INFECTED IMPLANTS AND INTERNAL FIXATION DEVICES

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Infection which occurs at the site of implanted material or prosthetic devices can present a challenging clinical management scenario. Postoperative foreign bodies include suture material, absorbable fixation devices, stainless steel wire, Kirschner wire, stainless steel or titanium internal fixation, allogeneic bone grafts, vascular grafts, tendon grafts, and arthroereisis or arthroplasty implants. This discussion is directed mainly toward three implant materials: silicone, titanium, and stainless steel implants. Few studies with large patient volumes and long term follow up are available concerning podiatric implant procedures. There have been many published reports of postoperative infections involving total knee and total hip arthroplasty procedures. Several of these studies have included large series of patients, with long term follow up. This research provides the best source of reliable information as a basis for clinical treatment. By summarizing this research, we can come to certain recommendations to help make decisions involving infected implants and internal fixation devices.

BIOFILM GLYCOCALYX

"Virtually every surface examined in natural, industrial and pathologic ecosystem is colonized by biofilms consisting of adherent sessile bacterial populations enmeshed within a glycocalyx matrix."[1]

Bacterial populations attempt to colonize all surfaces or living skin and mucous membrane surfaces. With respect to surgical implants, this exposure can occur either at the time of surgery (a surgical "sterile field" is only a temporary situation) or anytime after the implant procedure (the internal content of the body is not a sterile environment). Low-virulence, sessile microorganisms attempt to invade these areas and attach themselves to living and nonliving structures. Their metabolism excretes a matrix film that is made up of glycoproteins and carbohydrates. This layer is called the biofilm glycocalyx or "bacterial slime" layer. It acts as a barrier to the host defenses. Within this matrix, these bacteria are shielded from the effects of surfactants, antibodies, and antibiotics.

Some pathogenic bacteria (*pseudomonas aeruginosa,* staph and strep species) also produce glycocalyx. Other opportunistic organisms can find shelter in the biofilm and the "establishment of these consortia on the surfaces of artificial implants or on the mucosal surfaces of the pulmonary and urinary tracts heralds the onset of infections which readily become chronic, despite heroic antibiotic treatment regimens."

The biofilm glycocalyx blanket develops several layers that exclude oxygen, reduce nutrient availability and slow bacterial growth. The slow growth of the bacteria decreases the effectiveness of antibiotics. This area also becomes negatively charged and ionically retards the inward infusion of cationic antibiotics (aminoglycosides). Upper regions of the blanket may also contain "guard cells" that exclude or enzymatically neutralize antibiotics. The control and possible disruption of this chronic postoperative infections involving foreign bodies will persist.

CLINICAL AND LABORATORY FINDINGS

The first challenge of treatment is the diagnosis. A postoperative "superficial" wound infection is relatively easy to diagnose compared to a "deep" slow colonization infection at the implant interface. The typical aggressive erythema, edema and warmth is not present and the initial symptoms are minimal and gradually develop over time. One study states that 42 percent of the implant infections had an associated "wound complication." Obviously, the more difficult diagnosis to be made is in the 58 percent of the patients with no associated wound complications.

At the time of the diagnosis of an implant infection, the chief patient complaint is pain (100%) and fever (44%). Laboratory findings include increased sedimentation rate (54%) and leukocytosis (15%). Recurrent drainage and radiographic changes are also important indicators of infection. Cultures of the implant, cultures of the soft tissues, cultures of the bone and the histologic changes of the biopsied tissues ultimately make the diagnosis. These low-virulent glycocalyx-producing bacteria may not survive the transport to the laboratory or may be difficult to grow in-vitro. Negative cultures do not rule out infection. "Bacteria sequestered within a surface biofilm may not be identified by routine microbiologic culture techniques".[2] "Definitive diagnosis is possible only by culturing several samples of material obtained from the interface during revision operation."[3]

IDENTIFICATION OF THE ORGANISM INVOLVED

Usually (88 percent) a single organism is responsible for the implant infection. The most common organisms are staph epi (40 percent), staph aureus (30 percent) or other organisms: E.Coli, strep viridans, group-D strep (30 percent)

Time Interval Between Surgery and Diagnosis of Implant Infection

"The infection rate for patient with total hip arthroplasty increases significantly with time" Canner, et.al. study of 52 patients with infection following total hip arthroplasty Dec. 1984.

