CHAPTER 1

INTRODUCTION

The sagittal split osteotomy of mandible is one of the most commonly surgical technique that often stabilized by internal rigid fixation system. The application of miniplates transorally reduced surgical procedure and aesthetic problems previously association with the used of large reconstruction hardware in trauma and the precutaneuos application of the screw.[1] Most commonly used are rigid fixation system made of titanium alloy ,cobalt or stainless steel. The disadvantage of metallic fixation devices are the atrophic change of the underlying bone owing to lack of functional stimuli, possibility of an allergenic response, palpability, restrict growth in children, corrosion, carcinogenicity, hypersensive to cold, interfere to denture, post operative infection, painful that they must be removed after post operation[2] and stress shielding under plates resulting in osteoporotic changes has been observed that suggested the need to remove the plates.[3] For overcome these disadvantage, the resorbable plate and screw were developed that have been produced from material such as polylactic acid and polyglycolic polymers.The biological degradable materials cause no clinically important long-term inflammatory or toxic reaction in humans.[4] The use of resorbable polymer instead of the metallic material for bone fixation have been few reports craniomaxillofacial surgery.

The advantages of resorbable plate and screw may facilitate normal bone remodeling at the treatment site and decreased discomfort and cost for the patient. The biomechanical testing of the strength of sagittal split fixation-using screw and plates configuration supports the favorable clinical experience and provides useful laboratory test to evaluate the potential of bone fixation for this type of osteotomy.[5] A limited number of in vitro biomechanical test of resorbable bone fixation devices have been reported.

Review of the literatures

Bilateral Sagittal Split Osteotomy of the mandible

The evolution of the specialty of oral and maxillofacial surgery has paralleled the evolution of medical science in general. In reflecting on this process, an event that may have marked the beginning of this evolution, for oral surgery, was the introduction of the sagittal split osteotomy. A procedure evolved that could be accomplished intraorally, without facial scars and did not require the inconvenience of prolonged intermaxillary fixation. The following review of the literature is an attempt to isolate those modifications which marked significant advances in the technique.

The previously highly problematic horizontal mandibular osteotomy was modified in 1942[6] by introducing a technique in which a horizontal cut was made above the lingula just through the medial cortical plate and extended to the posterior border of the ramus. This cut was then connected to a horizontal cortical cut in the lateral cortical plate 1 cm below. The modification could be accomplished intraorally and afforded a larger medullary approximation. The procedure resulted in a minor decrease in complications but was far from being an acceptable approach.

Schuchardt's technique was expanded by increasing the separation between the horizontal cuts to 25 mm.[7] The horizontal cuts were connected with a cut along the medial aspect of the lateral oblique ridge. Neither Obwegeser nor Schuchardt advocated stripping of the masseter or medial pterygoid muscles. It is likely that to get the necessary exposure to make these cuts, there was rather wide periosteal stripping. Obwegeser advocated incising the 'periosteal band'. The increase in the distance between the horizontal cuts greatly increased the beginning of the sagittal split osteotomy. This article received little attention among US surgeons until Dr Obwegeser visited the USA and spoke to groups of oral surgeons in 1966. Del Pont's[8] modification advanced the lower horizontal cut to the buccal cortex of the mandibular body as a vertical cut between the first and second molars. In that same paper he reported a less quoted alternate technique that he called the 'oblique retromolar osteotomy'. In that technique the lingual horizontal cut was stopped just past the lingula. A vertical cortical cut was made in the area between the first and second molars, just as it was in his first method. These two cuts were connected by a cut passing from the lateral oblique ridge through to the mylohyoid groove on the lingual. This cut left both the medial pterygoid and the masseter muscles attached to the proximal fragment. For many US oral surgeons, Mohnac's review of maxillary osteotomies in 1966 served as a wake-up call. Most US oral surgeons were not aware of the advances of the European surgeons.[9] Hunsuck[10] found that it wasn't necessary to make an actual cut through to the lingual as Del Pont in 1961 had done in his connecting cut. The Del Pont lingual split would occur naturally as chisels were used to split the mandible. Hunsuck's superior cut was the same as the cut that Del Pont used in his oblique retromolar osteotomy. Hunsuck's anterior vertical cut was made in the area that he referred to as the 'union of the ascending ramus and the body of the mandible in the tooth bearing region'. In Hunsuck's article this area of 'union' was illustrated to be just distal to the second molar. A single wire was placed in the area of the vertical cut for stabilization. This technique, like Del Pont's, required only minimal muscle and periosteal stripping.

With Hunsuck's modification of the basic Obwegeser technique all of the major components of the contemporary design for the sagittal split technique were in place. The subsequent modifications have, generally, focused on attempts to manage or minimize intrasurgical or post surgical problems. These problems started to be reported in the literature in the late 1960s and early 1970s.[11,12,13] The initial popularity of this procedure went down precipitously among oral surgeons, with whom W.M.Wyatt[80] was acquainted, when these reports appeared. Many surgeons had just started doing this procedure, or were thinking of starting to do this procedure, and were dissuaded by the disturbing and intimidating negative reports.

