ARTICLE COVER SHEET
LWW—SCS
DIS

Article : scs20359
Creator : k2df14
Date : Friday October 27th 2006
Time : 20:52:16
Article Title :
Number of Pages (including this page) : 4
Template Version : 1.3

Extracttion Script is: sc_Extract_Xml

Discussion

Reflections on Complications to Bioresorbable Osteofixation Devices.

Recently, there was a report[1] on complications associated with bioabsorbable devices used in craniomaxillofacial (CMF) surgery. Although in CMF surgery this was considered an obsolete rarity in the past,[2] it seems that it is becoming a reportable incident. It was thought that the rarity of the condition is probably due to the use of relatively small devices and probably due to good vascularity in the region. With increasing use of bioresorbable devices of different geometries and polymers produced by various companies in CMF [1–8] it also brings to light some rare complications. These occurrences have to be followed up so that we can find a figure for and be aware of their incidence and can practice informed counseling for patients. One issue that has to be taken into consideration is that not all of bioabsorbable devices are the same. The only thing they share is that they are bioabsorbable. Polymers can be different in their chemical structure, molecular weight, manufacturing processing techniques, etc.[9] These factors may make a difference. Copolymers were used because they combine certain properties of more than one polymer in the implant. However, polymers are present in different percentages in the structure of the resulting copolymer in different products. It is important to ask if certain products have undergone appropriate animal studies done with proper models. Since their surge from the 1980s, bioabsorbable devices (second-generation biomaterials) have gained momentum due to the involvement of many companies in the market owning some version of bioabsorbable sets that makes these tools available to surgeons today. Currently, these products are very similar. They are made mostly from bioabsorbable polylactide copolymers such as poly-L/D-lactide (PLDLA) and polylactide-co-glycolide (PLGA). There are new polymers, new techniques that can be used to develop better bioabsorbable devices in future.

When using bioresorbable materials in CMF surgery for children and infants, appropriate biomaterials should be chosen in order to avoid complications such as those described in the report. Bioresorbable biomaterials can be manufactured with desired resorption time. Copolymers of PLA such as PLGA and PLDLA can be combined so that the resorption time is optimal even for infants. PLLA has a long resorption time and is probably more suitable for use in adult CMF surgery. We do not recommend it for infants.

In order to minimize the palpability of the plates in infants, bioresorbable plates with short resorption time can be placed beneath the bone in cosmetically critical areas. This has been proven safe and reliable in experimental and clinical works.[5]

The evolution of bioresorbable devices took place through strategies applied to gain strength for developed implants. One strategy is increasing the size, the molecular weight, and the use of slow-degrading polymers. We are still learning. We should understand that PLGA, and the bioresorbables we have today are not the final answers in many instances.

Cross-disciplinary knowledge and science led to the blurring of boundaries and it is generating innovative solutions, e.g. better devices and therapeutic measures. Thus, new education and training both of surgeons and biomaterials scientists should include a substantial amount of knowledge relevant to each party of these to enable making better inventions and make innovative devices successful in patients.[10]

The failure to identify, to document and report complications will make review, analysis and future development difficult. Thanks to Mackool et al[1] reporting incidents in this issue. Additionally, future in silico models will enable better design and performance of implants. This is one way to go to integrate advances made in IT. There is confusion in the literature regarding the terms ''biodegradation,'' ''bioresorption,'' and ''complete bioresorption.'' This concept has to be clear for all of us working in the field. Biodegradation refers to the fact that the material undergoes degradation in biological environment. It does not necessarily imply that degraded products will be absorbed. Bioresorption is the process, including also bioresorption of the degradation products. In many instances, there are no long-term in vivo studies to look at the product complete bioresorprion over many years.[6] In addition, many reports do confuse the description of ''bioresorption'' when they mean naked-eye or microscopical observation. We tried to

Address correspondence and reprint requests to Nureddin Ashammakhi, MD, PhD, FRCSEd, Institute of Biomaterials, Tampere University of Technology, PO Box 589 (Hermiankatu 12 B), FIN-33101 Tampere, Finland; E-mail: nureddin.ashammakhi@tut.fi

compare some reports and it is difficult to find indication as to regards important information such as microscopical magnification that was used.[11] With such redundant reports, it is difficult to compare results or make future progress that all of us need.

