Original Research Article

Incidence of infections associated with use of bioabsorbable implants in Orthopedic surgeries

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Abstract

Background: The incidence of placement of osteosynthetic materials has grown worldwide. Bioabsorbable materials are more commonly used now days in Orthopedic surgeries. Implants modify the risk of infection by bacterial adhesion, tissue integration, and immunomodulation. Bacterial adhesion to implant leads to interaction between bacteria and implant.

Aim: To evaluate the incidence of infections associated with use of bioabsorbable implants in Orthopedic surgeries.

Materials and methods: The infection rates among 1057 patients were treated with bioabsorbable osteosynthesis devices was investigated. The implant material used was PGA in approximately three fourths of the patients.

Results: Depending on the bioabsorbable material used, the infection rates varied from 0.7% (SR-PLLA) to 6.5% (SR-PGA and SR-PLLA together). In a comparison with metallic osteosynthesis devices, a total 522 ankle fracture patients were studied. There was no significant difference between the infection rates of the bioabsorbable fixation group (3.2%) and metallic fixation group (4.1%). The effect of bioabsorbable implants volume on wound infections showing a significant positive correlation between the incidence of infection and the implant volume when non-stained SR-PGA or SR-PLLA implants were used. In fracture patients the raising of the implant-bone volume ratio correlated with the rising incidence of infection.

Conclusion: Increasing the implant volume causes a higher incidence of wound infection when modern, non-stained implants are used. The increase in the incidence of infection is most prominent when SR-PLLA implants are used. Increasing the implant-bone volume ratio causes a higher incidence of wound infection on the tibial side.

Key words

Bio degradable agents, Polyglycolic acid (PGA), Poly-L-lactic acid (PLLA), Ankle joint.

Introduction

Infections comprise the most devastating complications associated with internal fracture or osteotomy fixation. Implants used in the fixation of bone make tissue more vulnerable to bacterial colonization by enabling bacterial adhesion to the surfaces and also by hampering the immunological responses to bacteria.

The bioabsorbable osteosynthesis devices have been in clinical use since 1984. Their indications now include numerous cancellous bone fractures and osteotomies as well as some soft-tissue injuries. Use of PGA as reinforcing pins, screws, and plates for bone surgery was first suggested by Schmitt, et al. in 1969 [1]. Since then there has been a lot of development in manufacturing biodegradable implants with properties appropriate for osteosynthesis.

Implants modify the risk of infection by bacterial adhesion, tissue integration, and immunomodulation. Bacterial adhesion to implant leads to interaction between bacteria and implant [2]. There are numerous implant-dependent factors affecting the bacterial adherence to the surface [3-5]. All implanted devices cause a foreign body reaction, the severity of which is dependent on numerous factors: tissue damage caused by trauma and surgery, material of the implant size and chemical composition of the debris particles present [6]. The most common bacteria are coagulase negative staphylococcus (Staphylococcus epidermidis) [6-8].

The present study aimed to evaluate the incidence of infections occurred by using the bioabsorbable implants during orthopaedic and trauma surgeries.

Material and methods

The present study included the patients who were operated at Department of Orthopedics, MNR Medical College and Hospital, Sangareddy between June 2009 to July 2015 for various orthopedic diseases and fresh fractures. The total number of the patients was 1057 with almost one half of the patients operated on for displaced ankle fractures. Other frequent indications were hallux valgus surgery and fractures around the elbow (**Table – 1**). The implant material used was PGA in approximately three fourths of the patients.

Table – 1: Distribution of patients.

Orthopedic disease	**No of cases**
Chevron osteotomy for hallux valgus	139
Bristow operation	30
Arthodesis of TC-, subtalar, and C-MC joints	12
Osteochodritis dissecans	8
Rupture of the collateral ligament of the thumb	52
Fresh fractures of	
Ankle	522
Radial head	43
Olecranon	34
Condyles of Humerus	32
Carpal or metacarpal bones	24
Patella	19
Foot	17
Knee (intra-articular distal femur or proximal tibia)	15
Others	110
Total	1057

The patient data for the study were identified from the records of Operation Theater and medical records section of MNR Medical College and Hospital, Sangareddy, Medak, Telangana. The details of the treatment of the patients were re-recorded from the patient files. The recorded details included the diagnosis of the patient, the operative treatment accomplished, the operation time, the implants

used, the demographic data, chronic diseases and medications, the date of the infection diagnosis, laboratory and bacteriological findings, and possible other findings

Related to the tissue reactions occasionally complicating the use of bioabsorbable implants. If there were implant removal operations, the complications of those operations were also recorded. All infections were diagnosed by a surgeon. An infection was diagnosed if pus was observed, there was secretion from the wound from which the same bacteria were continuously (at least twice) cultured or the patient had a wound infection reaction associated with the systemic manifestations of an infection, i.e. fever, high erythrocyte sedimentation rate, C-reactive protein (CRP) concentration, and leukocyte count. The bacterial cultures were collected either by aspirating pus into a syringe or, if it was not possible, by swabbing the wound. The infection was diagnosed as deep if it affected the implant channel.