Hinds and Kent[14] published their book 'Surgical Treatment of Developmental Jaw Deformities' in 1972. This book was the first widely distributed text on the subject in the USA. It provided a reference source and it served to broaden the base of interest in orthognathic surgical procedures. In 1977 a very important paper on the biological basis of the sagittal ramus split osteotomy was published by Bell and Schendel." This paper served todelineate the origin of some of the problems and directed the path of future modifications. The publishing of this research paper gave the technique a formal sense of credibility and validity. This paper was a subtle reminder to the clinical world that it was not wise to get too far ahead of corroborating research. Concurrent with the publishing of the Bell-Schendel paper Epker[16] published his modification, a modification that appeared to conform to the biological criteria. Specifically, the masseter was not reflected from the lateral surface of the ramus and the medial dissection was carried only to the lingula. No attempt was made to carry the dissection to the posterior border of the mandible. These are principles which had been expressed by previous surgeons but which were not being followed, according to the reports of complications. Wide stripping was advocated by many as one way of preventing relapse. Epker also introduced the high distal-low proximal wire. This wire was advocated as being an aid in seating the condyle to prevent 'condylar sag'. His connecting cut closely followed the lingual aspect of the lateral oblique line and the vertical cut was in the area between the first and second molars, completely through the inferior border. Both of these modifications were reminiscent of Del Pont. Epker did advise that the common use of surgical drains and head bandages, that evolved after Behrman's article, was probably not necessary.

In Europe, where this orthognathic revolution originated, the next major modification was occurring. Spiessl and his associates were experimenting with rigid internal screw fixation. In 1976 Spiessl et al. published their book 'New Concepts in Maxillofacial Bone Surgery' in which they introduced rigid internal fixation in the form of interfragmentary bone screws.[17] This book also encouraged the use of micro saws as a method of making precise bone cuts while preserving bone. Spiessl advocated a modification in which the lateral oblique ridge was removed to facilitate the use of smaller than traditional chisels to make the split closely follow the buccal cortical wall. Following the cortical plate in that manner decreased injuries to the mandibular nerve. He also included some preliminary studies on the variation of the location of the mandibular nerve relative to the buccal and inferior mandibular cortexes as the mandibular nerve coursed through the mandible. His research showed that the screws added to the stability of the fragments and decreased healing time because of fragment compression.

Surgical Correction of Dentofacial Deformities were published a two volume set in 1980. [18,19] This publication had a tremendous effect on the oraland maxillofacial surgeons in private practice. It appeared to give many surgeons the confidence to either begin to do orthognathic surgery again, after all of those 'disaster articles' in the seventies, or the confidence to begin to do orthognathic surgery. Screw technology just missed that publication. The screws were introduced in the third volume in Bell et al. [20]The introduction of the screw brought with it the almost immediate division of the profession into 'wirecamps' and 'screw camps'. The question seemed to be 'don't the lag screws torque the proximal fragment and won't that be a source of problems with joint function in the future?' Leonard and his associates in 1985[21] attempted to answer this question in their article. They took preoperative and postoperative CT scans of the mandible and examined the angle between the long axes of the condyle and the midsagittal plane. They deduced that there were no gross changes and that, therefore, the use of compression screws was not problematic. Leonard also emphasized the benefits of small spatula chisels and keeping close to the cortical wall to avoid nerve injury.

The location of the mandibular canal and its relationship to the sagittal ramus osteotomy was the first to report specifically on the mediolateral position of the mandibular nerve.[22] This research suggested to us that their study material favored the extension of the sagittal osteotomy cut into the area of the first molar for the following reasons: 1) the buccal cortical plate is thicker, 2) the total mandibular body width is thicker, and 3) the distance between the inner aspect of the buccal cortical plate and the mandibular canal is consistently greater in that location. They went on to describe this area as a 'bony prominence, an extension of the lateral oblique line'. They reported that, in their experience, the area just distal to the third molar is the area where the neurovascular bundle most often is in direct contact with the buccal cortical plate and that occasionally the neurovascular bundle and canal appears to be within the buccal cortical plate, so that area would be the least favorable for cuts to be made.

