

RESORBABLE ANTERIOR CERVICAL PLATES FOR SINGLE-LEVEL DEGENERATIVE DISC DISEASE

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OBJECTIVE: Resorbable spinal implants have generated increasing interest. There are minimal data in the literature on the use of resorbable anterior cervical plates. The purpose of this study is twofold. First, we present clinical outcomes of anterior cervical decompression and fusion (ACDF) for single-level degenerative disease using the first commercially available resorbable cervical plate. Second, we compare x-ray outcomes, including pseudarthrosis rates and angulation of healing, between patients receiving resorbable plates and a control group of patients receiving titanium plates.

METHODS: Twenty-four consecutive patients treated with single-level ACDF using a resorbable anterior cervical plate were prospectively evaluated with minimum 12-month follow-up (mean, 15 mo). As a control group, 93 consecutive patients treated with single-level ACDF using a titanium plate with minimum 1-year follow-up were assessed.

RESULTS: Overall outcomes were good in the resorbable plate group at a mean 15 months follow-up. Neck Disability Index scores decreased from a mean of 64.0 to 20.1% at follow-up ($P < 0.001$). Numerical Rating Scale pain scores decreased from a mean of 8.0 preoperatively to 2.9 at follow-up ($P < 0.001$). Three cases of pseudarthrosis [three of 24 (12.5%)] were identified in the resorbable plate group compared with two cases in the control group [two of 93 (2.2%)]. This difference was significant ($P = 0.047$). Angulation was measured on final x-rays using Cobb angles. Patients in the resorbable plate group healed with a mean 4.52-degree kyphosis, whereas patients in the titanium plate group healed with a mean 2.41-degree lordosis ($P < 0.001$).

CONCLUSION: This report describes, to our knowledge, the first series of patients to undergo ACDF with the first commercially available resorbable cervical plate. Healing in kyphosis and pseudarthrosis was significantly more likely with resorbable implants as compared with the use of titanium plating. Although ultimate clinical outcomes were good, x-ray outcomes may be better with the use of titanium plating.

KEY WORDS: Anterior cervical instrumentation, Resorbable implants

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Anterior cervical decompression and fusion (ACDF) is widely used for the treatment of degenerative disease of the cervical spine. Anterior decompression with fusion is the most commonly performed surgical procedure for the treatment of degenerative disease of the cervical spine (13). The most common approach to ACDF involves use of bone graft and instrumentation (19). Instrumentation most commonly involves titanium plating. Instrumentation may increase fusion rates and reduce complications in ACDF (8, 19, 24, 25). Titanium plating has been widely used and has a long track record. Theoretically, the plate is only needed until solid fusion occurs. Titanium has the disadvantages of permanence and can obscure postoperative imaging. Resorbable implants have been developed to try to improve on some of the shortcomings of titanium constructs. The Mystique plate

(Medtronic Corporation, Memphis, TN) is the first resorbable, commercially available, true anterior cervical plate. It is only available for single-level disease. To be considered a replacement for standard titanium plates, resorbable implants will need to demonstrate both excellent clinical results and, at least, equivalence to titanium.

We present the first study, to our knowledge, on the results of ACDF using resorbable plates. The purpose of this study is twofold. First, we present clinical outcomes of ACDF for single-level degenerative disease using the resorbable anterior cervical plate. Second, we compare x-ray outcome, including pseudarthrosis rates and angle of healing, between patients receiving resorbable plates and a control group of patients receiving titanium plates for single-level degenerative disease.

MATERIALS AND METHODS

Patient Selection

This is a prospective study of 24 consecutive patients who underwent ACDF with instrumentation using a resorbable Mystique anterior cervical plate treated from July 2005 to December 2005 by the authors (RKB and SG). The Mystique plate is constructed from a 70:30 poly(L-lactide-co-d, L-lactide) polymer. All patients were treated for single-level degenerative disease and all received corticocancellous allograft. Allograft alone was used for arthrodesis without any adjunct such as demineralized bone matrix or bone morphogenic protein. The freeze-dried grafts were reconstituted by placing them in normal saline at the start of the case and shaped by a Leksell rongeur (Elekta Instruments, Inc., Atlanta, GA) to fit the interspace. The endplates were prepared by burring down the cartilaginous endplates. Two patients had symptoms of myelopathy preoperatively, whereas 22 had radiculopathy. The series includes all patients treated by the authors through an anterior approach for single-level degenerative disease during the study period. Institutional Review Board approval was obtained for the study and informed consent was obtained from patients. Use of the Mystique plate was discontinued in our practice after December 2005.

