Rigid versus Resorbable Plate Fixation in Fronto-Orbital Advancement in Unicoronal Stenosis - A Retrospective Study

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Abstract

Introduction: Rigid plating fixation (RPF) and resorbable plating systems (RPS) advanced the field of reconstruction in craniomaxillofacial region. However, their performance in patients, particularly the effect on bone remodeling at site of hardware placement is not much documented. This manuscript aims to compare the performance of RPF and RPS in a cohort using a retrospective audit of case records. **Methods:** Archival records were searched for patients who had undergone cranial metal-RPF or RPS or combination for the correction of craniofacial deformities following inclusion-exclusion criteria. From records, data of the quality and quantity of bone formed along the site of plate fixation as compared with the adjacent site, accommodating or facilitating brain growth, and persistence of bone deformity at the site of hardware placement were collected at the end of the follow-up period. A total of 128 sites from 18 individuals (6 with exclusive metal-RPF and 12 with RPS) mean age of 7.45 ± 7.28 (Median 4; IQR of 8.88;2.6–11.5) who underwent cranial bone remodeling surgery formed the study group. **Results:** There was a statistically significant difference between the RPF and PRS system at the fronto-orbital suture ($P = 0.002$) and coronal suture ($P = 0.036$) with bone quality and quantity. **Discussion:** The RPF system was rigid but had a set of issues, while RPS has advantages and limitations. The qualitative difference in between the two systems is different. Due to inherent dissimilarity, the two systems cannot be interchanged and due diligence has to be exercised while deciding on the system. More prospective studies are needed to validate the findings.

Keywords: Fronto-zygomatic sutures, resorbable plates, rigid plating fixation, sonic welding, supraorbital osteotomy

Introduction

The evolution of rigid plating fixation (RPF) has happened over the years and much in the past five decades. This facilitated advances in surgical correction of paediatric craniomaxillofacial trauma and anomalies. It permitted direct bone healing, allows improved stability at fixed sites, decreased the risk of infection, and had a shorter recuperating time. Furthermore, the ease, less technique sensitivity, and aesthetic appearance than cumbersome external devices made it a popular treatment option. With the passage of time, there were reports of human and animal studies in which the plating systems were shown to significantly impact growth alterations in the cranial and midfacial regions.[1] These observations were clouded by the fact that similar disruption of bony and soft tissue elements also occurred without the application of such a system.[2] They strengthened the view that bony trauma, soft-tissue trauma, and the plating system act as independent factors to produce differential growth alterations as well as bone remodeling in the craniofacial region.[1] Conventionally, RPF is shunned in areas of highly active bone remodeling areas and/or growth, like in cranial crown, and often limited to frontal-zygomatic sutures. In craniofacial corrective surgeries, RPF was favoured in areas such as upper orbital osteotomy and rarely in coronal suture areas.[3-5]

The introduction of resorbable plating system (RPS) created a separate treatment niche in RPF. They were very useful in children as the bones were still soft and best suited to

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less-rigid material, such RPS was made of macromolecular polymers infused with polylactic acid. These molecules use a noninflammatory pathway for dissolution, ranging from 12 to 36 months while only active 3 months of fixation suffice to keep bone segments fixed owing to these dissolving capabilities, growth especially in children, usually is not hindered.[6]

There is a major lacuna in literature in terms of comparison of the performance of the metal-RPF and RPS in the cranium.[7-9] There are few reports from animal studies and systematic reviews although with inconclusive evidence. The aim of this manuscript is to compare the performance of RPF and RPS in this part of the world using a retrospective audit of case records [Figures 1 and 2].