The study of Wolfordl[23] responded to Rajchel's article[22]with a further modification of the sagittal ramus split procedure. Wolford and associates advocated bringing the vertical cut farther forward, This forward extension would make use of the documented increased space between the inner surface of the buccal plate and the neurovascular canal in the area between the first and second molars. Wolford went on to suggest the value of using position screws in preference to lag screws as a means of preventing possible nerve compression and condylar displacement. The horizontal cut was angled in a direction perpendicular to the ascending ramus, when possible, rather than paralleling the occlusal plane in order to place the cut into an area, according to Rajchel, having more distance between the cortical plates. With this cut there would be less likelihood of an unfavorable ramus fracture. There was also a comment in this article about their impression of the favorable effect of early mobilization on the joints as the result of the use of rigid fixation. Obwegeser's last appearance[24] in print, in an US journal,was in 1987. The article was titled 'Two ways to treat bird-face deformity'. The interesting aspect of that article was his use of a vertical cut that was farther forward than any that had been published in English literature. The vertical cut was shown to be between the second bicuspid and the first molar. Rajchel's paper[22], previously quoted, suggests that this anteriorly placed vertical cut is reasonable, since the nerve is usually still medially located at that point, depending on the location of the mental foramen.

Wolford[25] introduced the concept of the inferior border split. A speciallydesigned saw was used to cut the inferior border from the inferior side. This modification was deemed necessary because of their observation that, in the conventional split, the split usually occurred in the lingual cortical plate. The high lingual side split made the placement of the inferior border screw difficult because of the lack of bone to screw into below the neurovascular bundle or canal. The other disadvantage of the split on the lingual side was that the nerve frequently went with the proximal fragment and was thus more difficult to visualize and to separate.

The first study concerned the level of fusion of the buccal and lingual cortical plates in the area above the lingualwas reported by Smith et al.[26] Their research indicated that the fusion of cortical plates frequently occurs very near the superior tip of the lingula and posterior to the lingula. They suggested that the mean length of the horizontal cut should be about 18 mm. Their second study concerned the thickness of the buccal cortical plate and confirmed that the buccal plate is thickest at the lateral oblique ridge and that the lateral oblique ridge is a very favorable area for screw placement.[27] The ridge forms a natural band. The indications of bilateral sagittal split osteotomies are symmetric and asymmetric mandibular advancement, vertical lengthening of ascending mandibular ramus, correction of open bite, symmetric mandibular setback and minor asymmetric mandibular setback. Anatomic landmarks are the buccal fat pad, mandibular molars, retromolar area, anterior border of ramus, antegonial notch, temporal crest,external oblique ridge, coronoid process/sigmoid notch, lingula. Biologic considerations are the vascular supply. Epker[16] showed that blood supply is centripetal (inside to out); Periosteum is not the major source of the blood supply and medullary vessels are sufficient to maintain perfusion. However excessive stripping of soft tissue attachment should be avoided to a vascular segmental necrosis, osseous anatomy, thickness of the medullary portion influences the ease of osseous sagittal split, location of the inferior alveolar neurovascular (IAN) bundle and any impacted teeth should be considered in the pre-surgical work-up, 3rd molars should ideally be extracted 6-12 months prior to anticipated BSSO for bone healing. If rigid fixation is considered, the thickness of lateral and medial cortexes become more important. Technique of bilateral sagittal split osteotomies are the buccal fat pad is identified and delineated. Epinephrine solution is infiltrated along the external oblique ridge and medial ramus to IAN bundle. At region of the second molar, incision along the external oblique ridge, half way up the ascending ramus (inferior to the fat pad), to the region of the first molar and leave enough mucosa for closure. Infero-lateral dissection to the antegonial notch, without involving the masseter., superior dissection to expose the coronoid process and the sigmoid notch. A clamp on the coronoid may aid in retraction.Medial ramus dissection is done to expose the IAN bundle and lingula. No need to expose posterior mandibular border. Retractor placed just superiorly to lingula for protection. Long fissure (Lindemann) bur is used for a unicortical medial osteotomy just into the marrow space. This is just superior and posterior to the lingula. A lateral vertical unicortical cut is made in the region of the first/second molar which is the greatest distance from the IAN. Extending from external oblique ridge to involve the inferior border of the mandible. This will aid in initiation of a "good" split. The two cuts are now connected through the superior aspect with a fine fissure bur, this cut should be kept laterally. No alteration is made in the line of osteotomy at the site of an impacted 3rd molar. A reciprocating saw may be used for all osteotomies. This obviously is not for the novice. An egg-shaped bur could be used to remove the posterior edge of the distal segment. This will permit a fine fissure bur to initiate the inferior border osteotomy. Some use an inferior border saw for this portion of the osteotomy. An osteotome is now used to verify the rotary osteotomy. Osteotome is also directed above the IAN canal and at the vertical portion to initiate the split. A large flat osteotome would be used to complete the split by controlled wedging of the proximal segment away from the distal segment. Care must be taken to identify, isolate and protect the IAN. Any attachments should be teased away gently. Once the split is completed, residual medial pterygoid muscle attachment from the distal segment is stripped to interferences. Advancement; leave muscle attached to the proximal. Set-back; it could be stripped off using a J-stripper. IAN should be protected. Impacted 3rd's are removed at this time. Bony interferences are removed with bur, to allow for passive contact of the two segments. A clamp may be placed on the proximal segment for manipulation to verify removal of all interferences. Proximal and distal segments are now independent. Contralateral split is performed identically. Interocclusal splint is placed and MMF applied. The rigid internal fixation is used .Miniplate and screws are ideal. Site of extracted third molars pose a challenge for screw fixation. The complications were reported and divided these into life-threatening, disfiguring, subjectively discomforting, regression or relapse and miscellaneous. Regression and Relapse were reported that relapse of 1 to 2 mm seen in most cases that may be due to "condylar sag", improper segment fixation, "bad"split, hemarthrosis.

