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Biodegradable fixation for craniomaxillofacial surgery: a 10-year experience involving 761 operations and 745 patients

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Abstract. Patient acceptance, safety, and efficacy of poly-L/DL-lactic acid (PLLDL) bone plates and screws in craniomaxillofacial surgery are reported in this article. Included in the sample are 745 patients who underwent 761 separate operations, including more than 1400 surgical procedures (orthognathic surgery (685), bone graft reconstruction (37), trauma (191) and transcranial surgery (20)). The success (no breakage or inflammation requiring additional operating room treatment) was 94%. Failure occurred because of breakage (14) or exuberant inflammation (31). All breakage occurred at mandibular sites and the majority of inflammatory failure occurred in the maxilla or orbit (29), with only two in the mandible. Failures were evenly distributed between the two major vendors. PLLDL 70/30 bone plates and screws may be used successfully in a variety of craniomaxillofacial surgical applications. The advantages include the gradual transference of physiological forces to the healing bone, the reduced need for a second operation to remove the material and its potential to serve as a vehicle to deliver bone-healing proteins to fracture/osteotomy sites. Bone healing was noted at all sites, even where exuberant inflammation required a second surgical intervention.

Key words: biodegradable fixation; craniomaxillofacial surgery.

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The quest to develop ideal skeletal fixation methods for the craniomaxillofacial region continues. LUHR[16], MICHELET et al.[17], CHAMPY et al.[5] and others revolutionized the conduct of facial skeletal surgery with the introduction of bone plates and screws designed for the facial skeleton. The functional demands of the craniofacial region (forehead, calvaria) are much less than the maxillofacial region (maxilla, mandible, orbits) where the heavy forces of mastication are applied and dispersed superiorly and inferiorly. The required strength of plates and screws differs depending on the functional demands of the bones to be stabilized.

Initially, bone plates and screws were manufactured from a variety of metals, including stainless steel, vitallium, chromium–cobalt, and other metal alloys. BRANEMARK and TOLMAN's favourable experience with titanium led to the development of titanium bone plates and screws for use in the craniomaxillofacial region of infants, children and adults[3]. Possible interference with facial growth, the difficulty in removing the material with subsequent surgery, interference with imaging, generalized health safety, and

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concerns about bone healing and maturation encouraged the development of more biologically and physiologically compatible materials[2,25,27,30].

Although polylactate polymers for stabilisation in human surgery were introduced more than 40 years ago, their usefulness has only been appreciated recently[7,11,24]. The major concerns for use in the maxillofacial region are the strength of the material and its ability to withstand masticatory forces, and the extent of inflammation as the material begins to degrade. Inflammation is necessary for biodegradation, but the materials must be refined so that intense inflammation is not incited during the degradation progress. When intense inflammation develops, symptoms such as swelling, erythema, sterile abscess, drainage and secondary infection may occur.

The ideal fixation system for stabilisation of an osteotomy or bone fracture would provide adequate strength initially to permit bone healing during function, and then decrease in strength so that there was increasing physiological force transference to the bone. Biodegradable polymers can provide that; metals cannot.

In 1998, the senior author, whilst visiting Professors Christian Lindquist and Rita Suuronen at the University of Helsinki, observed multiple patients who underwent sagittal osteotomies of the mandible in which the segments were stabilized with polylactate screws. Returning from this trip, the author felt that biodegradable technology deserved a place in elective facial skeletal surgery, especially orthognathic and craniofacial applications. Identifying vendors whose products had adequate strength, biodegradation characteristics, and United States Food and Drug Administration (US FDA) clearance proved to be a formidable, but not an insurmountable task.

Not all polymers are similar and they vary in strength and degradation characteristics, depending on the exact content, the manufacturing and sterilisation processes. Polylactate is the major ingredient of most biodegradables used in the maxillofacial region. When the D and L isomers of polylactate are combined in a 70/30 ratio and the manufacturing process is controlled properly, adequate strength for use in the maxillofacial skeleton is achievable[24]. Initially, a single vendor (Bionx, LTD, Con Med Linvotech, Key Largo, FL, USA) was identified, whose extruded poly-L/DL-lactic-acid 70/30 (PLLDL) material met the criteria for use in the entire maxillofacial region. The senior author used this material from March 1999 until the vendor withdrew from the North American market in 2002. At that time another vendor (Inion Corp., Tampere, Finland) offered a heat-formed PLLDL70/30 polymer, the characteristics of which were similar, although it was not as strong. The dimensions of the plates and screws were increased, and this material was used subsequently. Both of these products were eventually approved for use in the entire craniomaxillofacial region by the US FDA.

