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Review Article

Bioresorbable Fixation of Facial Trauma: An Overview

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Abstract

Introduction: Facial fractures with or without bone displacement are commonly seen in individuals with trauma. The treatment in such cases should consist of repositioning and immobilizing the fractured fragments to restore the function and cosmetic problems. Traditionally, titanium plates were used to immobilize the displaced segments and were considered the' gold standard. However, the recent introduction of bioresorbable plates as a substitute benefits from minimizing the need for the additional surgical procedure of removing the metal plate. Nevertheless, there remain ambiguities regarding the stability of resorbable fixations, the duration needed for their resorption, the risk of foreign body reactions, and some technical obstacles with resorbable plates.

Aim of Work: This review aims at highlighting an overview of the currently available bioresorbable materials and osteofixation systems for facial trauma.

Methodology: The review is a comprehensive research of PUBMED, Google Scholar, and WHO official page from 1966 to 2018.

Conclusion: Many developments have been made in bioresorbable plate systems using bioactive/resorbable osteoconductive materials. We present an overview of presently available resorbable implant materials and their uses in maxillofacial trauma, focusing on recent advancements.

Keywords: *Bioresorbable Implants; Titanium Implants; Facial Fracture; Trauma; Bone Healing*

Introduction

Fractures of the facial bones can cause deranged occlusion. Road traffic accidents, assaults, and falls are significant causes of facial trauma, leading to functional and cosmetic problems. The mandible, zygoma, and nasal bones are the most often fractured during facial trauma. Fracture of the mandible bone may damage the inferior alveolar nerve leading to loss of sensation of the lower lip, teeth, and chin on the affected side. Other symptoms associated with swelling like pain, swelling, and hematoma may also appear [1].

Cheek prominence may get flattened due to zygoma fracture. Symptoms of diplopia and enophthalmos are also seen in zygoma fracture, as zygoma is an essential part of the orbit. Additionally, loss of sensation over the skin of the cheek and sometimes of the upper front teeth may also present if the infraorbital nerve is compressed during a fracture [1].

An essential requirement for the stable fixation and uneventful healing of bone pieces in maxillofacial osteosynthetic surgeries, such as facial trauma and bimaxillary osteotomies in orthognathic surgery, include maintenance of adequate blood supply, reduction of bone segments with stable fixation, healing of bone without complications, and optimal remodeling [2-7].

The titanium plate system can achieve stable fixation post-reduction of bone fractures [3,5-7]. This helps in distributing patients' masticatory functional load soon after the surgery. The widespread use of titanium as a general standard is because of its mechanical strength; it is easy to handle, displays minimal dimensional changes, scatters very little on computed tomography (CT) scanning, and is compatible with radiography and magnetic resonance imaging [8,9].

Once the bone healing is complete, these plates are frequently removed as the need for fixation is only short-term [3-5]**.** In approximately 5 - 40% of the cases, the titanium plates and screws are removed in a subsequent surgery once the bone healing is achieved. This is because titanium can affect facial growth, cause thermal sensitivity, migrate on bone, and interfere with diagnostic imaging [5,6,10,11]. Medication-associated jaw necrosis in the presence of Titanium craniomaxillofacial (CMF) implants has also been reported [11,12].

Particles of titanium have been found in regional lymph nodes and scar tissue covering the titanium plates leading to inadequate contact between the metal plate and bone surface. The need for predictability and precision has resulted in innovations in craniomaxillofacial (CMF) implants [8-11].

Biodegradable and bioresorbable implant materials

To overcome the flaws of metallic fixation devices, implants manufactured out of bioresorbable materials (e.g. polylactic acid and polyglycolic acid) have been developed. The use of these resorbable plates possibly eradicates the need for an additional procedure for their retrieval [1].

Bioresorbable and biodegradable osteosynthetic fixation implants have several benefits over titanium fixation: the need to retrieve the implants after healing, there is no corrosion and build-up of metal in tissues; radiolucency; reduced pain; and reduced stress-shielding as the implants tolerate a smaller load at first and gradually transfer the load as they degrade. They also have the advantage of less postoperative pain and are not affected by extreme climate changes [3-5,9,11].

Initial studies of the bioresorbable system showed uneventful primary healing of fractures, with progressive degradation of the implants. A lot of developments have been made since then to improve the bioresorbable fixation system [13,14].

Kulkarni., *et al*. did a study on the use of biodegradable implants in 1966. He studied the biocompatibility of poly-L-lactic acid (PLLA) in animals. The study showed that PLLA was non-toxic and slowly degraded [15]. Another study was done in which PLLA sutures were used in mandibular fractures with no serious inflammatory reactions or immunological responses [16].

