Discussion

Reflections on Complications to Bioresorbable Osteofixation Devices.

Recently, there was a report on complications associated with bioabsorbable devices used in craniomaxillofacial (CMF) surgery. Although in CMF surgery this was considered an obsolete rarity in the past, 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 surgery, 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. 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 bioabsorbables) 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 poly-lactide-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.

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.

The failure to identify, to document and report complications will make review, analysis and future development difficult. Thanks to Mackool et al 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 bioresorption over many years. In addition, many reports do confuse the description of “bioresorption” when they mean naked-eye or microscopical observation. We tried to
compare some reports and it is difficult to find indication as to regards important information such as microscopical magnification that was used.\(^\text{11}\) 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.\(^\text{10,12-14}\)

With the possibilities of adding drugs into polymeric devices, a third generation of implants\(^\text{15}\) was developed that can have controlled release of as microscopical magnification that was used.\(^\text{11}\) With such redundant reports, it is difficult to compare results or make future progress that all of us need.

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With the possibilities of adding drugs into polymeric devices, a third generation of implants\(^\text{15}\) was developed that can have controlled release of anti-inflammatory agents which can possibly exert certain control on inflammatory reaction.\(^\text{16}\) 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 combina- tional multifunctional devices,\(^\text{15}\) 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,*\(^\text{1}\) Willy Serlo, MD, PhD\(^\text{1}\)
Tampere Finland, Oulu Finland
*Institute of Biomaterials,
Tampere University of Technology,
Tampere, Finland
1Department of Surgery, Oulu University Hospital, Oulu, Finland

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