The purpose of this study is to report on patient acceptability, the safety and efficacy of using PLLDL bone plates and screws for craniomaxillofacial surgical applications. It reviews the experience of a single surgeon working in a single institution placing the material in the craniomaxillofacial region. It does not include cranial remodelling surgery performed in infants or children, in which other polymers that degrade more quickly and have other characteristics more suitable to infants and children are used. It does not include the experience of other surgeons working in the same institution using this material, nor does it include the author's experience outside of the single hospital setting. The exact material studied is PLLDL 70/30. Comparison of failures by vendors, sites of failure, and surgical category are reported, as well as the author's experience with the vendors and their representatives.

Materials and methods

All patients who underwent placement of PLLDL bone plates and screws in the craniomaxillofacial region by the senior author are included in this investigation. Initially, all orthognathic and craniofacial surgery patients were offered its use indiscriminately. During the past 4 years, patients $>$ 200 lbs (about 90 kg) and those with questionable ability to comply with a soft diet, have been cautioned that their chewing strength may exceed the strength of the material before being allowed to choose between metallic systems or biodegradable systems. The experience includes its use in selected trauma patients, who were offered the material based on their injury and the surgeon's perception of their ability to comply with postoperative instructions. The majority of trauma patients treated by the senior author were not offered a choice of material. Bone graft reconstruction and predental implant bone graft patients were offered the use of this material only if was clear that breakage was unlikely and the patient would be cooperative.

The demographic characteristics of the sample and the numbers of patients with specific surgical procedures are shown in Table 1. 745 patients were included in the study. They were involved in 761 separate operating room experiences and more than 1400 procedures. Fifteen patients underwent one additional surgery utilising the same material. One patient underwent three operations utilising the same material. There were 685 instances of orthognathic surgery (90%), 37 reconstructive procedures (5%), 19 patients underwent repair of facial fractures (3%), and 20 underwent transcranial surgery (3%).

The product was used exactly as metallic systems are used, without adding plates and screws to any particular osteotomy or

Table 1. Patient demographics.

	Gender		Race				
	Women	Men	Caucasian	African-American	Hispanic	Asian	Native American
$N = 745$	457 (61%)	288 (39%)	665 (88%)	59 (7.9%)	11 (1.5%)	10 (1.3%)	10 (1.3%)
Age (years)			Mean		Range		Median
			21.95 ± 10.9		1–76*		18
Type of surgery			Orthognathic	Reconstructive	Trauma		Transcranial
			685 (90%)	37 (5%)	19 (2.5%)		20 (2.5%)

* Ages have been rounded to the closest year.

situation. In general, for Le Fort I osteotomies four plates were used for stabilisation (two at the nasal region and two at the zygomaticomaxillary buttress). For sagittal osteotomies, four bicortical screws were placed transorally in a diagonal pattern as previously reported[28]. For genioplasty, three screws were used to secure the segment.

For bone graft stabilisation, generally a single screw was used depending on the size and location of the graft. For larger defects, bone plates and screws were used for stabilisation. Fracture sites were typically secured with a single plate. Just as with titanium systems, exceptional circumstances may require additional screws or plating configuration. Although each vendor has equipment for transbuccal placement, transoral placement without skin incisions was used exclusively when transoral surgery was performed.

Bone plates used to stabilize maxillary osteotomies were from the 2.0 mm system. In the mandible 2.7 mm screws were used at sagittal osteotomy sites and at genioplasty sites when heat-molded material was used. When self-reinforced (extruded) screws were placed at sagittal osteotomy sites or genioplasty sites, they were 2 mm in diameter. When body or symphyseal osteotomies were stabilized, the 2.0 mm plates were used with the extruded system and 2.4 mm bone plates and screws were used with the heat-molded system.