As a control group for assessing hardware failures and pseudoarthrosis rates, we evaluated 93 consecutive patients treated by the authors (RKB and SG) for single-level degenerative disease through ACDF with a minimum 1-year follow-up treated from May 2003 to June 2005. All patients in the control group were treated with corticocancellous allograft and titanium plating. The majority of patients (85 of 93 [91.4%]) received Synthes (Paoli, PA) small-stature plates. This group was retrospectively reviewed.

Follow-up Evaluation and Outcome Measures

All patients received cervical x-rays, including anteroposterior, lateral, and flexion-extension views at 3 months, 6 months, 12 months, and as clinically indicated in between regularly scheduled visits. All patients were followed for a minimum of 12 months. Fusion was defined as evidence of bridging trabecular bone across the graft-vertebral body interface and absence of motion on flexion-extension films. Vertebral body angulation was measured by the Cobb angle method using final x-rays measuring the endplates above and below the treated vertebral bodies (9). Only patients without pseudarthrosis were assessed to avoid biasing against the resorbable plate group.

For patients receiving resorbable plates, Neck Disability Index (NDI) and Numerical Rating Scale (NRS) pain scores were obtained preoperatively and at the study's end. The NDI involves 10 questions with responses scored from 0 to 5 and the final summation being converted to a percentage of disability (0 to 100%). NRS scoring was on an 11-point scale, 0 to 10, with 0 defined as "no pain" and 10 defined as "the worst pain imaginable." Both rating systems are validated outcome measures (7, 23). No patients were lost to follow-up.

Surgical Technique

Patients underwent ACDF by the standard Smith-Robinson technique (20). The resorbable plate was sized appropriately using a template and shaped as needed. Bending was achieved by placing the plate in a hot water bath to soften it by heating to over 70°C. After softening, the plate is manually shaped. The plate is removed from the hot water bath and as it cools, it hardens in the new shape. To recontour a plate, it is replaced in the water bath. As it warms up, it reverts to its original shape and again softens. Planned screw holes were tapped through the plate. This served to also cut threads into the plate itself.

Fixed-angle screws were then placed. Screws are not lag screws and do not pull the plate flush to the vertebral body if the plate is not contoured perfectly. The screws lock into the plate on full insertion. Screws are rigid. For the control group, titanium plates were inserted according to the standard technique.

Statistical Methods

A χ^2 test was conducted to compare differences in baseline characteristics between the resorbable plate and titanium control groups. A paired *t* test was used to determine statistical significance between baseline and final NDIs. Wilcoxon's signed-rank test was used for pairwise comparisons of NRS pain scores. Both tests analyzing pain scores were two-sided. Factors associated with pain improvement and pseudoarthrosis were analyzed by univariate analysis using logistic regression. *P* values less than 0.05 were deemed statistically significant. All statistical analyses were performed by using SPSS for Windows, Version 14.0 (SPSS, Inc., Chicago, IL).

RESULTS

Mean patient follow-up in the resorbable group was 15 months (range, 12–18 mo). Mean patient follow-up in the titanium plate group was 20 months (range, 12–31 mo). Patient characteristics in the two groups are presented and compared in Table 1. Patients in both groups were well matched. In the resorbable plate group, three patients developed pseudarthro-

TABLE 1. Patient characteristics

Characteristic	Resorbable plate group	Titanium plate group	Statistical <i>P</i> value
No. of patients	24	93	
Age			
<i>Mean ± standard deviation</i>	47.2 ± 9.3	46.1 ± 6.9	0.13
<i>Median</i>	44.5	44.0	
<i>Range</i>	31–73	35–71	
Sex			
<i>M</i>	12 (50.0%)	51 (54.8%)	0.67
<i>F</i>	12 (50.0%)	42 (45.2%)	
Level treated			
<i>C3–4</i>	1 (4.2%)	9 (9.7%)	
<i>C4–5</i>	2 (8.3%)	19 (20.4%)	
<i>C5–6</i>	12 (39.8%)	34 (39.8%)	0.55
<i>C6–7</i>	8 (26.9%)	25 (26.9%)	
<i>C7–T1</i>	1 (3.2%)	3 (3.2%)	
Smokers			
<i>Yes</i>	9 (37.5%)	34 (36.6%)	0.93
<i>No</i>	15 (62.5%)	59 (63.4%)	
Symptom			
<i>Radiculopathy</i>	22 (91.7%)	82 (88.1%)	0.63
<i>Myelopathy</i>	2 (8.3%)	11 (11.9%)	