Rigid fixation

Rigid internal fixation is the useful for bone fixation because reduced hospital admission time, good nutrition for healing, control airway easily and reduced recovery time.[29]

Various techniques of rigid internal fixation have been used in recent years by several authors to achieve skeletal stability.

Plates and screws were used in the rigid internal fixation instead of wiring fixation because increased mandible skeletal stability, decreased time of Intermaxillary fixation (IMF), more comfortable for patient in post operation[30,31] and less relapse tendency.[32]

Miniplate placed along the tension-banding line with monocortical screw fixation because they are sufficiently stable, relatively simple plate to adapt (titanium easier than stainless steel), screws are self-tapping. The study reported using transorally applied miniplates to obtain rigid fixation of the proximal and distal fragments with BSSRO for advancement and set back.[33] The study reported that miniplates and screws are stronger but increase relapse in distance more than 6-7 mm at B-point, Pogonion- point.[34] Miniplate and Screw fixation in BSSRO is useful for mandibular large advancement , although little cortical contact [36,37,38], the movement of mandible by bilateral sagittal split osteotomy advancement 5 mm have more stability.[35]And the most common use is metallic fixation device but had many disadvantages such as it made atrophic changes of bone that possibly to allergy response.[39]

Rigid internal fixation allows connection of bone fragments using plates and screws. Designed to provide efficient stabilization of fracture. Many shapes and sizes of plates designed for specific applications. Requires more extensive surgery and disruption of periosteum.

The bone healing

In nature bone healing, regeneration and repair are three phases of healing by callus rapid process, rehabilitation slow, low risk but with operative intervention (reduction and compression) found that their healing by callus, rapid process, rehabilitation rapid and lesser risk and the reduction was hold by semi-rigid (plaster), rigid (internal fixation).

Callus formation **:** endosteal and periosteal calluses act to stabilize the fracture fragments and callus formation is suppressed by rigid fixation or excessive motion. Step 1 is induction and proliferation of undifferentiated periosteal tissue. Step 2 is differentiation of callus tissue into woven bone. Step 3 is remodeling of woven bone to osteonal or lamellar bone.

The types of bone healing are primary union without callus and secondary union with callus.

1) Primary Healing in rigid fixation techniques : direct healing without a visible

callus; primary contact healing,primary gap healing (lag screws, compression plates, recon plate, external fixation, wire fixation, miniplate fixation) that no callus formation and have question of bone resorption.

2) Secondary bone healing : healing following formation of a callus , remodeling and strengthening that found in MMF, wire fixation and miniplate fixation.

Miniplates ; semi-rigid fixation that allows primary and secondary bone healing . easily bendable, more forgiving and short period MMF are recommended.

Intramembranous bone formation : occurs at periosteal surface ,pelvis, scapula, clavicle, skull and osteoblasts form a calcified matrix within collagen framework .Endochondral bone formation: occurs at growth plates and within callus and osteoblasts form osteoid on cartilagenous framework.

Healing under Plates was affected by stress shielding, vascular disturbance, number of cortices and biological fixation .

The titanium plate may provide protection from normal physiologic stresses as a result, alveolar bone loss, term "stress shielding".[51] But the resorbable material devices offer many advantages over their metallic. The elasticity of these devices is close to that of bone, thus enhancing the stress protection. As the bone healing, the resorbable plates will gradually, degrade, allowing physiologic stresses to be transferred back to the healing bone. As a result, stress shielding is avoided.

Osteosynthesis development

In the search for a simple osteosynthesis technique which would guarantee fracture healing without interfragmentary compression, Champy conducted mathematical & experimental studies based on the monocortical plate of Michelet &Moll.

Biomechanical principles of monocortical miniplate osteosynthesis are based on these studies performed in Strasbourg. From their measurements of the torsional, tensile and compressive forces at all points of the mandible, a tension banding osteosynthesis system was developed.

Using these osteosynthesis concepts has resulted in constitent success in mandible fracture treatment. Knowledge of masticatory stresses exerted on the mandible is fundamental because they determine the rational design and positioning of the osteosythesis plate.

The metallic fixation

The use of metallic materials for rigid internal fixation is the standard part of most every orthognathic procedure done today. The application of miniplates transorally reduced surgical procedure and aesthetic problems previously association with the used of large reconstruction hardware in trauma and the precutaneuos application of the screw.[1] Most commonly used are rigid fixation system made of titanium alloy ,cobalt or stainless steel.