Some studies have shown that the combinations of Titanium and resorbable plates may be adequate to overcome the displacing forces applied by the masseter muscle and can be used for internal fixation of isolated zygomatico-maxillary complex (ZMC) fractures in the adult [17].

Bioresorbable implant materials can let the newly formed tissue grow into any surface irregularities. As a result, in a resorbable osteofixation implant material, there are no toxic or mutagenic effects. However, there are certain shortcomings in using these materials due to their inadequate stiffness and weakness, which results in the rapid loss of initial implant strength and higher refracture rates [18-20].

The biodegradable implants disintegrate after placement with no sign of removal from the body. The biodegradation method depends on many factors such as molecular weight, the crystal form/geometry of the material, the tissue where it is implanted, the body fluid that contacts it, motion, and temperature [18-20]. An ideal biodegradable osteofixation implant material should provide excellent strength while disintegrating predictably throughout the healing process without any complications. The disadvantage of biodegradable implants includes reduced strength compared to titanium implants and unfavorable reactions such as inflammation and foreign body reaction [3,8-11].

On the other hand, using the bioresorbable system is becoming common because of its ease of use, easy adaptability, safe material, and complete absorbability. Various researchers have concluded that no statistically significant difference in the mechanical strength between Titanium and bioresorbable plates and screws in osteosynthesis of mandibular fracture exists [14-18].

Discussion

Types of bioresorbable osteosynthesis materials

The typical composition of these bioresorbable osteosynthetic materials consists of polymers and copolymers of PLLA, poly-D-lactic acid (PDLA), polyglycolic acid (PGA), and polydioxanone sulfate. Developed bioresorbable osteosynthesis materials consist of a base made of PLLA composite, hydroxyapatite as an osteoconductive material, and polyglycolic acid as an accelerator of bioresorption [9,21].

Plate system	Plate/screw conformation	Plate thickness (in mm)	Screw diameter (in mm)	Indication for osteosynthesis	Biodegradation period
GrandFix®	PLLA (100%)	1.0/1.5	2.2	Mid-face/ mandible	More than 3 years
GrandFix, Flat-type® SonicWeld Rx®	PLLA (100%) PDLLA (100%)	0.95 mm 0.8 mm/1.0 mm (0.3 mm/0.6 mm)	2.2 1.6 mm/2.1 mm	Mid-face Mid-face	More than 3 years 12 - 30 months
LactoSorb®	PLLA (82%) + PGA (18%)	0.9 mm/1.4 mm (0.5 mm)	1.5 mm/2.0 mm	Mid-face	12 - 18 months
RapidSorb®	PLLA (85%) + PGA (15%)	0.8 mm/1.2 mm (0.5 mm)	1.5 mm/2.0 mm	Mid-face	12 months
FIXORB-MX	PLLA (100%)	1.5 mm	2.0 mm	Mid- face/mandible	More than 3 years
SuperFIXORB-MX® (Osteo-transMX®)	Plate: PLLA (60 wt%) + u-HA (40 wt%) Screw: PLLA (70 wt%) + u-HA (30 wt%)	1.0 mm/1.4 mm (0.3 mm/0.5 mm)	2.0 mm	Mid- face/mandible	5.5 years

Table 1: *Shows commercially available resorbable osteosynthesis implant materials approved for use in oral and maxillofacial surgery [2].*

The bioresorbable polymers are primarily composed of high-molecular-weight aliphatic polyesters with repeating units of alpha-hydroxy acid (HOCHR-COOH) derivatives manufactured by ring-opening polymerization [9,21]. The macrophages' resorption of these polymers into water and carbon dioxide occurs in the citric acid cycle. Recent studies have shown the shift of the concept from "resorbable" to actual "bioresorbable," which exemplifies biodegradation and the encouragement of bioactivity, such as osteoconductivity [9,21].

The ideal requirements of a bioresorbable material are 1. It should support bony fragments during the healing process. 2. Should resorb completely once the healing is completed. 3. The metabolites should not cause any local or systemic reaction. 4. The quantity of material required must be modest. 5. The material should be flexible enough to be used at various sites in the maxillofacial region [9,21].

Polyglycolic acid (PGA)

Polyglycolic acid was the first clinically used bioresorbable polymer material. However, its use was limited due to its vulnerability to quick degradation. In almost 4 - 7 weeks of the surgery, it loses its mechanical strength even when the bone healing is not complete. There are also reports of complications due to inadequate removal of the acid-degradation products. All of these drawbacks have resulted in minimal use of pure polyglycolic acid in maxillofacial surgeries [4,10].

