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Implant sonication for the diagnosis of prosthetic elbow infection

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Abstract

Background—Periprosthetic infection is a potentially devastating complication of elbow arthroplasty, associated with formation of microbial biofilm on the implant surface. The definitive microbiologic diagnosis of periprosthetic infection after elbow arthroplasty may be difficult to establish. Our study aim was to compare the diagnostic accuracy of conventional periprosthetic tissue culture and culture of fluid derived from vortexing and bath sonication of the explanted hardware (a biofilm-sampling strategy).

Materials and methods—Patients undergoing revision elbow arthroplasty at our institution between July 2007 and July 2010, from each of whom 2 or more periprosthetic tissue cultures and 1 implant sonicate culture were obtained, were studied. A standardized definition of orthopedic implant—associated infection was applied.

Results—We identified 27 subjects with aseptic failure and 9 with prosthetic elbow infection. Rheumatoid arthritis was the most common underlying disorder. The Coonrad-Morrey prosthesis was the most common type of implant used. The sensitivities of implant sonicate and periprosthetic tissue culture were 89% and 55%, respectively ($P = .18$), and the specificities were 100% and 93%, respectively ($P = .16$). Coagulase-negative staphylococci ($n = 7$) and *Staphylococcus aureus* ($n = 2$) were isolated in cases of infection.

Conclusion—Culture of the implant by sonication is at least as sensitive as periprosthetic tissue culture to detect prosthetic elbow infection.

Level of evidence—Level I, Diagnostic Study.

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The study was approved by the Mayo Clinic Institutional Review Board (IRB No. 09-000808, entitled “Detection of Biofilms on Explanted Orthopedic Devices”).

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Keywords

Prosthetic joint infection; elbow prosthesis; implant; sonication; biofilm; periprosthetic tissue

Artificial joint replacement of the elbow is increasingly being used in orthopedic surgery, although it is performed less frequently than hip, knee, or shoulder replacement. Different types of prostheses have been used for elbow arthroplasty. The Coonrad-Morrey prosthesis, a semiconstrained hinged prosthesis with a high-molecular-weight polyethylene bushing and metal parts made of titanium and cobalt-chrome, has a long-term track record^{2,8,9,14} and is commonly used. Periprosthetic infection remains a severe and potentially devastating complication. Data on infection rates after elbow arthroplasty are sparse, with reported incidences of infection varying from 0% to 12% and averaging 5%.⁴ The infection rate for procedures performed at our institution decreased from 9% (between 1973 and 1979)¹¹ to 3% (between 1981 and 1994),¹⁸ likely because of the routine use of antibiotic-impregnated polymethyl methacrylate and careful handling of the surrounding soft tissue with improved surgical techniques.

Prosthetic joint infection is thought to be associated with the presence of bacterial biofilms attached to the implant. Conventionally, the microbiologic diagnosis of prosthetic joint infection has been based on culture of periprosthetic tissue samples. For hip and knee infections, the collection of 5 or 6 specimens has been recommended.³ We and other investigators have developed and validated a technique that involves vortexing and sonication of the explanted prosthesis to dislodge and disaggregate biofilm bacteria. We have shown that culture of samples obtained by sonication of the prosthesis is more sensitive than conventional periprosthetic tissue culture for the diagnosis of infection associated with hip/knee,¹⁶ shoulder,¹² and spinal implants.¹³ For hip/knee infections, the sensitivity of implant sonicate culture was similar to tissue culture if 5 or more tissue specimens were obtained.¹⁶ The purpose of the current study was to compare the diagnostic accuracy of conventional periprosthetic tissue culture and culture of fluid derived from vortexing and bath sonication of the explanted hardware (a biofilm-sampling strategy).

Materials and methods

Consecutive patients undergoing revision or resection of elbow implant arthroplasties at our institution between July 2007 and July 2010 were considered for study recruitment. Patients with 2 or more periprosthetic tissue specimens and their explanted prostheses submitted for culture were studied. Subjects with total implant elbow and radial head arthroplasties, but not those with radiocapitellar arthroplasties, were included. In many cases, the original implantation had been performed at an outside institution. Subjects with partial revision/resection of either the ulnar or humeral component were included. If only parts of the components were revised (eg, wires and bushings), subjects were excluded. We also excluded those who had orthopedic hardware placed around the joint for internal fixation of fractures. Finally, we excluded those who only had cement spacers submitted for sonication. For those who had more than 1 orthopedic procedure during the study period, only the first was included in the analysis.

