Original Article - Evaluative Study

Perspectives of patients about bioabsorbable internal fixation for maxillofacial fractures

Access this article online
Website: www.amsjournal.com
DOI: 10.4103/2231-0746.175769
Quick Response Code:

Constantin Landes, Sebastian H. Hoefer[1], Tereza Richards[2], Felix Walcher[3], Robert Sader[1]

Department of Cranio-Maxillofacial Surgery, Sana Hospital, Offenbach, [1]Department of Oral, Cranio-Maxillofacial and Facial Plastic Surgery, Goethe University Medical Centre, Frankfurt, Germany, [2]University of the West Indies, Mona, Kingston, Jamaica, [3]Department of Trauma Surgery, Medical Faculty University Hospital, Magdeburg, Germany

Address for corrrespondence:
Prof. Constantin Landes, Department of Cranio-Maxillofacial Surgery, Sana Hospital, Offenbach, Germany.
E-mail: constantinlandes@gmail.com

ABSTRACT

Purpose: Resorbable/bioabsorbable internal fixation provides effective treatment for maxillofacial fractures and avoids the need for metal hardware removal. We evaluated the initial knowledge, attitudes, subjective demand, and treatment satisfaction of patients concerning bioabsorbable osteofixation for maxillofacial trauma. **Materials and Methods:** From May 2007 to October 2009, there were 71 patients (63 males and 8 females; mean age: 35 ± 15 years) included in this prospective study. The patients completed preoperative and postoperative (4–6 weeks and 1 year) questionnaires. **Results:** After receiving information, 70 patients (99%) preferred resorbable/bioabsorbable bone fixation, usually because they preferred to avoid a second operation to remove metal hardware (67 patients [94%]). The higher cost of resorbable/bioabsorbable bone fixation was believed and justified by 41 patients (58%) and not justified by 30 patients (42%). No adverse events were reported by 27 of 34 patients (79%) at 4–6 weeks and by 14 of 21 patients (67%) at 1 year after surgery. Most patients were very satisfied with the outcome of surgery. **Conclusion:** Patients who have maxillofacial trauma have a high frequency of preference and high satisfaction with resorbable/bioabsorbable than metal osteofixation. Literature review showed increased activity in research and publication worldwide about resorbable bone fixation, suggesting that there may be increased patient demand for resorbable bone fixation in the future.

Keywords: Bioabsorbable, cost of care, craniofacial, osteoconductive, osteofixation, trauma

INTRODUCTION

Maxillofacial fractures are common injuries. Compared with the sequelae of trauma to the trunk and extremities, the face has a special importance for personal identity, self-perception, and communication. Therefore, patients perceive maxillofacial trauma and treatment with high attention and psychological distress.[1,2]

In the treatment of maxillofacial fractures, earlier resorbable, today bioabsorbable osteoconductive bone fixation systems are an alternative to metal internal fixation. Resorbable internal fixation avoids the disadvantages of metal internal fixation devices such as palpability, visibility, stress shielding, dysesthesia, temperature sensitivity, and interactions with diagnostic or therapeutic radiation. However, limited information is available about the patient's perspective about resorbable osteofixation systems for maxillofacial trauma and reconstructive surgery.[3,4] Literature

Cite this article as: Landes C, Hoefer SH, Richards T, Walcher F, Sader R. Perspectives of patients about bioabsorbable internal fixation for maxillofacial fractures. Ann Maxillofac Surg 2015;5:185-90.

search showed no studies evaluating the patient's perspective about resorbable fixation for the treatment of maxillofacial trauma. Furthermore, maxillofacial trauma patients may have social backgrounds that differ from with orthognathic surgery [Figures 1-3] because many trauma patients are injured because of assault, addictive behavior, sport, traffic accidents, and falls.[5]