Materials and Methods

Clinical records of the author's hospital patients who underwent cranial metal-RPF or RPS or combination for correction of craniofacial deformities (as fronto-orbital advancement) in the time frame of January 1995 to December 2018 (24 years) were collated. A total of 128 sites from 18 individuals (6 with exclusive metal-RPF and 12 with RPS; in all cases that required plating of fronto-zygomatic sutural area only metal-RPF was used) between the age of 6 months and 28 years, with a mean ± standard deviation age of 7.45 ± 7.28 (Median 4; IQR of 8.88; 2.6–11.5) underwent cranial bone remodeling with cranial metal-RPF or RPS or combination were identified. The patients with exclusively metal-RPF were ≥18 years and were performed before the year 2005, while the RPS was in children. From this cohort, details, and follow-up of healing along screw placement along the coronal, fronto-zygomatic suture, or upper orbital osteotomy were identified. Informed consent for the surgical procedure and the subsequent clinical investigation was earlier obtained from the primary caregiver of each patient during the procedure. Only records that had complete details were compiled and used for the study. As this study involved only a retrospective review of medical charts and data collection from archival hospital records with no personal data and identifiers being used for the study, the study was not subjected to IRB procedures.

The most common deformities were with 15-bilateral coronal suture fusion and 3-unilateral coronal sutural abnormalities. As the study was retrospective research, ethical committee clearance was not required. In all the cases, only the plates at the fronto-zygomatic suture, coronal suture, and/or upper orbital osteotomy site were considered for this study. Irrespective of the number of screws used, only the site for the purpose of this study, it is defined as a place where a single plate is used to fix bone.

For purpose of collection of data, the patient's case records were reviewed. Only cases that had postoperative follow-up for at least 18 months were included in the study. Some of the patients were treated elsewhere and followed at the center, owing to several reasons. The parameters collected were the quality and quantity of bone formed along the site of plate fixation as compared with the adjacent site (adequate/inadequate), accommodating or facilitating brain growth (adequate if the created area is filled by brain tissue and inadequate, if not) and persistence or absence of bone deformity at the site of plate placement. Only the bone quality and quantity were applicable to the plate-screw system at the fronto-zygomatic area.

Both the authors reviewed the preoperative, immediate postoperative, and follow-up (≤15 months postsurgery) images for the outcome measures and together marked the outcome.

In the RPS, the SonicWeld Rx plating system of KLS Martin was used. The screws were placed into predrilled, tapped holes, and later sonic welded.

Statistics

All data were entered and analysed using Statistical Package for Social Service (SPSS V 24, IBM, IL, USA). Descriptive statistics and Chi-square tests were appropriately employed. $P \leq 0.05$ was taken as statistically significant.

Results

The sample characteristics have been previously described. In all, in the study, there were 64 RPS plates (49.6%) and 65 (50.4%) metal-RPF plates in the three sutural areas. In the fronto-orbital area, there were 22 RPS and 11 metal-RPF used, while in the coronal, there were 43 RPS and 21 metal-RPF plates used. The entire fronto-zygomatic area was secured by rigid metal-RPF plates. The cohort had no major complications such as critical-sized wound dehiscence, chronic suppuration, nerve damage, and residual neurological disturbances. In addition, the perusal of notes revealed that the RPF evoked an initial strong reaction that manifested as huge periorbital swelling and ecchymosis in the initial three postoperative days to the extent of obscuring vision. This at the end of 72 h reduced considerably with appropriate medications. This was an anticipated reaction due to excessive tissue manipulation.

It was observed that 45.5% of the metal-RPF system used along the fronto-orbital suture had inadequate bone while the RPS had good bone quality at the end of the study period with statistical significance ($P = 0.002$) while the associated bone growth, although comparatively inadequate, there was no statistical significance ($P = 0.104$) [Table 1].

At the coronal suture level, 23.8% of metal-RPF cases and 4.8% of RPS had inadequate bone at the end of the follow-up period. This was statistically significant ($P = 0.036$) while there was some trend of residual brain deformity and persistence of deformity, they were not statistically significant [Table 2].