In this investigation, success was defined as evidence of healing in the desired position without the need for additional operating room surgery. Failure is defined as material breakage or an acute inflammatory response during the biodegradation phase, to the extent that another operating room procedure was necessary for restabilisation or for debridement. Low grade, well-controlled degradation with a draining intraoral fistula which was self-limiting and did not require an operating room procedure was not considered failure.

Results

Initially, all patients were informed of the author's minimal experience with the material and that the material was not US FDA approval. Surprisingly, 337 of the first 344 patients offered the use of this material accepted (98%), which demonstrated that the biodegradable material appealed to patients.

Table 2 lists the operations performed in this series. Although 90% of the patients had orthognathic surgery, most patients underwent multiple procedures at the same setting and many of these procedures were highly complex, involving simultaneous mobilisation of both jaws. The sample includes patients with craniofacial clefts and at least 10 syndromes, including Crouzon, Apert, cleft lip and palate, craniofacial microsomia, craniofrontonasal dysplasia, Down, Tourette, Binder.

Table 2. Types of surgery.

Osteotomies	
Le Fort I	314
Le Fort I segmental	139
Le Fort III	13
Transcranial osteotomies	20
Bilateral sagittal osteotomies of the mandible	553
Genioplasty	218
Inverted L osteotomies	37
Condylectomy with immediate reconstruction	26
Total mandibular subapical	10
Anterior mandibular subapical	6
Reconstruction	
Bone graft stabilisation	86
Trauma	
Mandibular fracture	7
Midface fracture	8
Forehead fracture	4

Table 3. Usage and results by vendor.

			Failure		
	Operations	Success	Breakage	Inflammation	Total
Inion	575 (75%)	541 (94%)	11 (2%)	23 (5.9%)	34
Bionx	179 (24%)	169 (94%)	2 (1.1%)	8 (4.5%)	10 (5.9%)
Macropore	7 (1%)	6 (86%)	1 (14.2%)	0 (0%)	1 (14.2%)
Overall		716 (94%)	14 (2.0%)	31 (4.0%)	45 (6.0%)

Table 3 summarizes the usage and results by vendors. Note that Inion was used in 75% of the patients and Bionx in 24%. Overall, the success rate was 94%. The success of the sample was 716 instances (94%), and a failure of 45 instances (6%). Of the 45 failures, 14 (31%) were attributable to breakage of the material and 31 (69%) were due to inflammation. The breakage rate for Inion was 2%, and the inflammation rate was 4%. For Bionx it was 1% breakage and 5% inflammation. In all 14 patients with breakage failure, the site of breakage was the mandible. In the 27 patients with inflammation failure, the maxilla was the region involved in 23 (87%). In two the mandible was involved with an inflammatory problem (7%). In the other two inflammation failures (7%), the orbit was the site of inflammation (Table 4).

Discussion

The population in this series reflects the gender, race, age, and surgical category distributions typical of the author's practice. Most are young Caucasian women undergoing elective facial osteotomies. The older patients tend to be bone graft candidates for pre-implant purposes. The

Table 4. Failure by site.

	Breakage (14)	Inflammation (31)
Maxilla	0	27 (87%)
Mandible	14(100%)	
Ramus	12	2 (6.5%)
Chin	3	
Body	0	
Orbit		2 (6.5%)

transcranial procedures (all involving neurosurgical expertise) performed are consistent with the author's practice and included cranial remodelling procedures for craniosynostosis, cranial vault reconstruction after full thickness cranial bone graft harvest, monobloc and bipartite osteotomies, and correction of orbital hypertelorism. The paucity of trauma patients reflects the unavailability of appropriate operating room personnel and vendor representatives, rather than a reluctance to use the material for this patient population. The author operates on most trauma patients during nonelective hours when dedicated staff is not available. The polylactate systems are complicated and require trained personnel who are attentive to detail and have adequate dexterity to load screws, taps and drills. The successful use of this material in trauma patients has been reported by others[15].