The development of bioabsorbable osteofixation devices has focused on resorption after successful bone fixation and fracture union. In addition, resorption of internal fixation devices may occur with incremental load to the healing callus without foreign body reaction.[6-8] Bioabsorbable fixation devices have been made from composite materials that include noncalcined, unsintered hydroxyapatite (HA) particles that contain carbonate ions uniformly distributed in a poly-L-lactide (PLLA) matrix. The PLLA matrix may contain 20–50% (±10%) HA by weight, and the composite is reinforced by forging (compression molding). Raw blocks are machined to make internal fixation devices that have high mechanical strength, absorbability, bone bonding capacity, and osteoconductivity.[9-11]

The purpose of this study was to evaluate the initial knowledge and attitudes about bioabsorbable osteofixation in patients who had suffered from facial trauma. The evaluation included a subjective assessment of patients about adverse events and whether they expected to have adverse events after bioabsorbable osteofixation for treatment of maxillofacial fractures. In addition, a literature search was performed to assess international research activity about bioabsorbable osteofixation as a possible indication of increasing demand from the patients and the professional's side.

MATERIALS AND METHODS

Subjects

Patients who underwent surgical treatment of facial (midfacial or mandible) fractures in our department between May 2007 and October 2009 were prospectively enrolled in this study. Patients who had acute facial fractures of moderate severity and who were good candidates for safe treatment with bioabsorbable osteofixation were included in the study (71 patients; 63 males and 8 females; mean age, 35 ± 15 years; range, 16–78 years). Other patients were excluded for (1) unwillingness to participate in the evaluation; (2) Intensive Care Unit stay; (3) inability to provide consent because of sedation, dementia, or mental handicap, and (4) potential problems with compliance because of drug or alcohol addiction. No patients were excluded because of general disease or age. All included patients signed a separate informed consent form about the use of osteoconductive bioabsorbable fixation devices and anonymity of evaluation, information, and participation documents. The study was performed in accordance with the Declaration of Helsinki and was approved by our faculty's ethical board (No. 226/06).

Evaluation

The patients were evaluated with a questionnaire (nine questions) to determine their perceptions and experience with resorbable/bioabsorbable internal fixation [Table 1 and Figure 1]. After they received the first two questions of the questionnaire, they were given general information about the operation (surgical approach, risks, and different types of fixation systems).

Using titanium bone fixation devices, 18% patients have adverse events such as heat or cold irritability, inflammation, palpability, plate loosening or plate fracture, interference with diagnostic or therapeutic radiation, local growth hindrance, impossibility of later hardware removal, local and systemic accumulation of titanium debris in the body, and unknown long-term consequences. Frequency of hardware removal is 3–31% (in our patients, 23%).[12-16] In patients who had resorbable bone fixation previously, 6% patients had adverse events, usually foreign body granuloma (subacute inflammation with occasional fistula and drainage) that required curettage.[6,7]

Besides the above-mentioned information regarding the disadvantages of the various materials used, the patients were also presented with the advantages of the various plating systems, for example, the positive handling attributes of the titanium plates.

By presenting both the advantages and disadvantages, the patients were put in a situation where they received a proper informed consent and were able to voice a truly own and informed decision.

After they reviewed this information, they were asked for their preferred plating system. In the patient's informed consent for surgery, the general operative procedure was discussed. The patients were scheduled for surgery with either osteoconductive bioabsorbable osteofixation (Osteotrans Mx, Takiron, Osaka, Japan) or titanium internal fixation devices (MODUS, Medartis, Basel, Switzerland) according to their informed decisions. The bioabsorbable implants were expected to be resorbed during 5–6 years after surgery.[10,11] After the patients had decided on their bone fixation preference, they anonymously received questions 3–7 before surgery and questions 8 and 9 after surgery (at 4–6 weeks and 1 year after surgery) [Table 1].

The preoperative questionnaire was completed by 71 patients (100%), early postoperative questionnaire by 34 patients (48%), and 1-year follow-up questionnaire by 21 patients (30%).

Literature search

A literature search was performed on April 18, 2013 with Internet databases (PubMed and EMBASE) using search words "resorbable osteosynthesis." The 211 articles found were analyzed about publication date, country and language of study, author number, and associated institutions The impact factor for each journal was found by searching for each title on Web of Science, Thompson-Reuters, New York, USA (subscription database subscribed to by our institution).