Reported disadvantages of metallic fixation devices include: atrophic change of underlying bone that decreased functional stimuli[50,51], made allergenic response[39], image scatter with CT scan , X-ray and radiotherapy[52,53], restricts growth in children[52] .Reported reasons for secondary procedure to remove devices[52] have been postoperative Infection , painful , thermal hypersensitivity[52,54], bother insert of the prosthesis , palpability[52], carcinogenicity[55,70], corrosion of metals causes allergenic responses and titanium particle found in local regional lymph node [55,56,57,58], risk of stress shielding that can make bone atrophy or osteopenia[59.60,61], hardware loosening with resulting extrusion[62], screw migration and sinusitis.[63]

Resorbable plate and screw

The first use of resorbable plate and screws was reported by Cutright DE et al. [40] The resorbalble material must fulfill several basic demands, including sufficient strength of material used to accomplish fixation, good compatibility between tissue and material, early union and minimum morbidity. In the later stages, after insertion into the bone, the material should decompose gradually, transferring the stresses slowly to the healing bone and preventing loss of mineral content and strength of bone tissue.

There are 2 types of the resorbable plate and screws were used in orthognathic surgery 1) the self-reinforced polyglycolic acid (SR-PGA) and poly L-Lactide (PLLA) plate and screws[41,64] ; 2) unreinfocrced PLLA plate and screws.[42,53]

The self- reinforced poly L-lactide screw was used in the bilateral Sagittal split osteotomies ; the pilot study in sheep found that the self reinforce poly L-lactide screw (2.5 mm , 3.5 mm) in the bilateral Sagittal split osteotomies is strong enough to secure fixation.[41]

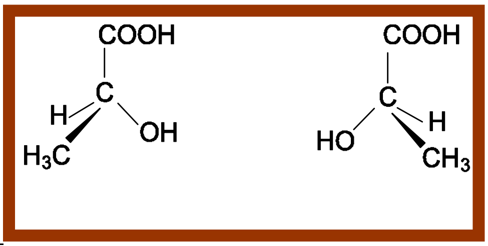
PLLA bone plate had an initial load at fracture of 650 N and a bending modulus of 5 Gpa.[20]

Tensile strength of poly lactide varies between 60-80 N/mm 2 whereas titanium grade 4 posseses tensile strength of 700-800 N/mm^2.[43]

The study of copolymer (PGA/PLA) in rabbit and human found that the degadation of resorbable microplate and screw and the distance of screw increased at 8 th month in rabbit model.[44] The using of resorbable fixation system in orthognathic surgery was also reported in the study of Shand JN, Higgic AA.[45] The result that indicate a relatively high resistance to biomechanical loads representative of mastication and suggest that 2.5 mm resorbable screws of this particular polylactic acid-polyglycolic acid copolymer may be effective in fixation of the postoperative unrestrained sagittal spit mandibular osteotomy.[46] The bioabsorbable poly-L-lactide (PLLA) miniplate provided effective osteosynthesis of the maxilofacial skeleton.[47]

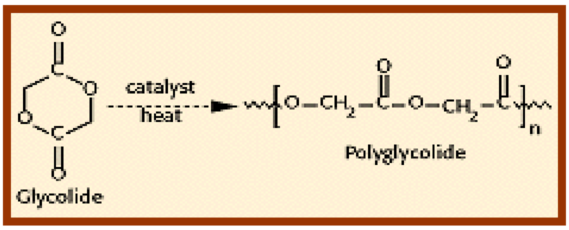
The study evaluated resorbable minioplate osteosyntheses in bilateral sagittal split osteotomies with major bone repositioning was reported by Constatin Alander,et al.[48] The results of biomechanical testing were compare to stainless steel and titanium suggest that poly-L-lactide (PLLA) plate and screw have properties suitable for fixation of bilateral sagittal split osteotomies. Poly-L-lactde plates have indications in areas of low stress and non-compressive load.[2] The intial reporting of clinical application of resorbable plates and screws in the movement of mandible by bilateral sagittal split osteotomies advancement <8 mm is the new choice of the rigid fixation by Carlo Ferretti, et al.[49] So that, the resorbable plate and screws was used replace the titanium plate and screws to overcome the problem.[40] Currently, most devices are manufactured by combining two polymers, mainly poly-D-lactide or polyglycolide with polylactide. The combination of butyl 2-cyanoacrylate glue such as biodegradible polylactic acid (PLA)/ poly glycolic acid(PGA) and copolymers , the period of degradation may complete in 18-36 months and final hydrolytic degradation product are lactic acid or glycolic acid into H_20 and CO_2. The chemical structure of polylactic acid (PLA)/ poly glycolic acid(PGA) and copolymers are shown in Fig. 1.