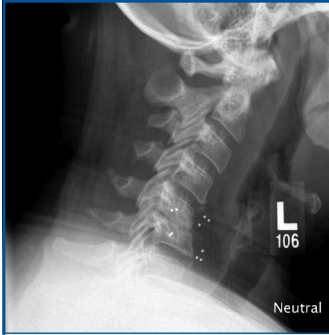


FIGURE 1. X-ray demonstrating graft collapse and lucency indicative of pseudarthrosis.



FIGURE 2. Successful arthrodesis is evident at a 3-month follow-up x-ray. Note the local kyphotic angulation.

sis (three of 24 [12.5%]) (Fig. 1). The pseudarthrosis rate in the titanium plate group was 2.2% (two of 93). The difference in pseudoarthrosis between resorbable plates and titanium plates was statistically significantly different (12.5 versus 2.2%, respectively, $P = 0.047$).

Alignment was measured using Cobb angles (Table 3). Mean angulation in the resorbable plate group was 4.52 degrees of kyphosis (Fig. 2). In the titanium group, mean angulation was 2.41 degrees of lordosis. This difference was statistically significant ($P < 0.001$). Fourteen of 21 patients in the resorbable plate group (excluding the three with pseudarthrosis) healed with some degree of kyphosis (67%). Fourteen of 91 patients in the titanium plate group (excluding the two with pseudarthrosis) healed with some degree of kyphosis (15%). This difference is statistically significant ($P < 0.05$).

Clinical outcomes are presented for the resorbable plate group. No patient had significant swallowing difficulty or developed recurrent laryngeal nerve palsy. Mean NDI scores decreased from 64.0 to 20.1% (mean difference, 45.9; 95% confidence interval, 37.8–54.1; $P < 0.001$).

Table 2 presents data on preoperative and postoperative NDI scores. NRS pain scores decreased from 8.0 to 2.9 at follow-up (mean difference, 5.8; 95% confidence interval, 4.8–6.8; $P < 0.001$).

Statistics	Baseline scores	Final scores
Mean	64.0%	18.1%
Range	34–88%	0–54%
Percentiles		
25	52.5%	2.0%
50	67.0%	16.0%
75	74.0%	36.0%

Statistics	Titanium group	Mystique group
Mean	2.41	-4.52
95% confidence interval	1.10 to 3.73	-6.91 to -2.13
Range	-10 to 9	-16 to 5
Percentiles		
25	0.5	-7
50	2	-4
75	7	0

^a Measured using Cobb angles. Negative angulation indicates kyphosis.

There was no association between development of pseudoarthrosis and preoperative smoking status ($P = 0.29$), age ($P = 0.70$), sex ($P = 0.54$), and level of surgery ($P = 0.85$). There was no association between clinical outcomes as measured by change in NDI scores and preoperative variables of sex ($P = 0.16$), age ($P = 0.16$), work status ($P = 0.34$), or workers' compensation status ($P = 0.99$). There was no association between change in NRS scores and preoperative variables of sex ($P = 0.06$), age ($P = 0.84$), work status ($P = 0.19$), or workers' compensation status ($P = 0.76$).