Subjects were classified as having prosthetic elbow infection if at least 1 of the following was present: (1) intraoperative purulence or gross evidence of infection surrounding the prosthesis, (2) acute inflammation on histopathologic examination of tissue sections, (3) sinus tract communicating with the implant, and (4) 2 or more positive periprosthetic tissue cultures and positive implant sonicate culture (for the same organism). Aseptic failure (AF) was defined as failure of the prosthesis not meeting these criteria. Preoperative antimicrobial

therapy was defined as receipt of antimicrobial agents (other than preoperative prophylaxis) within 4 weeks before the revision/resection surgery.

Preoperative peripheral blood leukocyte count with differential, erythrocyte sedimentation rate (ESR), and serum C-reactive protein (CRP) levels, as well as synovial fluid analysis (cell count with differential and culture), were obtained at the discretion of the treating clinicians. ESR was determined by the Westergren method. CRP levels were measured with the Roche/Hitachi Modular Analytics Systems (Roche Diagnostics, Indianapolis, IN, USA). Patients with rheumatoid arthritis were excluded from the analysis of inflammatory markers, as their levels may be elevated because of the underlying immunologic disorder.

All patients received standard perioperative prophylaxis with cefazolin or, in cases of colonization or prior infection with methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin. Typically, the first dose was administered 30 minutes before incision. In cases where infection was suspected, antimicrobials were not administered until samples for cultures were taken. Intraoperative tissue samples with the most obvious inflammatory changes were collected for histopathology and conventional culture. For most cases, 1 sample was taken from the joint pseudocapsule and 1 to 2 samples from each of the medullary canals (humerus and ulna) after removal of the implants but before mechanical removal of the bone cement. The fibrous tissue in the canal was removed with several instruments, including uterine curettes as well as backbiting osteotomes. Most of the time, the cement mantle was removed with osteotomes and high-speed burs.

Microbiologic specimens were processed within 6 hours of collection. The tissue specimens were homogenized in brain-heart infusion broth. The homogenate was inoculated in 0.1-mL aliquots onto aerobic sheep blood and chocolate blood agar plates (BD Diagnostic Systems, Franklin Lakes, NJ, USA) and incubated at 35°C to 37°C in 5% carbon dioxide aerobically for 2 to 4 days. The homogenate was also inoculated in 0.1-mL aliquots into anaerobic thioglycolate broth and onto anaerobic sheep blood agar and incubated anaerobically for 7 days. Turbid thioglycolate broth was subcultured. All media used underwent quality control to ensure that they supported growth of the organisms that they are designed to detect and were negative in the absence of an inoculated patient specimen or organism.

Explanted prostheses were placed in an autoclaved 1-L polypropylene wide-mouthed container (Nalgene, Lima, OH, USA), to which 400 mL of Ringer solution was added. The container was vortexed and sonicated at room temperature. Fifty milliliters of sonicate fluid were concentrated 100-fold by centrifugation, and 0.1-mL aliquots of the concentrated sonicate fluid were plated onto aerobic and anaerobic sheep blood agar plates, which were incubated at 35°C to 37°C in 5% to 7% carbon dioxide aerobically and anaerobically for 2 to 4 days and 14 days, respectively. On the basis of prior studies,^{12,16} optimal culture sensitivity and specificity of the concentrated fluid are achieved if there are at least 20 colony-forming units (CFUs) of the same organism on either plate. For low-virulence organisms, which are typically part of normal skin flora (eg, coagulase-negative *Staphylococcus* species, *Propionibacterium acnes*, and *Corynebacterium* species), we used a cutoff value of 20 CFUs per plate. For virulent bacteria, such as *S aureus*, any amount of growth was considered positive. We documented negative sonicate cultures of sterile prostheses as an internal negative control.

Because of the small sample size and non-normal distribution of the data as assessed by the Kolmogorov-Smirnov test, nonparametric methods were used for statistical analyses. The characteristics of patients with AF and those with infection were compared by use of the Wilcoxon rank sum test for continuous variables and the Fisher exact test or χ^2 test, as appropriate, for categorical variables. The sensitivities and specificities of the methods

studied to detect prosthetic elbow infection were compared by use of the McNemar test, a test of paired proportions. $P < .05$ (for a 2-sided test) was considered to indicate statistical significance.

Results

Fifty-seven consecutive subjects were considered for inclusion in the study. Eleven were excluded because only parts of the prosthesis components were revised. Eight were excluded because they had only a single periprosthetic tissue specimen or no specimens sent for culture. We excluded 1 patient with radiocapitellar arthroplasty, and another did not provide consent for research. Of the remaining 36 subjects analyzed, 27 had AF and 9 met criteria for prosthetic elbow infection. Of those 9 subjects, 2 did not have macroscopic or microscopic findings consistent with infection and were diagnosed solely based on microbiologic findings.