The H-index for each journal and for the countries so indicated was found by searching SCImago Journal and Country Rank (available on the Internet). The Impact Factor and H-index are for the journals and countries as stated in those databases at the date and time of search (April 18, 2013) and preparation of the bibliometric overview was April 19.[17-19]

Data analysis

Data analysis was done with a spreadsheet program (Excel, Microsoft Corp., Redmond, WA, USA). Total number and percentages were calculated for each question.

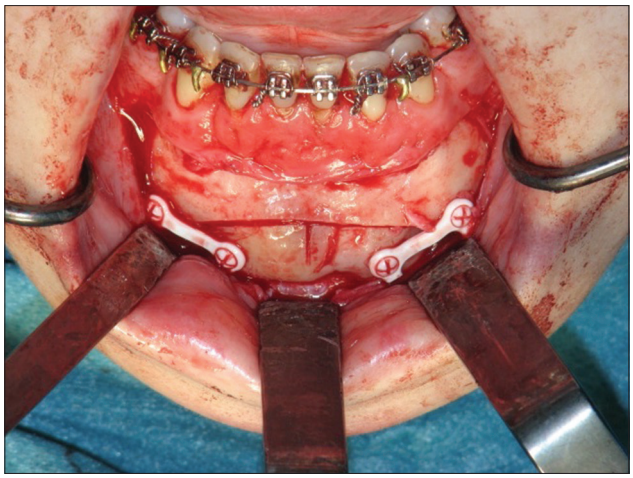

Figure 1: Genioplasty

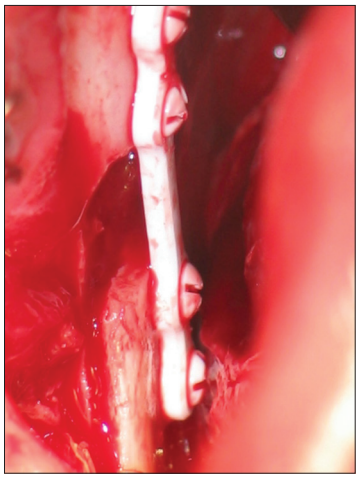

Figure 2: Mandible osteotomy

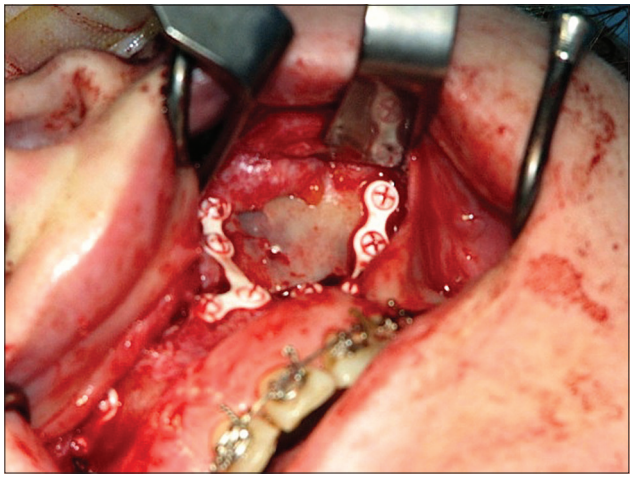

Figure 3: Le Fort I osteotomy

RESULTS

Preoperative assessment

Before surgery, most patients had not previously heard about resorbable/bioabsorbable bone fixation, and most patients anticipated no adverse events or occurrence of inflammation or instability [Table 2]. After receiving information, most patients preferred resorbable/bioabsorbable bone fixation, usually because they preferred to avoid a second operation to remove metal hardware and most patients were bothered about later metal hardware removal with metal fixation devices [Table 2]. The higher cost of bioabsorbable fixation to health insurance companies for resorbable/bioabsorbable bone fixation was believed justified or not justified by many patients [Table 2]. All the patients chose resorbable/bioabsorbable internal fixation except 1 patient who chose titanium internal fixation. Results of surgery (intraoperative feasibility and handling, success of retention and bone healing, and long-term sequelae) were reported previously.[20]

Postoperative assessment

At both 4–6 weeks and 1 year after surgery, most patients had no adverse events and most patients were very satisfied or satisfied with the outcome of surgery [Table 3]. The most frequent adverse event was swelling [Table 3]. The 1 dissatisfied patient complained of the residual swelling which was moderate.