DISCUSSION

There is a growing body of literature on the use of bioabsorbable 70:30 poly(L-lactide-co-d, L-lactide) polymer implants in spinal fusion surgery. Devices made of this material have been used in craniofacial and spinal surgery without complications (5, 10, 12, 21, 22, 26). Most use of resorbable devices in spinal surgery has involved interbody spacers (5, 22, 26). Spacers have been used for posterior lumbar interbody fusion and ACDF with good results. Scattered reports exist on the use of a resorbable anterior cervical mesh as a graft containment device in ACDF (12, 21). This mesh can be considered a precursor to the plates used in the current study. In 2002, Vaccaro et al. (21) reported the first nine patients treated with a resorbable anterior cervical mesh as a graft containment device. The x-ray fusion rate was 77% and there were no reoperations or complications. In 2004, Park et al. (12) reported results of 26 patients treated with the same mesh device. The fusion rate was 96.2% with one patient undergoing reoperation and placement of a titanium plate. Overall outcomes in both series were good. The fusion rate in our series with use of the first commercially available resorbable plate was 87.5%, in between the previously published rates using the mesh product. Prospective studies evaluating fusion rates in single-level ACDF with plating suggest fusion rates approaching 100% (3, 6, 16). These results are consistent with our arthrodesis rate of 97.8% in the titanium plate group. Thus, our results appear to be consistent with previously published outcomes.

Our data suggest fusion rates are somewhat higher with use of titanium hardware. Although controversial, there are data suggesting that the use of metal instrumentation in single-level anterior cervical fusion increases arthrodesis rates (8). The possibility that our finding is spurious cannot be excluded as a result of the small number of pseudarthrosis events in both groups. Additionally, we found a clear and consistent difference in local angulation with use of resorbable plating resulting in consistent kyphosis as compared with consistent lordosis with titanium implants. Kyphosis is biomechanically unfavorable and may be associated with increased adjacent segment degeneration, mechanical neck pain, and neurological deficit (9). Use of titanium implants has been shown to assist with maintenance of postoperative lordosis compared with noninstrumented fusions (9). The resorbable plate may be associated with increased kyphosis resulting from inadequate rigidity or unrecognized implant fracture because the devices are radiolucent.

The use of corticocancellous allografts has been extensively studied for anterior cervical fusion in the era before the popularization of anterior cervical plates in an effort to reduce donor site morbidity from autograft (1, 4, 11). It was clear from studies that, in the absence of plating, use of corticocancellous grafts was associated with an increased incidence of graft subsidence, kyphotic angulation, and pseudarthrosis. This led to widespread use of cortical grafts such as fibular struts and machined cortical grafts, which did not seem to have these problems to the same extent (17, 18). The relative structural weakness of corticocancellous grafts as compared with cortical grafts is felt to be a major contributor to this phenomenon (17). Despite this, it is well known that cancellous bone is a better substrate for arthrodesis than cortical bone (2). We used corticocancellous allografts in conjunction with plating under the theory that instrumentation would counteract the disadvantages of structural graft weakness through stress shielding while retaining the biological advantage of cancellous bone contact. There are limited data in the literature on the use of this type of construct. Previous data, however, indicate excellent results with use of corticocancellous and cancellous allografts in conjunction with plating. Balabhadra et al. (2) reported a 96% fusion rate in a study of 98 patients using cancellous allografts. Samartzis et al. (14, 15) reported a 100% fusion rate in 35 patients undergoing surgery for single-level disease and in 33 of 35 patients undergoing multilevel fusions (total of 78 levels treated). Our own data extend these results by demonstrating a 97.8% fusion rate in 93 patients with titanium plating. Use of titanium plating counteracts the tendency toward graft subsidence and angulation seen without plating. This is demonstrated by the lordotic healing in the titanium group.

The results with use of resorbable plating appear more consistent with data in unplated fusions using corticocancellous grafts, demonstrating pseudarthrosis and kyphosis. It is possible that results may be different with use of cortical allografts. As previously indicated, in unplated ACDF, use of cortical allografts was associated with improved fusion rates and angulation as compared with corticocancellous graft. Future studies

will be required to address this issue. In summary, use of the current resorbable cervical plate appears to result in a loss of many of the advantages of titanium instrumentation.

CONCLUSION

This report describes, to our knowledge, the first series of patients to undergo ACDF with the first commercially available resorbable cervical plate. Healing in kyphosis and pseudarthrosis was significantly more likely with resorbable implants as compared with use of titanium plating. Although ultimate clinical outcomes were good, x-ray outcomes may be better with use of titanium plating.