Demographic and clinical characteristics, laboratory and radiographic data, and type of surgery are shown in Table I. The mean age of subjects with infection was 61 years. There were proportionally more female patients in both groups. Rheumatoid arthritis was the most common indication for arthroplasty ($n = 14$). The Coonrad-Morrey design was the most common type of prosthesis implanted. The median time from implantation to revision or resection surgery was longer in subjects with AF than in those with infection (48 months and 21 months, respectively).

The sensitivities of implant sonicate and periprosthetic tissue culture for the detection of periprosthetic elbow infection were 89% (95% confidence interval [CI], 52%-100%) and 55% (95% CI, 21%-86%) ($P = .18$), respectively, and the specificities were 100% (95% CI, 85%-100%) and 93% (95% CI, 76%-99%) ($P = .16$), respectively.

Microbiologic findings are shown in Table II. Coagulase-negative staphylococci ($n = 7$) and *S aureus* ($n = 2$) were isolated in patients with infection. Two cases of *S aureus* infection were detected by culture of implant sonicate but not by culture of periprosthetic tissue. In 2 cases, where coagulase-negative *Staphylococcus* species grew in a single tissue culture, implant sonicate culture grew coagulase-negative *Staphylococcus* species (at 20 CFUs per plate). All but 1 subject with infection due to coagulase-negative staphylococci had positive implant sonicate cultures (ie, 20 CFUs per plate).

Three subjects with infection had received antimicrobial agents within 4 weeks before revision or resection arthroplasty. One of the three had negative periprosthetic tissue cultures whereas the implant sonicate culture grew MRSA. For the other 2 subjects, the same organism grew in both the periprosthetic tissue and the implant sonicate culture. Among the 3 subjects with infection who had synovial fluid cultures performed preoperatively, 2 were positive. For the 1 subject with a negative synovial fluid culture and infection, both periprosthetic tissue and implant sonicate cultures were positive for coagulase-negative *Staphylococcus* species.

Among subjects with AF, 12 had some bacterial growth in either tissue culture ($n = 6$) or implant sonicate culture ($n = 3$) or both ($n = 3$). No organism grew in sonicate fluid at 20 CFUs per plate or more. *P acnes* was the most commonly isolated organism in patients with AF (5 of 11) and was typically isolated in a single periprosthetic tissue specimen.

As shown in Table I, among subjects with infection, 2 underwent 1-stage exchange, 6 had 2-stage exchange, and 1 had resection without reimplantation. For those who underwent 2-stage exchange, the median time to reimplantation was 53 days. The median time to follow-up after surgery for infection was 28 months. Recurrence of infection developed in only 1

patient; this was due to coagulase-negative *Staphylococcus* species, and this patient had undergone partial revision and was not receiving antimicrobial suppression.

Discussion

We have previously reported infection rates after implant elbow arthroplasty at our institution. In this article, we describe our findings between July 2007 and July 2010 for cases where vortexing and sonication of the retrieved prosthesis were performed in a solid container. Implant sonication is a simple technique, albeit slightly more labor-intensive compared with tissue culture. The associated processing for sonication takes approximately 7 minutes. Only 1 implant sonicate culture is required compared with a requirement for multiple tissue cultures. Many laboratories are already equipped with sonicators that can be used to sonicate orthopedic devices. An added benefit is that sonicate cultures have a shorter time to positivity than tissue cultures.⁷

From 1981 through 1994, 757 consecutive total elbow arthroplasties were performed at Mayo Clinic. Postoperative infection occurred after 25 procedures (3%).¹⁸ Twenty-three infections developed after a primary arthroplasty and two after a revision procedure. *S aureus* was the predominant pathogen, followed by coagulase-negative *Staphylococcus* species. From 1994 through 2007, 358 elbow arthroplasties were performed at the Schulthess Clinic in Zurich, Switzerland. Infection occurred in 27 (8%).¹ Nineteen infections developed after a primary arthroplasty and eight after revision arthroplasty. Again, *S aureus* was the predominant pathogen, followed by coagulase-negative staphylococci. Finally, in a retrospective review of 10 consecutive arthroplasties performed in patients with documented infections of the elbow, recurrent infections developed in only two,¹⁷ suggesting that previous infection is not a contraindication to implantation or reimplantation of an elbow prosthesis.