For the first 53 patients, implants made of PGA/PLA co-polymer were used. All the patients were treated for displaced ankle fractures. Indications for SR-PGA and SR-PLLA implants include most cancellous bone fractures and osteotomies, and ligament injuries.

For qualitative results, the Chi-square test with Yates's corrections was used. For quantitative results, the Student's T-test was used.

Results

In the study of 1057 patients, the incidence of wound infection in association with different bioabsorbable materials was as follows: PGA/PLA co-polymer 3.8 % (2/26 cases), polyglycolide 4.0 % (58/721 cases), polylactide 0.7 % (3/210 cases), polyglycolide and polylactide together 6.5 % (12/93 cases), metallic and bioabsorbable material together 7 cases without infections. The infection percentages observed with bioabsorbable and metallic fixation were 3.2% and 4.1%, respectively. The incidence of infection within any bioabsorbable subgroup did not differ from that of the metallic fixation group. There were four cases of deep infections (0.4%) in the bioabsorbable fixation group (three patients treated with SR-PGA implants, one with PGA/PLA implants). The incidence of deep infection with metallic implants was similar (eight cases, 0.4%).

The most commonly observed bacteria were Staphylococcus aureus and Staphylococcus epidermidis (**Table - 2**). Staphylococcus aureus was cultured from all deep infections in the bioabsorbable group. In the metallic fixation group the staphylococcus species were also the most frequent findings.

Table – 2: Bacteria cultured from infected wounds.

Species	No	Deep infection
Staphylococcus aureus	13	4
Staphylococcus epidermidis	15	2
Diphteroid	4	-
Enterobacter cloacae	6	1
Beta-hemolytic streptococcus	3	-
Streptococcus agalactiae	3	-
Staphylococcus species (indefinite)	5	-
Other	19	-
Total	68	-

Discussion

The present patients operated on by using bioabsorbable implants were slightly younger than those operated on with metallic implants. In earlier series there has been a considerable number of soft tissue complications associated with the operative treatment of ankle fractures in the elderly population [9, 10]. This finding was not, however, verified by Makwana, et al. [11]. The age distribution of the comparison groups may have biased the present results by raising the infection rates in the metallic fixation group, since patients with a wound infection were found to be older than those without one.

There were a few patients who met the clinical and laboratory criteria and were thus diagnosed as infections, even though all bacterial cultures were negative. In a study it has been suggested that, after the initial one-week postoperative rise has settled, CRP levels of more than 36 mg/l are pathognomonic of bacterial complications in ankle fracture patients [12].

The bacterial spectrum associated with ankle fractures consisted mainly of staphylococcus species. This finding is in accordance with earlier culturing results of orthopedic implants. Staphylococcus aureus has been the most often found pathogen, and also coagulase negative staphylococci (mainly epidermidis) have been frequent findings [13, 14. 15]. In vitro studies [16] have shown that the use of non-absorbable polymers favor S. epidermidis over S. aureus, but it could not be confirmed in a clinical setting. In fact, all the deep infections met in the bioabsorbable fixation group had S. aureus cultured from the wound.

Studies on incidence of wound infection in association with bioabsorbable osteosynthesis the largest groups of patients were operated on for dislocated ankle fracture or hallux valgus. The incidence of infection has varied from no infections in 23 feet [17] to 13 infections in 161 feet [18] when metallic K-wire fixation was used. In other series there was one infection in 70 feet when no internal fixation was used [19]. In the earlier literature the use of bioabsorbable fixation in hallux valgus surgery has yielded lower incidences of infection compared to the present series, but patient groups have been rather small, fewer than 100 patients per group [20, 21].

In the present study, there was a total of 75 infections in 522 patients (3.9%) operated on for ankle fractures. In previous studies the infection rate has varied considerably, from 1.8% [22] to 8.6 % [2]; also incidences between 3-5% have been reported [23-26].

Conclusion

In a large series with Orthopedic and traumatologic indications involved the incidence of infection in conjunction with bioabsorbable osteosynthesis devices ranges from three to four per cent. In ankle fracture patients, most wound infections are caused by staphylococcus species. Deep infections are rare, approximately 0.4 percent, and are caused by several species with frequent staphylococcal involvement. There is no difference between the bacterial floras associated with bioabsorbable or metallic implants. Increasing the implant volume causes a higher incidence of wound infection when modern, non-stained implants are used. The increase in the incidence of infection is most prominent when SR-PLLA implants are used. Increasing the implant-bone volume ratio causes a higher incidence of wound infection on the tibial side. On the fibular side no such correlation exists.

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