and magnesium alloys usage.

4. Biodegradable Polymers

Bone internal fixation with low Young's modulus close to the human bone's has the ability to reduce or eliminate the loss of BMD which is common with the use of metallic implants (Harrison et al., 2010). Besides, a good internal fixation is expected to be biodegradable, biocompatible, bioresorbable, non-carcinogenic and mechanically compatible with the human bone. Biodegradable polymers have, therefore, been recently used as internal fixations because they meet most of these criteria. Some of these biodegradable polymers are poly(L-lactide-co-glycolide) (LPLG), poly(DL-lactide) (DLPLA), poly(dioxanone) (PDO), poly(DL-lactide-co-L-lactide) (LDLPLA), poly(glycolide) (PGA), poly(DL-lactide-co-glycolide) (DLPLG), poly(glycolide-co-trimethylene carbonate) (PGA-

TMC), poly(e-caprolactone) (PCL), poly-L-lactic acid (PLLA) and a host of others (Agrawal et al., 2001; Gunatillake et al., 2003; Middleton et al., 2000; Törmälä, 1992, Mehmood et al., 2014). However, some of these polymers in their virgin form are brittle, hydrophobic and have slow biodegradation profile (Xiao et al., 2012).

The setbacks noticed in the polymers have been severally worked upon (with great success) by researchers to offset the weaknesses (Adeosun et al., 2016; Deepthi et al., 2016; Navarro-Baena et al., 2016; Wang et al., 2016; Gbenebor et al., 2018). For instance, Wang et al., (2016), investigated a composite of PLLA reinforced with hydroxyapatite. The resulting composite was found to have a reasonably fast degradation profile and a bending strength (114 MPa) comparable to the human bone's (Keller et al., 1990). In the in-vivo test, a reasonable level of biodegradation was achieved within 36 weeks with the remains having pores and hollows as revealed by Environmental Scanning Electron Microscope. The pores and hollows are very good for cell adhesion and cell proliferation. Cell adhesion is one of the reasons for the struggle in creating porous metallic fixation (Chen et al., 2017; Harrison et al., 2010; Liu et al., 2017). This struggle simply fizzles out with the use of biodegradable polymers, since they have a ready surface for cell adhesion and proliferation.

The resulting composite of PLLA/hydroxyapatite engineered by Wang et al., (2016) showed a significant increase in the impact strength (Figure 6) and torsion-compression (Figure 7).

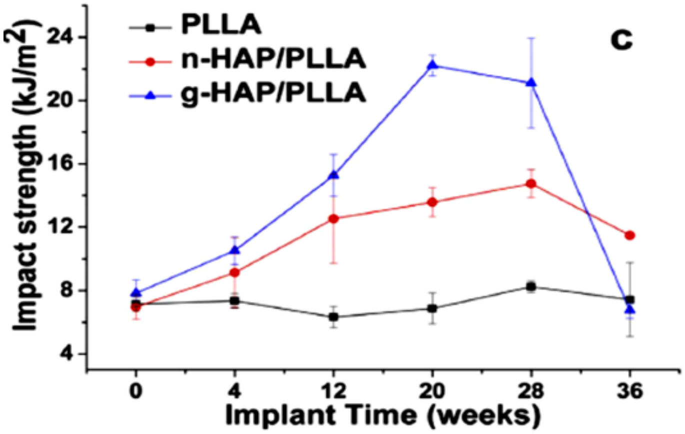


Figure 6: Effect of reinforcing PLLA with n-HPA and g-HPA on the Impact Strength (Wang et al., 2016)

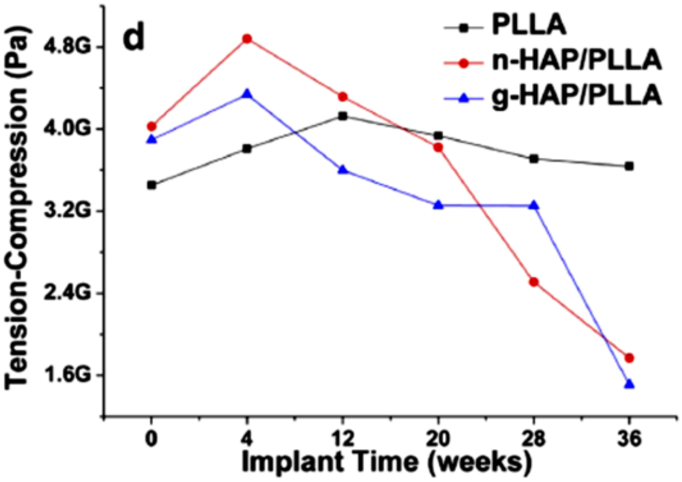


Figure 7: Effect of reinforcing PLLA with n-HPA and g-HPA on the Torsion-Compression Strength (Wang et al., 2016)

Figure 8 is a chart showing the range of glass transition temperatures, Tg (^{0}C) (i.e minimum and maximum), Young's modulus, E (GPa) and the minimum degradation time, Dt (months) of some biodegradable polymers. It is obvious that the Young's modulus of these unreinforced polymers are very low. Research has shown that reinforcing some of them resulted in composites with higher mechanical strength than their virgin form (Razaket al., 2012). Their degradation times, however, have no comparison with other materials. The degradation products of some of them are also quite human friendly.