In our study 6 infections developed after a primary arthroplasty and 3 after a revision procedure. One revision procedure was done because of prior infection. Of note, in our study we included patients whose implant had been submitted for sonication and not all patients who had their prostheses explanted. All study subjects with prosthetic elbow infection based on the diagnostic criteria used had a microbiologic diagnosis from either the tissue or implant sonicate culture. The sensitivity of implant sonicate culture was not significantly different from that of periprosthetic tissue culture. Notably, the number of subjects in this study was smaller (n = 36) compared with the numbers in our studies of hip (n = 124), knee (n = 207), or shoulder (n = 156) implants.

In our prior studies of implant sonication, we included only total implant arthroplasties after complete removal of the prostheses.^{12,13,16} In this study we included patients with partial revisions or resections where either the ulnar or the humeral component was removed. There were 6 such patients (22%) in the AF group and another 3 (33%) in the infection group.

We included 1 patient with radial head arthroplasty. This patient had growth of MRSA in synovial fluid culture aspirated from the joint preoperatively and in implant sonicate culture. However, the pathogen did not grow in the 2 tissue cultures that were obtained. A possible explanation is that areas not affected by infection were sampled for tissue culture. Missing the diagnosis because of inadequate sampling may be of particular concern in partial arthroplasties. The use of the sonication technique needs to be further validated in partial arthroplasty or partial revision/resection.

Preoperative antimicrobial treatment may be given after a recent diagnosis of periprosthetic infection or for chronic suppression. Treatment also may be given for an infection at another

unrelated site. Antimicrobials may decrease the diagnostic yield of conventional cultures. In a retrospective study of culture-negative prosthetic joint infection, 32 of 60 subjects (53%) had received a prior course of antimicrobial therapy.⁵ In our study 4 patients were receiving preoperative antimicrobials. One had AF, and the other 3 had confirmed infection. For 1 of these 3, the organism was recovered from implant sonicate culture only. All subjects had cemented implants before revision. For most cases, we do not know whether the cement was antimicrobial impregnated. Hence, we cannot draw conclusions about the potential impact of antimicrobial elution from bone cement on culture results.

In a previous study where sonication was used for the microbiologic diagnosis of prosthetic shoulder infection,¹² *P. acnes* was associated with two-fifths of the confirmed cases. In the current study *P. acnes* was only isolated from prostheses not considered to be infected. Similarly, in a retrospective study performed at the Schulthess Clinic, no cases of infection due to *P. acnes* were identified.¹ Hence, despite the proximity of the elbow to the shoulder joint and axilla, the microbiology of elbow implant infection resembles that of prosthetic hip and knee infection more than it does prosthetic shoulder infection. We and other investigators^{10,15} have shown that a single periprosthetic tissue specimen positive for *P. acnes* should not be considered definitive evidence of infection. This finding is confirmed by the present study, because *P. acnes* was only isolated in cases of AF and mainly from single tissue cultures.

At the Schulthess Clinic in Switzerland, among 27 patients with infection, 19 (70%) were free of disease at follow-up (median time, 2.7 years) and 8 (30%) had a relapse (median time, 0.56 years).¹ At our institution, between 1976 and 2003, 29 patients were treated with reimplantation of a total elbow prosthesis after a prior resection arthroplasty because of infection.⁶ After a mean surveillance time of 7.4 years, improvement in function was encountered in most patients, but infection recurred in 8 (28%). In the current study, infection recurred in only 1 patient (8%), who underwent partial revision and did not receive antimicrobial suppression. However, the median follow-up period was shorter (20 months) than in the other studies.

Our study has several limitations. There is no gold-standard diagnostic modality for identifying prosthetic elbow infection. We used a standardized definition based on widely accepted clinical practice. Two of the diagnostic criteria used, macroscopic evidence of infection and evidence of acute inflammation on biopsy, have some degree of subjectivity dependent on the operating surgeon and pathologist, respectively. Moreover, inflammatory changes may not always be obvious in the surgical field, and sampling error may occur. The study size was small, because elbow implant arthroplasty is performed much less frequently than hip or knee arthroplasty, even at major specialized centers. This may be why our data failed to reach statistical significance. In our analysis we included subjects with at least 2 tissue cultures. On the basis of a mathematical model, sampling of 5 or 6 sites has been recommended to increase diagnostic performance.³ Nonetheless, sampling of fewer sites is commonly encountered in clinical practice. Finally, ESR, CRP, and synovial fluid parameters were not obtained in all patients. The diagnostic utility of these markers should also be investigated in further studies.