Lactic Acid



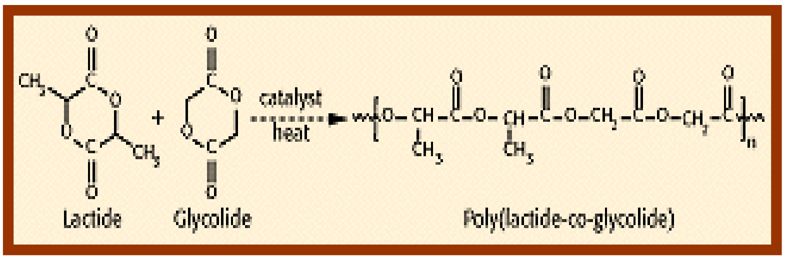
+LACTIC ACID (L) -LACTIC ACID (D)

Glycolide



glycolide monomer ⇨ PGA homopolymer*(Poly- Glycolic-Acid)*

Lactide + Glycolide



lactide + glycolide monomers ⇨ PLGA copolymer

Fig. 1 The chemical structure of lactic acid, glycolic acid, PLGA copolymer.

Since 1970's the excellent biocompability of PLA implants have been documented in hundreds of publications. Copolymers of polylactic and polyglycolic acids (PLGA) have shown to be comparable to the biocompatability of PLA. PLGA implants have been successfully used for a variety of craniomaxillofacial applications. In 1966 Kalkarni reasoned that polylactic acid would be useful for degradable surgical implants since hydrolysis would yield lactic acid , a normal intermediate of carbohydrate metabolism.

Polylactic acid, also known as PLA or polylactide, is prepared from the cyclic diester of lactic acid (lactide) by ring opening addition polymerization. Since lactic acid is a dissymmetric compound (non superimposable on its mirror image) it occurs as two optical isomers (stereoisomers) called L (*levorotary*) and D (*dexorotary*) Lactide. In the human body the L isomer exists in carbondioxide metabolism and the D isomer is found in acidic milks. If the polymer consists of only the L isomer it is called poly L Lactic acid (PLLA) which has been most commonly used in orthopaedic implants because of its high strength and low elongation. Because of the stereoregularity of the molecules PLLA is highly crystalline and has a Glass Transition Temperature of 57^{o} C and melting point of 174-184^{o} C. The methyl group makes PLA hydrophobic and thus resistant to hydrolysis. If it contains both isomers it is called a steriocopolymer, poly D L Lactic acid often referred to as P(L/DL) LA or PDLLA. PDLLA is unable to arrange into an organized crystalline structure and has a lower tensile strength and more rapid degradation time.

Properties of PLLA homopolymer are high initial strength bending strength 140 - 300 MPa. Bending modulus 3 - 10 GPa, crystallinity up to 75 %, complete loss of strength in vivo within 36 - 52 weeks ,heterogeneous degradation of amorphous phase leaves slowly degrading crystalline debris, good clinical biocompatibility ,reported incidence of foreign body reactions is low.Complete bioresorption takes 4 - 6 years.

Polyglycolic acid, also known as PGA or Polyglycolide, is the simplest linear aliphatic polyester. It was first reported by Bischoff and Walden in 1893 who noted that polymer formation from glycolide monomer was a reversible reaction. This polymerization reaction was further investigated by Caruthers in 1932 but did not result in development of a commercial product until Schmitt invented the synthetic absorbable suture application in 1967. PGA is a hard crystalline polymer melting at 224-228^{o} C with a Glass Transition Temperature of 36^{o} C. It lacks a methyl group which makes it hydrophilic and thus more susceptible to hydrolysis and faster degradation than polylactide. The oldest and best know commercial product made of PGA is Dexon.

Properties of PGA homopolymer are high initial strength bending strength 200 - 400 MPa. Bending modulus up to 6-20 GPa, crystallinity up to 55 %, heterogeneous degradation of amorphous phase leaves slowly degrading crystalline debris, complete loss of strength in vivo within 3-6 weeks, fast degrading and tolerated better by pediatrics than adults.

Polymers are often referred to as plastics; plasticity is deformation, permanent bending or stretching under load and the opposite characteristic to plasticity is elasticity that is temporary bending or stretching under load-returns to original size/shape/orientation. Most materials under load are first elastic and then plastic.

Monomer is Basic unit and polymer is chain of monomers that often formed by condensation reactions and/or heat. Homopolymer is a chain using only one monomer repeated and copolymer: a chain using more than 2 different monomers.

Polymer Characteristics

The microstructure of a polymer affects its properties. If the polymeric chains are randomly orientated in disorder and thus loosely packed, the polymer is called amorphous. If the chains lie parallel and thus are tightly packed, the polymer is called crystalline. Even crystalline polymers are not entirely crystalline and always contain both crystalline and amorphous regions and are best termed semi crystalline.

Copolymerization of PLLA with PGA or PDLA , theirs mechanical properties and degradation rate can be tailored by copolymerization of PLLA with PGA or PDLA. The crystallinity is expected to decrease with copolymerization, while the rate of degradation will increase simultaneously due to the more hydrophilic nature of the glycolide counterpart. Vicryl was developed by Ethicon (90:10 glycolide:lactide) to give a longer strength retention time whilst absorbing in 3-4 months. The initial use of a copolymer of PLLA and PGA was in craniofacial surgery in children.