Literature review

Literature review identified 211 articles that were published in 88 different journals, most frequently during the previous 12 years and in the Journal of Craniofacial Surgery, Journal of Oral and Maxillofacial Surgery, or British Journal of Oral and Maxillofacial Surgery [Table 4]. There were 25 different countries of location of the institutional affiliation of the first authors, most frequently Germany, United States, and France [Table 4]. The articles were published in 9 languages, most frequently English [Table 4]. The main topics of the articles were mandible fractures, orthognathic surgery, degradation, zygomatic and midfacial fractures, cranioplasties, minor fractures of the limbs, and thoracic surgery.

DISCUSSION

The present study showed that most patients had no previous knowledge about resorbable/bioabsorbable internal fixation [Table 2], even though these devices have been used in our service since 1998. Nevertheless, most patients preferred bioabsorbable instead of metal fixation devices to avoid a second operation for metal hardware removal [Table 2]. A previous study about patients having orthognathic surgery noted that 66% patients had known about resorbable internal fixation, possibly because of repeated preoperative interviews in the outpatient clinic and information transmitted between patients. Trauma patients typically require urgent treatment because of the accident and have shorter preoperative time than orthognathic patients to obtain information about their surgery.

The high preference for resorbable internal fixation noted in the present study (99%) [Table 2] was similar to that reported previously in patients who had distal radius fractures (95%) or orthognathic surgery (98%).[3,4] This preference was similar for trauma and reconstructive patients, even though many patients who had craniofacial trauma had been injured in interpersonal violence and had a different social background than orthognathic patients (data not shown). The present study showed

Table 1: Questionnaire to evaluate perceptions of patients about Resorbable/Bioabsorbable internal fixation for Maxillofacial fractures

Questionnaire	Question No.	Question	Purpose of question
Preoperative*	1	Have you ever heard of resorbable/bioabsorbable osteofixation, (plates and screws that disintegrate in the body and are applied to fix fractures and bone defects)?	To evaluate the level of general knowledge
	2	What would you think are their benefits and potential adverse effects?	To address undefined preoperative anxiety or irrational concepts
	3	With this information in mind, would you prefer titanium or resorbable/bioabsorbable osteofixation?	To show the informed preference of the patient
	4	Why have you decided to receive titanium or resorbable/ bioabsorbable fixation?	To provide details about the reasons for the patient's preference
	5	What was the decisive point?	To show the patient's interest within the issue
	6	Does the possibility of later surgery to remove metal bother you?	To evaluate whether metal removal is a major issue for the patient
	7	Do you consider 50% higher implant cost justified for resorbable/ bioabsorbable fixation, keeping in mind the avoidance of surgery to remove metal and overall treatment cost reduction?	To evaluate the patient's perception of the higher cost to health providers for resorbable/bioabsorbable implants but avoidance of metal implant removal
Postoperative	8	Have you had any adverse effects?	To identify adverse events
	9	How satisfied are you with the outcome of the operation?	To estimate patient satisfaction

*Questions 3 to 7 were given after the patient received information about resorbable/bioabsorbable internal fixation

Table 2: Responses to preoperative questions to evaluate perceptions of patients about Resorbable/Bioabsorbable internal fixation for Maxillofacial fractures*

Question No.	Question	Reply	Number (%) patients
1	Heard of resorbable/bioabsorbable fixation	No	43 (61)
		Yes	28 (39)
2	Possible adverse events†	None	37 (52)
		Inflammation	14 (20)
		Instability	14 (20)
		Incomplete or no resorption	2 (3)
3	Preferred resorbable/bioabsorbable internal fixation	Yes	70 (99)
		No	1 (1)
4,5	Reason for preference/decisive point	Avoid second operation for hardware removal	67 (94)
		Recommendation by other patients	4 (6)
6	Bothered about later metal hardware removal	Yes	65 (92)
		No	6 (8)
7	Higher cost of resorbable/bioabsorbable implant justified	Yes	41 (58)
		No	30 (42)