Another issue is the sensitivity of the matter in children, how much one has to be aggressive and how much and what literature (evidence-based surgery) can be applied to be ethically sound decision, enabling to give proper counseling and explanation and also use proper management of complications and alternatives: When to say ''no'' to bioabsorbable devices; Why they are there altogether; What are their absolute or relative indications in CMF, if any?

Inflammation is a badly reported event. Its existence was denied in early reports on the new synthetic Dexon suture. Although there were reports on fluid collection with synthetic sutures, the move towards its use was strong enough to leave this history out. It seems that things were compared to catgut at that time and so regarded as non inflammation-causing suture. In some instances, an explanation was linked with surgical trauma. Is there a wound without inflammation? Is there an implant that does not elicit inflammation? It is the degree and timing that make difference, not the occurrence of inflammation itself? It is these problems that may give rise to a major issue such as osteolysis, fluid accumulation, sinus formation, palpability, infection, etc. It is not only the imbalance between the release of degraded products on one side and their clearance on the other side. The process of barriers to clearance such as thick fibrous tissue formation should also be considered as possible problem. [10,12–14]

With the possibilities of adding drugs into polymeric devices, a third generation of implants[15] was developed that can have controlled release of anti-inflammatory agents which can possibly exert certain control on inflammatory reaction.[16] However, the issue is complex because inflammation is a part of implant clearance and also a part of wound healing. One has to adjust release to balance these two aspects properly before such implants can be of help. In preliminary animal studies we could not see any major difference between anti-inflammatory releasing and plan PLGA implants in rats.

Research continues on this frontier as one way to improve the compatibility and functionality of bioresorbable further. The future lies in combinational multifunctional devices,[15] i.e. drug delivery, other functions. Reports by authors are the only way to know about the problem so we may seek and develop solutions. Otherwise, the science we are practicing will have a similar attitude as seen in the 1970s on synthetic sutures.

Nureddin Ashammakhi, MD, PhD, FRCSEd,*†
Willy Serlo, MD, PhD,‡
Tampere Finland, Oulu Finland
**Institute of Biomaterials,*
Tampere University of Technology,
Tampere, Finland
†*Department of Surgery, Oulu University*
Hospital, Oulu, Finland

REFERENCES

1. Mackool R, Yim J, McCarthy J. Delayed degradation in a resorbable plating system. J Craniofac Surg 2006;17:194–197
2. Ashammakhi N, Suuronen R, Tiainen J, et al. Spotlights on naturally absorbable osteofixation devices. A Review. J Craniofac Surg 2003;14:247–259
3. Eppley BL, Pietrzak W. A resorbable rivet system for pediatric craniofacial surgery: biomechanical testing and clinical experience. J Craniofac Surg 2006;17:11–14
4. Ylikontiola L, Sundqvist K, Sandor GKB, et al. Selfreinforced bioresorbable self-treinforced poly-L/DL-lactide [SR-P(L/DL)A] 70/30 miniplates and miniscrews are reliable for fixation of anterior mandibular fractures: a pilot study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2004;97:312–317
5. Serlo W, Ashammakhi N, Törmälä P, et al. Case report: a new technique for correction of trigonocephaly in an infant: application of an absorbable endocranial plate. Childs N System 2000;16:595–597
6. Serlo W, Kaarela OI, Peltoniemi H, et al. Self-reinforced polylactide osteosynthesis devices in craniofacial surgery. A long-term follow-up study. Scand J Plast Reconstr Surg Hand Surg 2001;35:285–292
7. Cohen S, Mittermiller P, Holmes R, et al. Clinical experience with a new fast-resorbing polymer for bone stabilization in craniofacial surgery. J Craniofac Surg 2006;17:40–43
8. Ashammakhi N, Renier D, Arnaud E, et al. Successful use of biosorb osteofixation devices in 165 cranial and maxillofacial cases: a multicenter report. J Craniofac Surg 2004;15:692–701
9. Ashammakhi N, Moreira A, Gonzalez AM, et al. Review: new resorbable bone fixation biomaterials in craniomaxillofacial surgery: present and future. Eur J Plast Surg 2004;26:383–390
10. Ashammakhi N. Editorial. Reactions to biomaterials: the good, the bad and ideas for developing new therapeutic approaches. J Craniofac Surg 2005;16:195
11. Tiainen J, Soini Y, Törmälä P, et al. Self-reinforced polylactide-polyglycolide 80/20 screws take more than 1 years to resorb in rabbit cranial bone. J Biomed Mater Res (Appl Biomat) 2004;70B:49–55
12. Ashammakhi NA. Neomembranes: a concept review with special reference to self-reinforced polyglycolide membranes. J Biomed Mater Res (Appl Biomater) 1996;33:297–303
13. Ashammakhi N, Rokkanen P. Absorbable polyglycolide devices in trauma and bone surgery. Biomaterials 1997;18:3–9
14. Bergsma JE, De Bruijn WC, Rozema FR, et al. Late degradation tissue response to poly(L-lactide) bone plates and screws. Biomaterials 1995;16:25–31
15. Ashammakhi N, Törmälä P. Editorial. From past to present and future is today. From inert to multifunctional biomaterials. J Craniofac Surg 2004;15:897
16. Viitanen P, Suokas E, Törmälä P, et al. Release of diclofenac sodium from polylactide-co-glycolide 80/20 rods. J Mater Sci Mater Med, **AQ1**