Degradation of PLA and PGA.

The advantages of using lactic acid and glycolic acid based polymers as biomaterials is their degradation into molecules belonging to natural tissue metabolism.

The degration process are 3 stages; the stage 1 is the hydrolysis that the water attacks the chemical bonds converting the long polymer chains into shorter water-soluble fragments, the stage 2 is the metabolization that metabolized into monomeric acids which enter the citric acid (Krebs) cycle and the stage 3 is the excretion that excreted as water and carbon dioxide that are shown in Fig. 2.

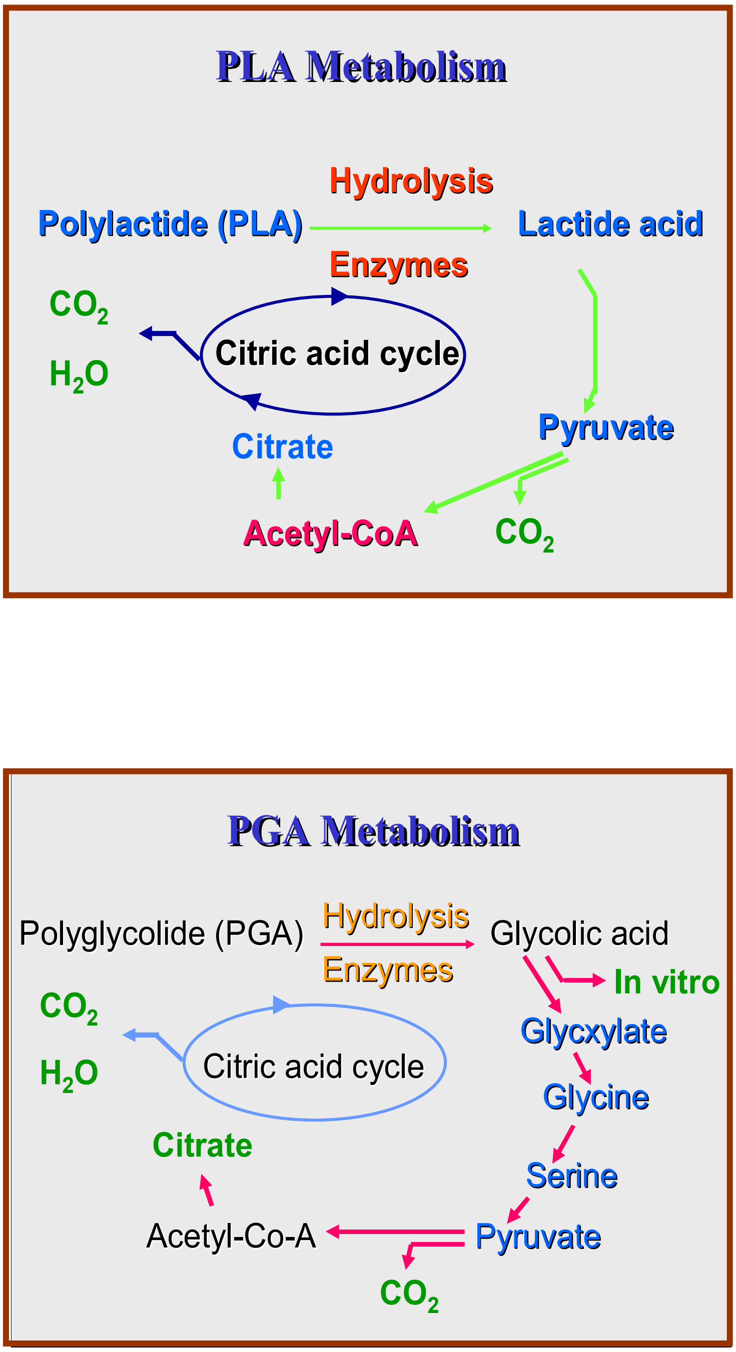


Fig. 2 The metabolism of PLA and PGA.

Resorbable plate and screws in rigid fixation have the potential advantages of such devices are :1)The devices degrade with time thereby reducing stress protection and the companying osteoporosis. 2)These is no need for a secondary surgical procedure to remove the resorbable devices. 3)Endurance implants are easily contoured intraoperatively to closely match targeted anatomy.

Resorbable plate and screws in rigid fixation may have initial strength for stability 12 weeks after operation.[77] The mineral resorbable can reinforce with polymer matrix and the material may strong enough for weight bearing area of human skeleton.[77]

The advantages of resorbable plate and screw are no second surgery required for implant removal that reduced patient trauma & cost, the material degrades & will only be present for about 2 years that reduced long-term infection risk. No long term implant palpability or temperature sensitivity that reduced patient complaints. Non-metallic that no imaging interference. Predictable degradation to provide progressive bone loading & no stress shielding that Improved chance of bone healing. And implants supplied sterile that reduced cross infection potential.