Poly (lactic acid) (PLA): PLLA and PDLA

Polylactic acid (PLA) is a high-molecular-weight bioresorbable polymer with two stereoisomeric forms, namely poly-L- lactide (PLLA) and poly-D-lactide (PDLA). PLLA is resistant to hydrolysis due to its crystalline and hydrophobic structure. As a result, bio-resorption with complete loss of strength does not occur in the first 2 years of implantation *in vitro.* However, clinically the resorption of PLLA takes almost 3.5 years. The drawbacks of PLLA include late-degradation tissue response and foreign-body reactions. Since the early 1990s, PLLA has been used as "the first generation" bioresorbable osteosynthetic material [10].

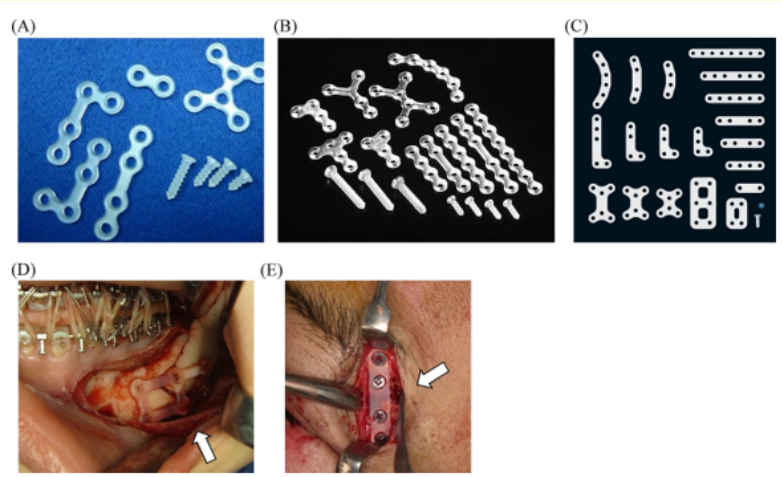

Figure 1: *First-generation bioresorbable materials used in Maxillofacial osteosynthesis. (A) The GRAND FIX® system. (B) The FIXORB-MX® system. (C) The GRAND FIX® flat-type system. (D) 3-D bioresorbable plate osteosynthesis of setback mandibular bilateral sagittal split ramus osteotomy (BSSRO) using the GRAND FIX® system. (E) Thin/flat-type bioresorbable plate osteosynthesis (GRAND FIX®, flat type) for the internal fixation of the zygomatico-maxillary complex fracture [2].*

PDLA, on the other hand, has lower crystallinity and is less resistant to hydrolysis, making the degradation process lengthier. Due to the high biocompatibility, it is used in areas like mid-face and mandible [18].

Copolymers of PGA, PLLA, and PDLA

Copolymers of PGA, PLLA, and PDLA were desired over pure PGA and PLLA as "the second generation" as quickly bioresorbable osteosynthetic materials (Figure 2). Their properties can be regulated by changing the proportion of glycolide to lactide for various compositions. The speed of hydration and hydrolysis can rise when crystalline PGA is co-polymerized with PLLA [18] The ratio of the monomers used during synthesis determines the degradation time of the copolymer. In general, the more the glycolide content, the faster is the rate of degradation [10,18].

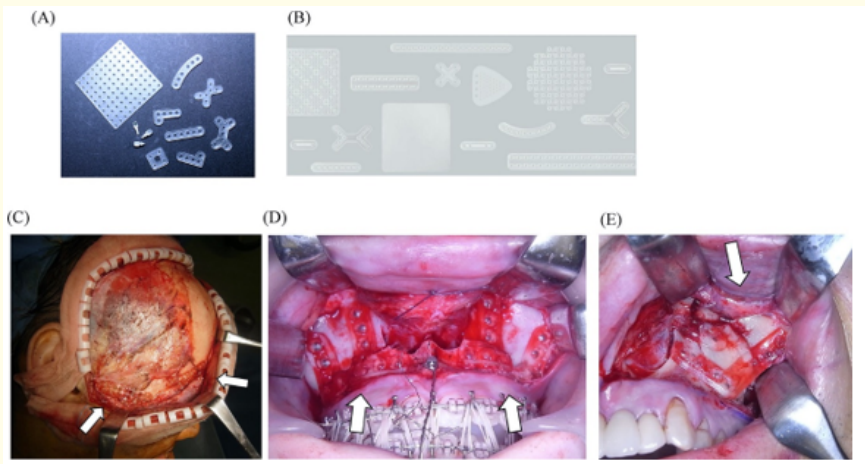

Figure 2: *Second-generation rapidly bioresorbable materials being used in maxillofacial osteosynthesis. (A) The LactoSorb® system. (B) The RapidSorb® system. (C) 3-D bioresorbable plate osteosynthesis of Le Fort II/III mid-face fractures using the LactoSorb® system. (D) Double-L-shape bioresorbable plate osteosynthesis (LactoSorb®) for the internal fixation of Le Fort I advancement. (E) Bioresorbable plate osteosynthesis (RapidSorb®) for the internal fixation of a complex left zygomatico-maxillary fracture [10,18].*