The diagnosis of an immediate postoperative superficial wound complication, within three weeks, was made in 42 percent of the surgeries. The interval for the diagnosis of an implant infection is variable: less than 3 months (37 percent), 3 months to 1 year (29 percent), 1 to 4 years (24 percent), longer than 4 years (10 percent). An associated diagnosis of rheumatoid arthritis produced a delay (average 2 years) in the diagnosis of implant infection. Concerning internal fixation devices, the removal of the device after adequate bone healing (3 to 6 months) and before bony overgrowth would eliminate this long term complication. Concerning arthroplasty implants and realizing the infection rate continue over a five year period, the alternative of implant removal after satisfactory encapsulation and its consequences should be explored. Current complication topics of "avascular necrosis of distal first metatarsal osteotomies", "avascular necrosis of the proximal phalanx after implant arthroplasty", "osteolysis along the implant stem", and "osseous engulfment of an implant" could be explained by the presence of a slow growing implant interface colonization infection that goes undiagnosed.

Hematogenous Infection

Overall, 50 percent of the infections diagnosed after 1 year were documented as hematogenous spread. Hematogenous infections were identified from four distant septic foci: severe skin infections or a remote ulcer, the oral cavity, the urinary tract, and abdominal wounds. Documented infections include staph epidermitis, *staph aureus*, strep species, *e. coli*, pseudomonas, cornybacteria, enterobacter, and candida. Several cases of hematogenous spread of infection from dental procedures to implants have been reported. One case occurred five years after a total hip arthroplasty and four days after dental manipulation. The organism identified is usually a common oral flora (Peptostreptococcus or Actinomcyes).

Associated Risk Factors

A diagnosis of rheumatoid arthritis is associated with an infection rate over twice the osteoarthritis infection rate. With rheumatoid arthritis, the infection rate for men is over three times the infection

rate for women. With osteoarthritis, the infection rate is the same for men and women. With rheumatoid arthritis, oral steroid use was not a factor. A very significant finding was 50 percent of infections had previous surgery in the area. Age is a factor with the average age of a successful result being 50 and the average age of the patients with infections was 65. Previous surgery in the area is a significant risk factor. 50 percent of the implant infections had previous surgery in the area prior to the index surgery.

FOUR TREATMENT OPTIONS

The treatment options for an implant infection are: 1) the original implant is maintained, 2) the implant is removed, 3) the implant is removed and an arthrodesis is performed, and 4) the implant is removed and the area is reimplanted either immediately or at a later date.

Original Arthroplasty Implant Remains

When the infection is treated with the original implant left intact the success rate varies from 23 to 77 percent. Several articles have challenged the higher success rates by criticizing the short term follow up of the studies. Overall, intravenous antibiotics were given for 28 days followed by five weeks of oral antibiotics. The duration of intravenous antibiotics was significant in one study: 45 percent failure rate if virulent organisms (gram neg bacilli or group-D strep) were treated with systemic antibiotic less than 28 days and 8 percent failure rate if treated longer than 28 days.

Specific studies stated various success rates, antibiotics alone 2 percent, with repeated aspirations 50 percent, and with open debridement 50 percent. Repeated aspirations had the same success rate as open debridement. Ingress/egress tubes often resulted in secondary infections. The "virulence" of the organism was a factor on the success rate: staph aureus (40 percent), strep (90 percent) and gram negative organisms (0 percent) successful or they were not treated with this option.

In one study, the time interval between the index surgery and diagnosis of infection was not a factor. In another study, a significant time interval was identified with successful results diagnosed at 21 days and failure diagnosed at 36 days average.

"We now regard this treatment as less effective than other options, and believe that it should be reserved for perioperative infections or late infections when there are no risk factors and the infecting organism is of low virulence and is sensitive to suitable antibiotics" Wilson, et al. study of 67 total knee arthroplasty infections July. "The low success rate (23 percent) was disappointing" Schoifet, et. al study of 31 total knee arthroplasty infections treated with debridement and retention of the implants Oct. 1990.