AUTHOR QUERY

AUTHOR PLEASE ANSWER QUERY

AQ1 = Please update bibliographic information if already published.

END OF AUTHOR QUERY

LIPPINCOTT
WILLIAMS & WILKINS

Journal of Craniofacial Surgery

2005/2006 Author Reprint Rates

In addition to using this form to order reprints, it is to be used to calculate any additional publication fees your article may incur. Publication fees include color separation charges and page charges. Prices are subject to change without notice. Quantities over 500 copies---contact our Healthcare Dept. at 410-528-4426. Outside the U.S. dial 4420-7981-0700.

Fax or mail your order to Lippincott Williams & Wilkins, Author Reprints Dept, 351 W. Camden St., Baltimore, MD 21201. Fax: 410-528-4434

Rapid Ordering can be accessed at http://www.lww.com/periodicals/author-reprints. A confirmation of your order will be e-mailed to you.

For questions regarding reprints or publication fees please e-mail us at reprints@lww.com or contact us at 1-800-341-2258.

Reprint Pricing:

100 copies = $375.00

200 copies = $441.00

300 copies = $510.00

400 copies = $585.00

500 copies = $654.00

*Author(s) Name*_____

*Title of Article*_____

*Article #*_____*Publication Mo/Yr*_____

Payment must be received before reprints can be shipped. Payment is accepted in the form of a check or credit card; purchase orders are accepted for orders billed to a U.S. address.

☐ *MC* ☐ *VISA* ☐ *Discover* ☐ *American Express*

*Account #*_____ *Exp. Date*_____

*Name*_____

*Address*_____

*Dept/Rm*_____

*City*_____ *State*_____

*Zip/Postal Code*_____*Country* _____

*Telephone*_____*Signature*_____

Reprint Cost

Quantity of Reprints = _____ $_____

Covers (Optional)

$108.00 for the first 100 copies $_____

$18.00 each add'l 100 copies $_____

Color Fees (If your article contains color figures, use Rapid Ordering.)

Publication Color Charge *(You may have included color figures in your article. The costs to publish those figures may be included on the reprint invoice or they may be invoiced separately.)* $_____

Reprint Color Cost *($70.00/100 reprints)* $_____

Shipping

Add $5.00 per 100 reprints for orders shipping within the U.S. and $20.00 per 100 reprints for orders shipping outside the U.S. $_____

Tax

U.S. and Canadian residents add the appropriate tax, or submit a tax exempt form. $_____

Shipping Information

*Ship:*_____*copies to:*

*Name*_____

*Address*_____

*Dept/Rm*_____

*City*_____ *State*_____

*Zip/Postal Code*_____*Country* _____

*Phone #*_____