Discussion

The evolution of plating systems for the fixation of the craniofacial skeleton was an important progressive step in the advancement of the field of corrective craniofacial surgery, especially in the paediatric age group. It has evolved from rigid

Table 1: Outcome parameters at the level of the fronto-orbital suture between the 2 plating systems

	Resorbable plating system	Rigid metal plating system	*P*
Bone quality and quantity			
Adequate	22 (100)	6 (54.5)	0.002
Inadequate	0	5 (45.5)	
Brain growth/ residual deformity			
Adequate	22 (100)	9 (81.8)	0.104
Inadequate	0	2 (18.2)	
Persistence of deformity			
Residual deformity			Not computable
No deformity	22 (100)	11 (100)	

Table 2: Outcome parameters at the level of the coronal suture between the 2 plating systems

	Resorbable plating system	Rigid metal plating system	*P*
Bone quality and quantity			
Adequate	40 (95.2)	16 (76.2)	0.036
Inadequate	2 (4.8)	5 (23.8)	
Brain growth/residual deformity			
Adequate	41 (97.6)	19 (90.5)	0.256
Inadequate	1 (2.4)	2 (9.5)	
Persistence of deformity			
Residual deformity	0	2 (9.5)	0.108
No deformity	42 (100)	19 (9.5)	

external frame fixation, external fixations, and internal fixation with stainless steel wires. This gave way to metallic plating systems. Initially, surgical-grade stainless steel was made from iron-chromium-nickel alloys, which later gave way to Vitallium and titanium. Later, it was observed that there was an erosion of the bone at sites of plates, the plates embedding into cranial outer table molds associated with the plates, deleterious stress shielding effect, and plate migration. The transcranial movement of the plates due to bone remodeling, in children, may reach dura, causing intimate contact with the brain. As there is always a heightened risk of infection or critical-sized wound dehiscence with any inserts, the risk of infection also persists. When positioned in crucial growth areas, especially in children, these metallic inserts pose a significant risk for affecting the continued growth of the cranial bone.[6]

In animal models including rabbits and lambs, placement of metallic screw-plates along sutures caused local growth restrictions. However, there was compensatory regional growth occurring in animal models. The occurrence and extent of this compensated growth alteration were dependent on the amount of hardware, location, and timing of the growth in children. In certain other studies, this growth alteration is triggered by the local bone hypertrophy caused by localised periosteal elevation by the hardware.[7-9] However, in certain newborn rabbits, it was identified that placing even resorbable hardware could cause local asymmetry during the growth phase, which later was reversible.[10] All these studies involved critical areas such as coronal, frontal, or sagittal sutures. There are very less human studies in this aspect. In our personal experience, placement of metallic rigid hardware along sutures, as was done in the distant past, even for a brief period, caused noticeable localised defects that were reversible. While the resorbable systems did not cause these brief spells of concern, the results of this study as reflected in the table add to strengths to our observations. The bone tissues are supposed to fill the newly created void. However, in a few cases in the metal-RPF system, there has been a void detected indicating that the brain has not filled the newly created space.

In the fronto-zygomatic area, there was a need for a stronger fixation system, as the force vectors are different and there is a need to hold the two vital bony segments in constant approximation. Hence, universally the metal-RPF is used. Furthermore, the RPS system, in tropical countries such as India, at the body and higher immediate temperature, may bend and yield which may contribute to the relapse. In other places such as the coronal and fronto-orbital region, the bony segments are held together till the continuity is established. Furthermore, the results show that with metal-RPF there is a small percentage of instances where there is the persistence of defect, reduced bone formation, and areas filled with brain tissue. Although such instances are miniscule, the chance of such a phenomenon should be considered by the operating surgeon. They should be forewarned of such a possibility while using metal-RPF in craniofacial reconstruction.

There are very limited studies that compare the efficacy of the RPS system as compared to the RPF, especially in noncritical areas. Hence this study was devised to address these lacunae using a retrospective approach to avoid bias or influencing a clinical decision. The study compared sites of RPS or RPF and studied the clinical course for a reasonably long period of 18 months. To the best of our knowledge, no study has been undertaken with this approach.