There is a learning curve with the use of polylactate systems, and part of the curve is patient selection. At first, all patients were offered the use of the material indiscriminately, but because of breakage in larger patients and those unable to comply with postoperative eating and movement limitations, the author began discouraging use in these groups 4 years ago. Since then there has been no instance of breakage. The failure rate may reduce further with more careful patient selection.

Two of the three vendors were very open and facilitative, knowing that the products were new and that many of the logistics had to be sorted out (Bionx and Inion). They also had on-site representatives to assist the operating room staff. After a brief trial involving seven patients (who are included in the sample), one vendor (Macropore, Medtronic Sofamor, Danek, San Diego, CA, USA) was discontinued because of the corporate response when a problem occurred in a single patient.

The single vendor who manufactures self-reinforced polymer by extrusion (Bionx) has withdrawn distribution of its craniofacial products in North America for reasons unknown to the author, although they are unrelated to safety. The craniofacial material remains available in Europe, but the vendor has not improved its technology and instrumentation related to placement, delivery, packaging and handling. At least one other vendor (Inion) has invested heavily in improving instrumentation, packaging and sterilisation and distributes to North America.

When new technology is brought to market, its safety and efficacy must be proved by multiple sources to make it attractive for use. This series of patients (745) undergoing a variety of craniomaxillofacial procedures (>1400) over a 10-year period suggests that PLLDL has a definite place for many surgical applications. The failure rate of 6% is within the same range of experience as titanium when applied the same way. Although the failure rate for titanium has been studied extensively in fracture patients, the failure rate in elective circumstances, especially orthognathic and craniofacial surgery, has been surveyed less[4,18–20,22]. The report by SCHMIDT indicates the need for removal of titanium plates and screws in orthognathic surgery is 10%[23]. The use of PLLDL has a failure rate of 6%. The failures of this study population (6%) compare favourably with the failure rates for titanium systems.

In 14 instances of failure, the problem was breakage of the screws and/or breakage of the bone around the screws. All of the breakages occurred in the mandible, primarily at sagittal osteotomy sites. The muscle activity in the mandibular ramus is considerable, and if patients are not cautious with chewing, problems can occur as masticatory force exceeds the strength of the screws and/or bone. In three instances, the breakage occurred at genioplasty sites where the suprahyoid muscle activity was influential. In two of the patients, inability to cooperate with postoperative instructions contributed to the breakage (one had Down syndrome and the other Tourette syndrome). The third patient was a muscular male exceeding 200 lbs (90 kg). When breakage of this material occurred, it happened within the first 3 weeks following surgery. Early detection requires careful clinical vigilance of the occlusion, mandibular symmetry, and symptoms. The breakage rate between the two major (1% and 2%) vendors was similar.

Inflammation requiring removal occurred in 31 instances (4%) of 761 operations. Inflammation was not observed when patients used the material on more than one occasion. This suggests that multiple usages do not increase sensitivity to the material. When inflammation was noted, it almost always occurred in the maxilla and/or orbit (94%), and rarely in the mandible. Since the material was only used on three occasions in the orbit, this represents 67% failure at this site. The bulk of the material and the limited perfusion of the tissue of the floor of the orbit are likely explanations of this observation. These experiences, although limited, discourage the author from further using this material in orbital floor defects.

Inflammation depends on the patient's immune response, the amount of material used, the thickness and perfusion of tissues in which the material is implanted, and its sterility. Bone plates are bulky, and the mucosa overlying the maxilla is thin. Bone screws alone are less bulky and when placed at sagittal osteotomy sites are covered by the well-perfused masseter and oral mucosa. The greater amount of material used in the maxilla and the thinness of the overlying mucosa are likely explanations for the maxilla being the most frequent site of inflammation.

When an exuberant inflammatory response was noted, it occurred 4–20 months post surgery. Most patients who demonstrated this reaction did so between months 12 and 15. The rate of failure because of inflammation by vendor was minimally different, even though the plates and screw sizes were different between the systems.