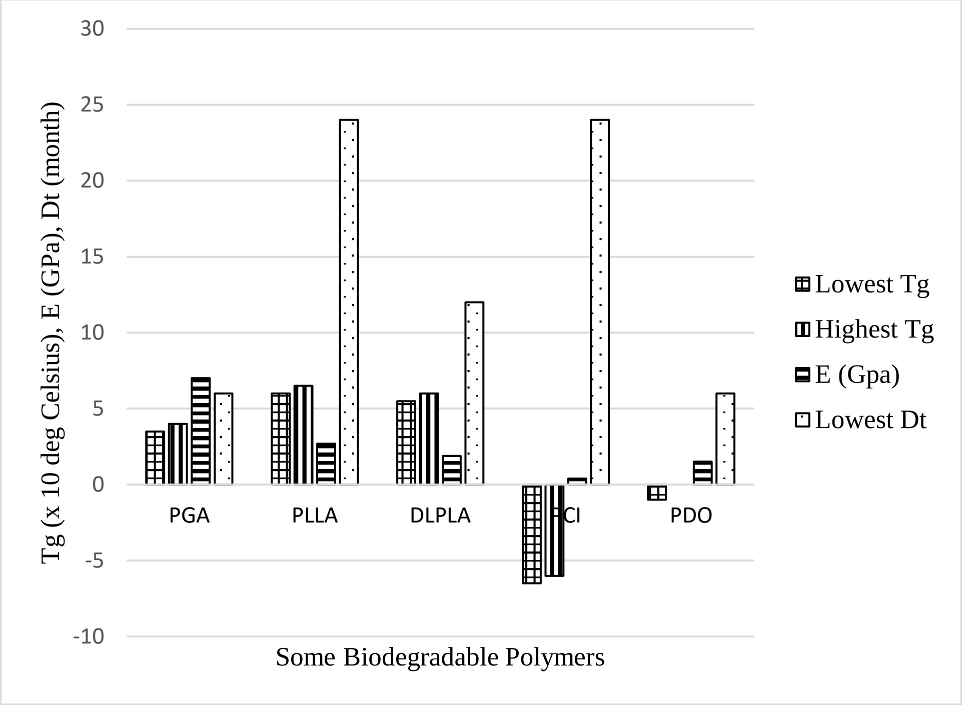


Figure 8: Thermal, mechanical and Degradation Properties of some Biodegradable Polymers (Gunatillake et al., 2003; Middleton & Tipton, 2000)

If the advantage of the formability of these polymers is properly harnessed, the use of fabrication methods like solid freeform, fused deposition, rapid prototyping, low-temperature deposition, precise extrusion, indirect solid free form, injection moulding (Abu Bakar, Chenag, & Khor, 2003; Aslam et al., 2016; Hutmacher et al., 2001; Jammalamadaka & Tappa, 2018; Michael et al., 2016; Mondrinos et al., 2006; Taboas, Maddox, Krebsbach, & Hollister, 2003; Thomson, Yaszemski, Powers, & Mikos, 1995; Xiong, Yan, Wang, Zhang, & Zhang, 2002; Xiong, Yan, Zhang, & Sun, 2001) and many other suitable processing techniques could produce biodegradable polymer composites having stronger mechanical properties and enhanced biocompatibility

Conclusion

Osteosynthesis depends more on the material used than anything else. The choice of material dictates the mechanical, biocompatibility, biodegradability and bioresorbability properties. Since research is still in progress on ideal material for bone internal fixation, it is proper to:

1. make a revisit to the use of biological material (especially bones) as some of the animal skeletons show excellent mechanical properties and reasonable resorbability and biocompatibility, except for few itches afore highlighted. The use of cattle bone can be particularly investigated. Improvement on material for sterility can also be focused so as to make resorption of skeleton more effective.
2. take great care in the use of metallic fixations. The mechanical properties of some of them are unreasonably too high for proper fracture healing and their resorption properties very poor, although some of them are biocompatible.
3. beam searchlight on the biodegradable polymers and improve its use. Biodegradable polymers have shown excellent biocompatibility, biodegradability, bioresorbability and degradation products that are non-carcinogenic. The enhancement of their weak mechanical strength should be the focus of researchers for some decades more.

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