The biomechanical testing

The biomechanics factors, governing the healing efficiency in fractured bone treated by plate and screws are (1) the degree of bone contact developed at the fracture interface, (2) stability provided to the fractured bone in terms of reduced movement at the fracture interface and (3) necessary and sufficient stress-shielding of the bone at fracture interface as well as away from it.

With biomechanical test model, the main problem is how to imitate the human masticatory muscles when examining the stability of rigid fixation techniques. More recently, the 3-point biomechanical test model was developed as the best imitate the masticatory muscles[1]; in the previous study, the 3-point bovine rib model in preliminary study undertaken to investigate the biomechanics of the internal fixation system for the bilateral sagittal split osteotomies in vitro found that the model is inexpensive, discriminating and reproducible method that more accurately represent the human mandible in function.[1]

The biomechanical data; The maximum load that is the peak of the stress strain (load /displacement) curve(Fig. 3), the displacement at maximum load is the distance at which maximum load is achieved, the stiffness is defined at the rate of change of strain as a function of stress. Yeild point, which defined yeild load and yield displacement and stiffness may be the most important factors in the assessment of mechanical characteristics of fixation devices.

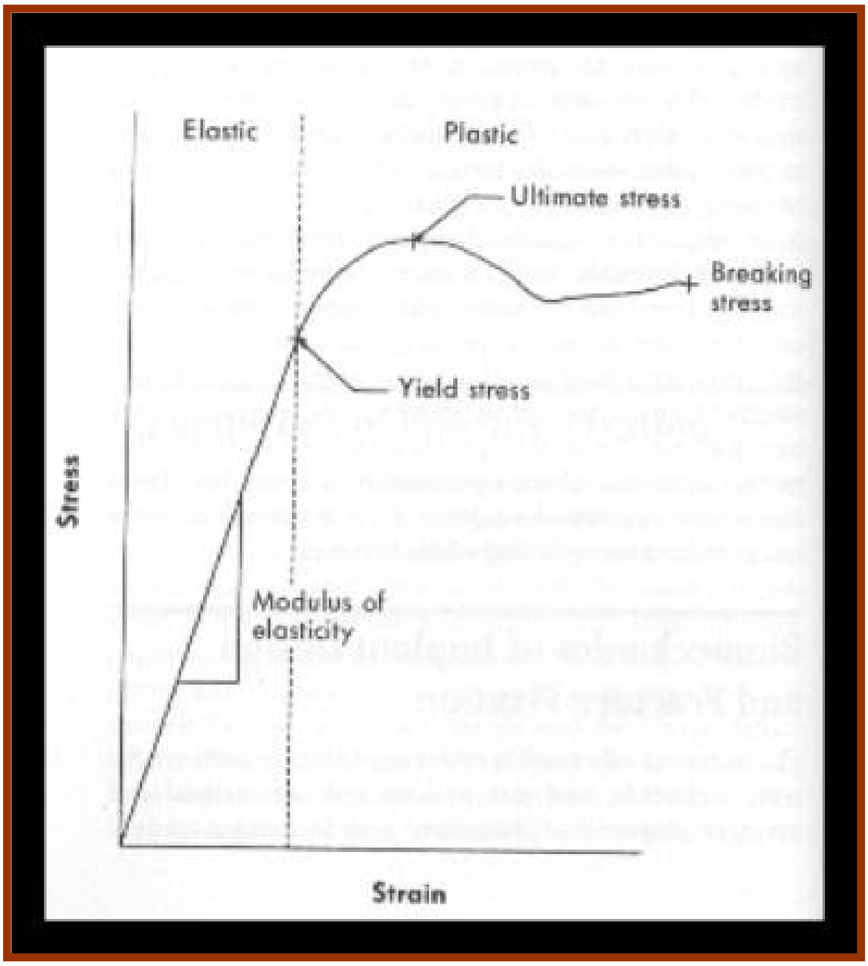


Fig. 3 The load-displacement curve.

The question of the study.

Is the biomechanical strength of the resorbable plate and screws (PLA/PGA) adequate for fixation when using in bilateral sagittal spit osteotomies?

The purpose of the study

To compare the biomechanical strength between resorbable plate and screws with titanium plate and screws in fixation of bilateral sagittal split osteotomies of the porcine mandible.

The knowledges from the study

1) The biomechanical strength of the resorbable plate and screws (PLA/PGA) in bilateral sagittal split osteotomies.

2) The biomechanical strength of the resorbable plate and screws (PLA/PGA) in bilateral sagittal split osteotomies comparing with the conventional titanium plate and screws fixation system.

3) The obtained experimental data could be used to support the clinical application of the resorbable plate and screws (PLA/PGA) in bilateral sagittal split osteotomies as the alternative fixation system.