The author observed complete bone healing when he operated on the 31 patients who required removal of the biodegradables in spite of an exuberant inflammatory response. The author uses autogenous bone grafts liberally at osteotomy sites and, even when exuberant inflammation was present requiring reoperation, bone healing exceeded that observed with titanium systems. The complete healing observed may be attributable to the enhanced tissue perfusion secondary to low-grade inflammation, which is necessary for biodegradation to occur. It is not surprising that 40 of the 43 failures occurred in the orthognathic surgery patients, especially considering the distribution of surgery in the sample (Table 5). Of these failures in the trauma category, two occurred because of inflammation occurring in the orbit after use of PLLDL mesh. The other occurred in a brittle diabetic who underwent open reduction of a mandibular symphysis fracture.

There is mounting evidence that titanium is not as innocuous as once thought[1,12,18–21,2]. The author has treated several patients who developed problems (pain, infection, thermal sensitivity, and

Table 5. Failure by type of surgery.

Orthognathic	Reconstructive	Trauma	Transcranial
40	0	3	0

palpability) more than 20 years after placement of titanium bone plates and screws, requiring removal. This indicates that the complication rate of titanium requiring removal increases the longer that patients are followed. In comparison, no patient developed problems with PLLDL 70/30 hardware requiring removal after 20 months. There are parts of the world where titanium hardware is routinely removed after healing, requiring a second operation. The advantage of using PLLDL in these settings is the reduced need for the second operation.

To place polylactate screws requires drilling, tapping, and screw insertion. The plates are bent just as titanium plates are; however, the heat-molded plates cannot be cold bent, they require heating in a bath. One vendor (Inion) has incorporated trimethylcarbonate to increase the working time for bending to about 15 min.

When initially used, tapping and screw insertion were done by hand. Now, battery-powered equipment is available to improve operating time, reduce hand fatigue and the potential for repetitive motion injury, and to improve tapping and screw insertion accuracy. Tapping is the purest form of passive fixation since there is no self-threading required, as with most titanium systems. Self-tapping titanium systems force the screws to thread the bone during insertion. Theoretically, the advantages of pre-tapping, especially when fixing sagittal osteotomies is the passiveness of the fixation and the concerns of condylar displacement during screw insertion.

Minor mobility with the use of the polylactate systems in the maxilla is expected and is much more frequent than with the use of more rigid titanium systems. It is the author's contention that this movement facilitates elastic dental traction to detail occlusion easily during the early postoperative period. This is unlike less forgiving titanium, which is too rigid and does not easily allow movement of segments.

This report does not study stability or outcome assessment. As previously reported, there is no difference in stability of mandibular advancement when the sagittal osteotomies are stabilized with titanium or polylactate screws[26]. Other groups have reported similar findings with maxillary osteotomies and bimaxillary osteotomies[6,8–10,13,14]. Although stability of maxillary osteotomy or bimaxillary osteotomies stabilized with PLLDL plates and screws has not yet been reported by the authors, there appears to be no difference.

This study indicates that PLLDL can be used safely and successfully (94%) for craniomaxillofacial surgical applications, especially maxillary and mandibular osteotomy stabilisation. The author has used it extensively and successfully for all types of osteotomies and in bone graft reconstruction of the face and cranium. Experience with facial bone fractures is limited, but in select cases it can be used successfully. The systems require tapping, and this adds time to the operation. Additionally, the systems are awkward and more technically challenging. Patient appeal is very high (98%), and after 20 months there is no need for another operation to remove the material. The failure differences amongst vendors are similar, and the need for second operations to remove or replace this material is 6%.

The future of this technology lies in the hands of the manufacturers. They must make the systems for placement and handling easier and they must price the material so that it is competitive with alternative systems.

The greatest benefit of using PLLDL is its ability to permit healing to occur and to allow gradual transference of physiological force to bone over time. Whilst this is occurring, the material degrades and is eliminated from the body via the Krebb cycle as water and CO_2. A potential benefit of using biodegradable materials is the ability to serve as vehicles for the delivery of bone-healing proteins, which enhance the healing response. Although this seems futuristic, it has already been successfully used in this manner[29].

Addendum

Since completion of this report, the author has discontinued the use of biodegradable fixation since the vendors are unable to provide on-site representatives available to assist operating room personnel during placement. This discontinuation represents lack of corporate support and not dissatisfaction with the material.

Competing interests

None declared.

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Ethical approval

Not required.

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