*N=71 patients. Data reported as number patients (%). †Total, 67 replies. Four questionnaires were returned without possible adverse effects

Table 3: Responses to postoperative questions to evaluate perceptions of patients about Resorbable/Bioabsorbable internal fixation for Maxillofacial fractures*

Question No.	Question	Reply	Number (%) patients	
			Early postoperative (4 to 6 week)	Late postoperative (1 year)
No. patients			34 (48)	21 (30)
8	Adverse events	None	27 (79)	14 (67)
		Swelling	4 (12)	3 (14)
		Inflammation	1 (3)	2 (10)
		Paresthesia or dysesthesia	1 (3)	2 (10)
		No reply	1 (3)	0 (0)
9	Satisfied with outcome	Very satisfied	19 (56)	13 (62)
		Satisfied	13 (38)	7 (33)
		Not satisfied†	1 (3)	1 (5)
		No reply	1 (3)	0 (0)

*N=34 patients at 4 to 6 weeks and 21 patients at 1 year after surgery. Data reported as number patients (%). †This patient reported residual swelling as adverse event, which was moderate on clinical examination

a large information gap between the subjective perspectives of patients (high demand for bioabsorbable/resorbable osteofixation) and the common treatment offered to patients (titanium internal fixation).

The most common negative factor noted about metallic implants was the second operation necessary for metal removal [Table 2], similar to previous findings with orthognathic surgery and surgery for treatment of distal radius fractures.[3,4] Many patients were

Table 4: Characteristics of articles identified in a literature search about Resorbable internal fixation of bone*

Characteristic	No. of articles
Year of publication	
1980-89	16
1990-99	50
2000-12	145
Total	211
Most frequent journals†	
Journal of Craniofacial Surgery (impact factor, 0.822; H index, 42)	23
Journal of Oral and Maxillofacial Surgery (impact factor, 1.64; H index, 64)	18
British Journal of Oral and Maxillofacial Surgery (impact factor, 1.95; H index, 43)	11
Country of institutional affiliation of first author	
Germany (H index, 704)	73
United States (H index, 1305)	42
France (H index, 646)	12
United Kingdom	8
The Netherlands	8
Switzerland	7
Austria	6
South Korea	6
Sweden	6
Turkey	5
Finland	3
Italy	3
Spain	3
Canada	2
Denmark	2
Other‡	10
None provided	15
Language of publication	
English	150
German	49
French	6
Other§	6

*N=211 articles. †Total, 88 journals. ‡Brazil, Czech Republic, China, Greece, Hong Kong, India, Iran, Japan, Poland, and United Arab Emirates: 1 article each. §Czech, Danish, Finnish, Polish, Russian, and Spanish: 1 article each

previously unaware about the medical necessity of removal of metal fixation devices (3–31%; in our patients, 23%).[12-16] Metal hardware removal may be indicated for the treatment of heat or cold irritability, dysesthesia, stress shielding noted on radiography, palpability, exposed hardware, mechanical irritation, and interference with diagnostic or therapeutic radiation. Many patients believed that adverse events with bioabsorbable fixation may include inflammation, instability, or absence of resorption but that plate removal may not be required for these events [Table 2].

The literature search showed extensive research activity worldwide about resorbable internal fixation, mostly for mandible fractures and orthognathic surgery. Resorbable internal fixation devices have been used frequently for zygomatic and midfacial fractures and cranioplasties.[16,20,21] The present and two previous studies about the perspectives of patients suggest that the level of knowledge and preferences of patients should be considered in further developing the international experience with resorbable/bioabsorbable internal fixation devices.