From the observation of records, qualitatively we observed minor plate movements. If it takes place, it happens after a period of time. The bone remodeling, especially growth vectors could push the metal plates inwards (towards dura in the coronal region) or outwards depending on the growth movements and site of placement. A recent large summative summary of several research manuscripts that compared the use of metallic titanium and resorbable plate-screw systems to fix fractures of the upper two-thirds of the developing facial skeleton concluded a lack of superior evidence. The work identified that the RPS systems lacked strength but had relatively less complication as compared with the RPF systems. The study also added that in situations adjacent to the sinus or those prone to contamination, RPS provided better outcomes. It also outlined the need for a

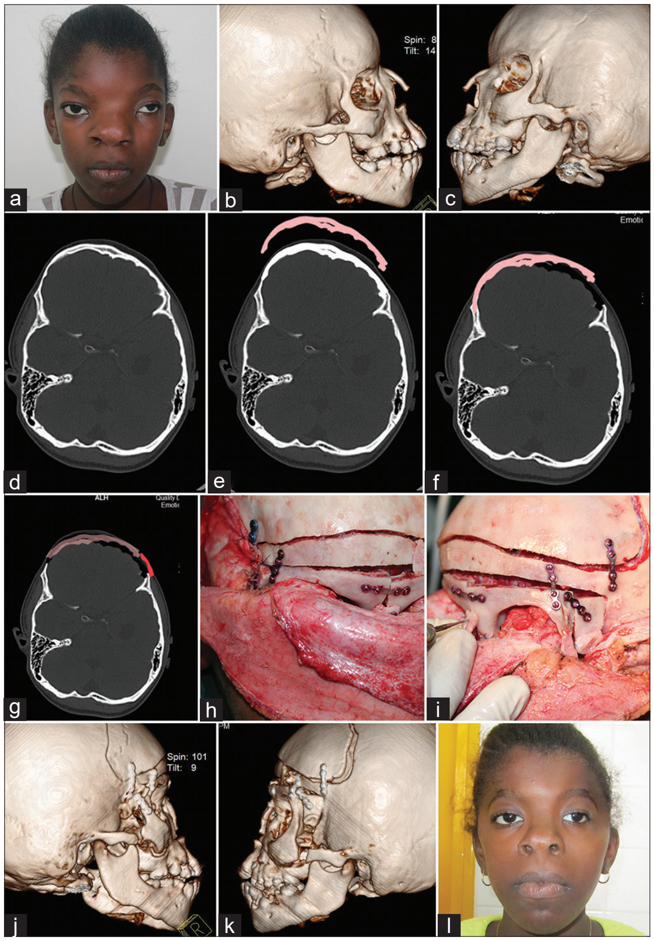

Figure 1: (a) Pre-operative view of a case of unicoronal synostosis with hypertelorism. (b) and (c) Preoperative 3D CT scan imaging. (d-g) The various sections show the images of the pre-operative planning for the calvarial segmental shift. (h-i) Intra-operative view showing rigid plate fixation (Titanium) at the frontozygomatic suture and at the upper orbital osteotomy site. (j-k) Postoperative 3DCT showing rigid plate fixation at the Frontozygomatic and supra-orbital area. (l) Postoperative view showing better aesthetic appearance