Conclusion

We showed that implant sonicate culture is at least as sensitive as periprosthetic tissue culture to detect prosthetic elbow infection. Further studies with larger sample sizes are required to definitively establish whether implant sonication compared with periprosthetic tissue cultures results in the improved diagnosis of infection after elbow arthroplasty.

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Table I

Characteristics of study subjects

Characteristics	Subjects with AF (n = 27)	Subjects with periprosthetic elbow infection (n = 9)	P value
Age [mean (range)] (y)	60 (24-88)	61 (38-75)	.87
Gender [No. (%)]			
Male	6 (22%)	1 (11%)	
Female	21 (77%)	8 (89%)	.65
Underlying joint disorder [No. (%)]			
Osteoarthritis	3 (11%)	2 (22%)	.58
Rheumatoid arthritis	9 (33%)	5 (56%)	.27
Acute fracture/trauma	6 (22%)	1 (11%)	.65
Post-traumatic arthritis/nonunion	9 (33%)	1 (11%)	.39
Associated conditions [No. (%)]			
Diabetes mellitus	5 (19%)	0	.30
Immunosuppressive therapy	8 (31%)	3 (30%)	>.99
Type of prosthesis [No./total No. (%)]			
Coonrad-Morrey	11/19 (58%)	5/6 (83%)	
Other	8/19 (42%)	1/6 (17%)	.36
Presence of clinical symptoms [No. (%)]			
Pain	26 (96%)	5 (56%)	.009
Local signs	5 (19%)	8 (89%)	<.001
Fever	0	1 (11%)	.25
Timing [median (range)] (mo)			
Time to clinical failure [*]	37 (5-127)	13 (0-76)	.048
Time to revision/resection [†]	48 (8-260)	21 (6-80)	.034
Case definition [No. (%)]			
Macroscopic evidence of infection [‡]	0	4 (44%)	
Acute tissue inflammation [‡]	0/18	0/2	
Presence of sinus tract [‡]	0	4 (44%)	
Preoperative laboratory findings [No./total No. (%)]			
WBC $10 \times 10^9/L$	4/21 (19%)	2/9 (22%)	>.99
ESR >30 mm/h	3/16 (19%)	3/4 (75%)	.06
CRP >10 mg/L	3/16 (19%)	3/4 (75%)	.06
Preoperative laboratory findings [median (range)]			
ESR (mm/h)	16 (3-58)	41 (27-60)	.03
CRP (mg/L)	6.5 (<3-39.1)	56.4 (9.8-268.8)	.005
Synovial fluid analysis [No./total No. (%)]			
Fluid leukocyte count >1,700/ μL	3/5 (60%)	1/3 (33%)	
Fluid differential >65% neutrophils	1/5 (20%)	3/3 (100%)	
Positive synovial fluid culture	0/7	2/3 (66%)	

Characteristics	Subjects with AF (n = 27)	Subjects with periprosthetic elbow infection (n = 9)	P value
Radiographic loosening [No. (%)]	24 (88%)	7/8 (88%)	>.99
Surgical procedure [No. (%)]			
One-stage exchange	13 (48%)	2 (22%)	
Two-stage exchange	13 (48%)	6 (66%)	
Resection without reimplantation	1 (4%)	1 (11%)	

WBC, Blood leukocyte count.

Where the denominator is shown, data were not available for all study subjects.

* Time between last surgery at implant site and onset of symptoms.

[†] Time between last surgery at implant site and revision/resection of implant.

[‡] Considered a diagnostic criterion for prosthetic joint infection.

Table II**Results of periprosthetic tissue and implant sonicate cultures**

	Organisms
AF (n = 27)	
Positive periprosthetic tissue and implant sonicate cultures, same organism	0
Positive periprosthetic tissue and negative implant sonicate cultures	Coagulase-negative <i>Staphylococcus</i> species (CNS), n = 1 <i>Propionibacterium acnes</i> , n = 1
Positive implant sonicate and negative periprosthetic tissue cultures	0
Prosthetic joint infection (n = 9)	
Positive periprosthetic tissue and implant sonicate cultures, same organism	CNS, n = 4
Positive periprosthetic tissue and negative implant sonicate cultures	CNS, n = 1
Positive implant sonicate and negative periprosthetic tissue cultures	CNS, n = 2 <i>S aureus</i> , n = 2*

The organisms listed were isolated in 2 or more periprosthetic tissue cultures or grew with 20 CFUs per plate or greater for implant sonicate cultures, except for *S aureus*, which was considered significant when isolated in any quantity.

* Implant sonicate cultures grew *S aureus* with less than 20 CFUs per plate and 20 to 50 CFUs per plate, respectively.