In the present study, most patients had no adverse events [Table 3]. The adverse events noted by some patients (swelling, inflammation, and paresthesias) are not specific to resorbable/bioabsorbable plates and may occur with titanium internal fixation devices. In a previous study of orthognathic surgery patients, postoperative questionnaires showed that 73% patients had no adverse events, and adverse events included hypaesthesia (12%), mastication problems, swelling, fistulas, inflammation, and pain; however, 55% patients were very satisfied and 37% were satisfied postoperatively and on long-term follow-up 64% were very happy and 23% were happy, while 6% were not sure and 7% unhappy with the outcome of surgery.[4] The unhappy patients were not patients with complications, but patients postoperatively unhappy with their facial appearance. Therefore similar results were attained regarding postoperative satisfaction.

Many studies have shown that resorbable plates may provide sufficient stability for treatment of craniofacial fractures.[20-23] In the present study, fewer patients were concerned about fracture stability (20%) [Table 2] than patients in a previous study of distal radius fractures (29%),[3] possibly because patients may perceive less bone loading after craniofacial trauma than trauma to the limbs. Nevertheless, stability is a concern in some patients who doubt that resorbable plates may have adequate strength for craniofacial fracture fixation; in comparison, no orthognathic surgery patients were concerned about instability, possibly because patients were informed in advance about biodegradable fixation, which may have increased their confidence.[4]

Follow-up studies typically have fewer dropouts after orthognathic surgery than craniofacial trauma.[20] This was observed in the present study compared with our earlier evaluation in orthognathic patients who had bone fixation with poly-L/DL-lactide-trimethylene carbonate implants.[4] Craniofacial trauma patients who return for follow-up typically are patients who have questions or adverse events, and this may cause negative selection bias.[20,21,24] Therefore, the present study from a single center with few patients at 1-year follow-up may be limited by negative selection bias.

Although most patients (58%) felt that the higher cost of treatment with more expensive resorbable/bioabsorbable fixation devices was justified, many patients (42%) would not be willing to pay the additional cost of biodegradable fixation that may not be covered by their health insurance [Table 2]. Therefore, there is a discrepancy between patient demand and willingness to pay, even though the patients were informed about the risks and costs of metal hardware removal that would be avoided with resorbable fixation. Follow-up study of this issue may be of interest because of possible future cost restrictions for health care that may include a lack of health insurance coverage for metal hardware removal. Although many countries are scientifically active [Table 4], publication activity may not necessarily be related to health insurance coverage for resorbable/bioabsorbable fixation devices.

CONCLUSION

In summary, the present study showed a high patient preference for resorbable than metal internal fixation for the treatment of maxillofacial fractures. Patient's education about resorbable/bioabsorbable implants may enable patients to make better informed decisions and avoid the risks and costs of metal hardware removal. The literature review suggested that fractures with mild or moderate displacement may be treated effectively