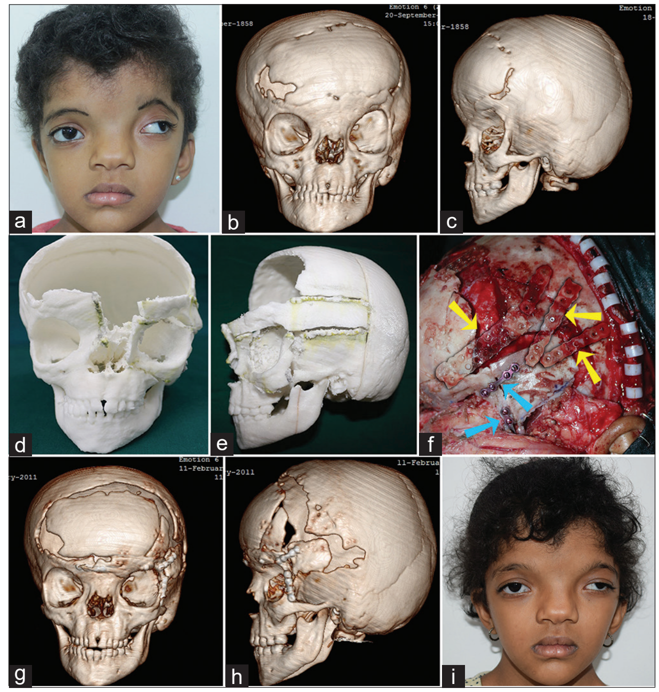

Figure 2: (a) Preoperative view of a case of Unicoronalstenosis. (b) and (c) Preoperative 3DCT scan showing synostosis at the coronal and sagittal suture. (d) and (e) 3D stereolithographic model for preoperative planning. (f) Intra operative picture shows RPF (blue arrow) at the Frontozygomatic region and RPS (Yellow arrow) at the fronto-orbital and coronal area. (g-h) Postoperative 3DCT scan showing plate fixation at the frontozygomatic and supraorbital region. (i) Postoperative view

sufficiently powered, prospective comparative study to perform a better assessment.[11,12] The same team of authors performed a systematic analysis of all published studies for paediatric mandibular fractures and identified that the material was not a major factor with regard to fractures pattern. They concluded that neither material removes the need for maxilla-mandibular fixation.[12] The comparison of growth of orbital bone rim after supraorbital osteotomy in children with craniosynostosis was performed using sutures (nonrigid fixation) and titanium or resorbable osteosynthesis plates revealed that the material had no major role to play in the outcome which resonates with our present study.[3] Similarly, comparison of titanium with resorbable plates showed a similar trend.[13] Animal studies have shown that in growing individuals, rigid fixation produces altered bone growth, especially when the plate screw is removed.[1] There are reports in the literature where in RPF systems are associated with leaching of metal ions in the plate-screw region, growth alteration due to rigid metallic hardware, corrosion, visibility, palpability, and cold sensitivity. However, the much-acclaimed impact on overall growth restriction is largely unproven.[1] Neurological issues emanating from hardware transmigrating to duramater causing headaches have been reported.[14] However, in our cohort, we did not encounter such incidences.

Literature indicates that there would be residual elements of RPS as long as about 9 months in the area of placement causing continuous low grade, beneficial healing reactions.[15] On the contrary, metallic-RPF systems have been shown to leach metallic particles including titanium on the longer run. This could have potential ramifications.[16] Hence the metallic hardware has substantial inherent risk. Additionally, a study has indicated that the RPS systems are relatively soft and flexible as compared to those of the metal-RPF system. With the help of the nanoindentation approach, they demonstrated that the metal-RPF and RPS cannot be used interchangeably.[17]

Limitations include a heterogeneous sample in terms of age, relatively short follow-up, and qualitative outcome rather than a quantitative approach. Future studies need to evolve parameters that are objectively measurable to lend more support to the findings.

Conclusion

A plating system is needed for rigid fixation. Though metallic plate-screw system provides much-needed rigidity, they fail in terms of the need to be removed, interfering with bone remodeling, migration, prone to infection, wound dehiscence, and healing. We compared the performance of the metallic and resorbable systems. The results show the relative, qualitative superiority of the resorbable system. It also removes the need for a second surgery to remove the plates. Large-scale studies would be needed to establish the role of the surgical margins, and pattern of placement of screws in influencing the clinical outcomes. Future prospective studies should include more parameters that can shed more light into the behavior of the metallic-resorbable plate-screw systems.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

Dr. SM Balaji is associated as the Editor-in-Chief of this journal and this manuscript was subject to this journal's standard review procedures, with this peer review handled independently of the Editor-in-Chief and their research group.

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