Arthroplasty Implant Removal

The most difficult decision is the removal of the implant. The implant materials being discussed (silicone, titanium, stainless steel) exhibit different physical properties. Increased elastic modulus and porosity would theoretically increase the harboring of bacteria. The elastic modulus of silicone is greater than titanium which is greater than stainless steel. The stability of the bone fragments, the stability of the internal fixation, and the mobility of an implant arthroplasty are factors to consider. Theoretically, the advantages of increased effective vascularity to the bone and decreased edema in the soft tissues afforded by rigid, stable fixation outweigh the disadvantages produced by the presence of the device. Concerning an implant arthroplasty, the disadvantage produced by the presence of the device by harboring the organism outweighs the functional advantage of the implant. The presence of the arthroplasty implant itself does not contribute to the healing process. The debridement of the adjacent bone is also a factor. If an arthrodesis or reimplantation is contemplated, the surgeon will often be too conservative with the bone resection and there is a higher chance of continued infection. Removal of the implant with minimal bone resection resulted in a 20 percent recurrence of infection. Implant removal and "effective" bone resection is the definitive treatment with an infection recurrence rate of zero percent. "Only excisional arthroplasty consistently eliminated infection and resulted in a clinically satisfactory result" Canner, et al. study of 52 total hip arthroplasty infections Dec. 1984.

Arthroplasty Implant Removal and Arthrodesis

After failure of options 1 and 2, when arthrodesis with internal fixation was performed, 100 percent of the patients had a successful osseous union with no infection. The use of internal fixation in an area of previous infection has a much higher success rate than the use of an arthroplasty implant in an area of previous infection. This would seem to confirm the opinion that osseous stability enhances the healing potential in the face of infection and this outweighs the disadvantage of the presence of the implant.

Implant Removal and Reimplantation

Two options are available, a one-stage primary reconstruction with implant removal, debridement and reimplantation during the same surgery, or a two-stage reconstruction with initial implant removal and debridement followed by reimplantation at a later date. The success rate for the one-stage is 40 to 90 percent and the two stage is 60 to 95 percent. The time interval between removal and reimplantation is significant. The reinfection rate is higher if reimplantation was performed less than a year after first implantation (27 percent) compared to longer than a year (7 percent).

Overall, the probability of infection after reimplantation is 13 to 20 percent. The diagnosis of infection was made an average 3 years after reimplantation (range 2 to 13 years after reimplantation). As previously discussed, several articles have challenged the higher success rates by criticizing the short term follow up of the studies. Concerning one-stage total hip arthroplasty procedures, there is a 50 percent infection rate if the bone cement is not totally removed during the reimplantation and an 11 percent infection rate if all the bone cement is removed. This confirms the previous discussion concerning implant removal and effective bone resection.

"The two stage reconstruction is an effective, safe technique even when the infection is caused by a virulent organism" McDonald, et al. study of 82 total hip arthroplasty infections treated with resection and reimplantation July 1989. "Of the various treatment options that were studied, removal and delayed replacement of the knee prosthesis resulted in the best functional results" Wilson, et al. study of 67 total knee arthroplasty infections July 1990.

RECOMMENDATIONS

The authors would like to provide certain recommendations to help make clinical decisions involving implants and internal fixation devices.

1. Concerning infection, the follow up to determine the success of implant arthroplasty and internal fixation procedures should extend at least 5 years postoperative.
2. The unsatisfactory long term success rate of an arthroplasty implant infection treated without removal would suggest that the progress of this treatment method be carefully evaluated and attempted for only a short period of time.
3. Removal of asymptomatic arthroplasty implants should be discussed and researched in relation to complications and functional results.
4. Removable of implants should be accompanied by 1) aerobic and anaerobic cultures of soft tissues and implant and 2) soft tissue biopsy.
5. Fixation devices should be removed after satisfactory bone healing (3 to 6 months) and before the remodeling process has completed.
6. Removable fixation devices (buried smooth Kirschner wires, screws, plates, staples) are preferred over non-removable fixation devices (buried threaded Kirschner wires, stainless steel wire, absorbable fixation).
7. The diagnosis of "avascular necrosis" or "detritic synovitis" should be confirmed with a bone biopsy and culture from the implant interface.
8. Reimplantation of an internal fixation device has a much higher success rate than the reimplantation of an arthroplasty implant.
9. Antibiotic prophylaxis for dental procedures should be initiated in a patient with an arthroplasty implant.
10. Further investigation and long term documentation specific to podiatric implants needs to be conducted.

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