Copolymers of L-,D-lactides, such as SR-P(L/DL)LA 70/30, a copolymer comprised of 70% PLLA and 30% PDLA, consume all their strength *in vitro* after 48 weeks of implantation. Lactosorb® (Biomet Inc., Jacksonville, Florida, USA) is a copolymer of PLLA (82%) and PGA (18%). RapidSorb® (DePuy Synthes CMF, West Chester, PA, USA) is comprised of the same polymers in almost the same proportion of 85:15. Both Lactosorb® and RapidSorb® are only suited for mid-face and maxillary osteosynthesis. These copolymers are made in such a way that they provide sufficient strength for at least 6 - 8 weeks and get completely resorbed in the next 12-18 months [10,18].

u-HA/PLLA bioactive/resorbable material

Recently, hydroxyapatite was mixed into PLLA because of its well-known osteoconductive capacity. SuperFIXORB-MX® (TEIJIN Medical Corp., Osaka, Japan) (also known as OSTEOTRANS MX® overseas) plates are composed of a combination of unsintered hydroxyapatite (u-HA) and carbonate ions combined with PLLA [9,21].

Composites of unsintered hydroxyapatite/poly-L-lactide (u- HA/PLLA) are the "third-generation" bioactive/bioresorbable osteosynthetic material. As the u-HA/PLLA nano-composites are osteoconductive and biodegradable, they can be used for total replacement by bony parenchyma. The hydrolysis and biodegradation of the PLLA by body fluids begin soon after implantation. As a result, the molecular weight of PLLA declines, and the u-HA fraction grows for about 2 years. After around 4 years, PLLA matrix is completely absent, and most of the u-HA particles are replaced by bone after 5.5 years [22,23].

As compared to the 1st and 2nd generation of bioresorbable polymers, u- HA/PLLA osteoconductive composites retain the bony segments with more stability during maxillofacial surgery. These composite polymers are accepted for osteosynthetic facial surgeries of the mid-face and mandible. One of the disadvantages of u- HA/PLLA is a pain to touch in fragile facial skin areas such as the periorbital region [22,23].

Bone-like regenerative tissue was seen on the bone-facing surface of the extracted plates and screws. This implied that the plates directly adhered to bone and encouraged the osteoconductivity of the u-HA/PLLA plate system to quicken bony healing in maxillofacial boney segments. Therefore, as u-HA/PLLA composite demonstrates bioactive, osteoconductive, and biodegradable properties, and it may prove to be the next-generation material in oral and maxillofacial surgeries [22,23].

Clinical significance

The bioresorbable osteosynthetic implants are mainly used to reduce bone fragments in fractures, osteotomies, and bone grafts. The most preferred location for the use of these bio-resorbable plates is in the mid-facial region as there is relatively less biomechanical stress in this area and ease of access to this location during surgery [4,8-11].

Earlier studies have shown that stability in the mid-facial fracture sites can be achieved with acceptable results when u-hydroxyapatite/poly-(L-lactic) acid (u-HA/PLLA) and poly- L-lactic acid (PLLA) plates are used (similar to titanium plates) [9-11,21]. Bos., *et al.* in 1987 showed the prospect of using biodegradable plates and screws in cases of zygomatic fractures. This technique was soon used for other maxillo-facial surgeries like 3-D reconstruction of traumatic orbital fractures [20,21].

Park., *et al*. suggested that the site of fracture and presence or absence of infection should determine the selection of resorbable plates and screws. The biodegradable plates should be used in cases of minimally loaded maxillofacial fracture cases [24].

A meta-analysis of five trials of the maxillofacial fracture fixation operation demonstrated that the bioresorbable group had a substantially lower rate of adverse effects when compared with the titanium group. [10,11] Palpability was more often reported in patients with titanium plates than patients who received a resorbable fixation. Moreover, the resorbable group did not significantly increase infection, paraesthesia, foreign-body reactions, dehiscence, malocclusion, material-related complications, exposure, or mobility [10,11,25].

Conclusion

The bioresorbable fixation system has undergone significant advancement. These advancements helped patients and oral and maxillofacial surgeons and offered substantial improvements over traditional titanium metal plate systems. This review study briefly discussed the currently available bioresorbable osteosynthesis materials and osteofixation systems.

Even though the bioresorbable osteosynthetic materials have certain drawbacks that need to be resolved, they are still feasible compared to the traditional titanium plate system. A bioresorbable system ensures predictable postoperative stable fixation for bony healing without complications and ideal remodeling. It also provides skeletal stability similar to conventional titanium devices for specific limited applications.

We still need further studies regarding improving these bioresorbable osteosynthetic materials in terms of foreign body reactions, mechanical strength, and bioresorption time.

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