with resorbable bone fixation. The high preference of patients for resorbable implants and the avoidance of a second operation for metal hardware removal are factors that may encourage insurance companies to pay for the higher cost of resorbable implants.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Soni CV, Barker JH, Pushpakumar SB, Furr LA, Cunningham M, Banis JC Jr, *et al.* Psychosocial considerations in facial transplantation. Burns 2010;36:959-64.
2. Bradbury E. Meeting the psychological needs of patients with facial disfigurement. Br J Oral Maxillofac Surg 2012;50:193-6.
3. Mittal R, Morley J, Dinopoulos H, Drakoulakis EG, Vermani E, Giannoudis PV. Use of bio-resorbable implants for stabilisation of distal radius fractures: The United Kingdom patients' perspective. Injury 2005;36:333-8.
4. Ballon A, Laudemann K, Sader R, Landes CA. Patients' preoperative expectations and postoperative satisfaction of dysgnathic patients operated on with resorbable osteosyntheses. J Craniofac Surg 2011;22:730-4.
5. Wermker K. Incidence, etiology and classification of condylar fractures. In: Kleinheinz J, Meyer C, editors. Fractures of the Mandibular Condyle: Basic Considerations and Treatment. New Malden, Surrey, UK: Quintessence; 2009. p. 29.
6. Böstman OM, Pihlajamäki HK. Adverse tissue reactions to bioabsorbable fixation devices. Clin Orthop Relat Res 2000;371:216-27.
7. Landes CA, Ballon A, Roth C. Maxillary and mandibular osteosyntheses with PLGA and P (L/DL) LA implants: A 5-year inpatient biocompatibility and degradation experience. Plast Reconstr Surg 2006;117:2347-60.
8. Neff A. Kraniofaziale traumatologie. In: Horch HH, editor. Mund-Kiefer Gesichtschirurgie. München: Elsevier; 2007. p. 68-95.
9. Shikinami Y, Okuno M. Bioresorbable devices made of forged composites of hydroxyapatite (HA) particles and poly-L-lactide (PLLA): Part I. Basic characteristics. Biomaterials 1999;20:859-77.
10. Shikinami Y, Matsusue Y, Nakamura T. The complete process of bioresorption and bone replacement using devices made of forged composites of raw hydroxyapatite particles/poly l-lactide (F-u-HA/PLLA). Biomaterials 2005;26:5542-51.
11. Hasegawa S, Ishii S, Tamura J, Furukawa T, Neo M, Matsusue Y, *et al.* A 5-7 year *in vivo* study of high-strength hydroxyapatite/poly(L-lactide) composite rods for the internal fixation of bone fractures. Biomaterials 2006;27:1327-32.
12. Kahle WK. The case against routine metal removal. J Pediatr Orthop 1994;14:229-37.
13. Orringer JS, Barcelona V, Buchman SR. Reasons for removal of rigid internal fixation devices in craniofacial surgery. J Craniofac Surg 1998;9:40-4.
14. Islamoglu K, Coskunfirat OK, Tetik G, Ozgentas HE. Complications and removal rates of miniplates and screws used for maxillofacial fractures. Ann Plast Surg 2002;48:265-8.
15. O'Connell J, Murphy C, Ikeagwuani O, Adley C, Kearns G. The fate of titanium miniplates and screws used in maxillofacial surgery: A 10 year retrospective study. Int J Oral Maxillofac Surg 2009;38:731-5.
16. Eppley BL, Morales L, Wood R, Pensler J, Goldstein J, Havlik RJ, *et al.* Resorbable PLLA-PGA plate and screw fixation in pediatric craniofacial surgery: Clinical experience in 1883 patients. Plast Reconstr Surg 2004;114:850-6.
17. Garfield E. The history and meaning of the journal impact factor. JAMA 2006;295:90-3.
18. Hirsch JE. An index to quantify an individual's scientific research output. Proc Natl Acad Sci U S A 2005;102:16569-72.
19. SCImago: SJR – SCImago Journal and Country Rank; 2007. Available from: http://www.scimagojr.com. [Last retrieved on 2013 Apr 19].
20. Landes C, Ballon A, Ghanaati S, Tran A, Sader R. Treatment of malar and midfacial fractures with osteoconductive forged unsintered hydroxyapatite and poly-L-lactide composite internal fixation devices. J Oral Maxillofac Surg 2014;72:1328-38.
21. Eppley BL. Zygomaticomaxillary fracture repair with resorbable plates and screws. J Craniofac Surg 2000;11:377-85.
22. Landes CA, Kriener S, Menzer M, Kovàcs AF. Resorbable plate osteosynthesis of dislocated or pathological mandibular fractures: A prospective clinical trial of two amorphous L-/DL-lactide copolymer 2-mm miniplate systems. Plast Reconstr Surg 2003;111:601-10.
23. Suzuki T, Kawamura H, Kasahara T, Nagasaka H. Resorbable poly-L-lactide plates and screws for the treatment of mandibular condylar process fractures: A clinical and radiologic follow-up study. J Oral Maxillofac Surg 2004;62:919-24.
24. Ellis E 3rd, McFadden D, Simon P, Throckmorton G. Surgical complications with open treatment of mandibular condylar process fractures. J Oral Maxillofac Surg 2000;58:950-8.