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COMMENTS

This is the first report that I am aware of to describe a reasonably sized series of patients treated with anterior cervical decompression and fusion (ACDF) using resorbable plates. The use of such devices is attractive from a biological standpoint; because the benefit of plate fixation is really limited to the immediate postoperative period, it would be nice to have a device that worked in the short term and then was resorbed to avoid potential long-term consequences of esophageal erosion, migration, and stress shielding. Bindal et al. found that although early clinical results were good using the resorbable plate, kyphosis and pseudarthrosis rates were higher at a 1-year follow-up. Early clinical results are good even without fusion after an anterior cervical discectomy. The reason for performing a fusion is to avoid late kyphosis and associated morbidity. If the use of a resorbable plate is truly associated with higher kyphosis and pseudarthrosis rates, then this technology may not be ready for widespread application. Because of the historical cohort design of the study, the evidence presented is far from definitive but is certainly intriguing.

Daniel K. Resnick
Madison, Wisconsin

Bindal et al. provide unique information regarding a resorbable cervical implant. Of note, both the pseudarthrosis and postoperative kyphosis rates were greater when the resorbable plates were used than when rigid metallic plates were used in similar patients. This is unexpected, as is the subsidence-related kyphosis. The indications for resorbable plating systems are yet to be defined. I, personally, fail to understand a need for such a technology. Although the authors point

out that clinical outcomes were equivalent, the long-term outcomes most likely will not be so. This is because the pseudarthroses become symptomatic with time, and the end-fusion degeneration changes (adjacent-segment degenerative changes) progress at an accelerated rate due to the abnormal cervical alignment (kyphosis). These factors even further diminish my enthusiasm for resorbable plate technology. The authors have presented an honest evaluation of their findings.

Edward C. Benzel
Cleveland, Ohio

Bindal et al. present a prospective clinical series on the first resorbable cervical plate, which was used in a small series of patients with single-level degenerative disease. Follow-up was a minimum of 12 months.

The control group consisted of a much larger group with single-level ACDF who were treated using titanium plates.

Radiological results were clearly not as good for the patients with resorbable plates as they were for those with titanium plates. Angulation was increased, and there were one or two more nonunions. It should be noted, however, that although there is statistical significance in the pseudarthrosis rate, the numbers are quite small, and this may not be a real issue. The changes in angulation are also statistically significant, but rather small.

Our interest in absorbable hardware is different than that found in many other institutions. We have long argued and have published biomechanical data showing that adjacent segment changes are markedly diminished when internal stresses within the fused segment are minimized; that is, less metal! Rather than being concerned about the radiological issues, we are concerned about the effects on adjacent segments.

Under those circumstances, one might argue that a slightly higher deformity rate in a single-level anterior cervical fusion is irrelevant. Unfortunately, the follow-up provided is not long enough to make that determination.

Frankly, I would have enjoyed seeing a third arm in this study, namely, individuals undergoing anterior cervical discectomy with no hardware whatsoever. I suspect that the results would have been similar, but might not have been as good as those for the patients with non-metallic plates.

In the presence of similar clinical results and acceptable nonunion rates and deformity, and with the premise of significantly decreased adjacent-segment degenerative changes, this effort warrants continuation. The authors have provided a carefully considered effort and honest reporting of what, to some extent, are negative results.

Dennis J. Maiman
Milwaukee, Wisconsin

In the present manuscript, Bindal et al. report the results of a prospective study of 24 patients with degenerative disease who underwent single level ACDF. Corticocancellous allograft and anterior instrumentation using a resorbable anterior plate were employed. This group was then compared retrospectively to a cohort who underwent single level ACDF using corticocancellous allograft and anterior instrumentation using a titanium anterior plate.

The results document statistically significant postoperative improvement in the Neck Disability Index and Numerical Rating Scale, when compared to preoperative scores. When the study group was compared to the cohort, a significantly higher nonunion rate was found. In addition, a significantly greater degree of kyphosis was seen, even with exclusion of patients harboring a nonunion. The authors conclude that,

while short-term clinical outcomes were acceptable, resorbable plates yielded inferior radiographic outcomes.

These data illustrate both the strengths and weaknesses of the present generation of resorbable anterior cervical plates. This particular implant is marketed as a graft-containment plate. As no graft extrusions were reported, one may conclude that the plate was successful in controlling this complication. However, as discussed by the authors, corticocancellous allografts, when used in this manner, appear to require supplemental rigid fixation to reap their theoretical biological benefits. These data suggest that the studied resorbable implant is not sufficiently rigid to do so.

Christopher Wolfa
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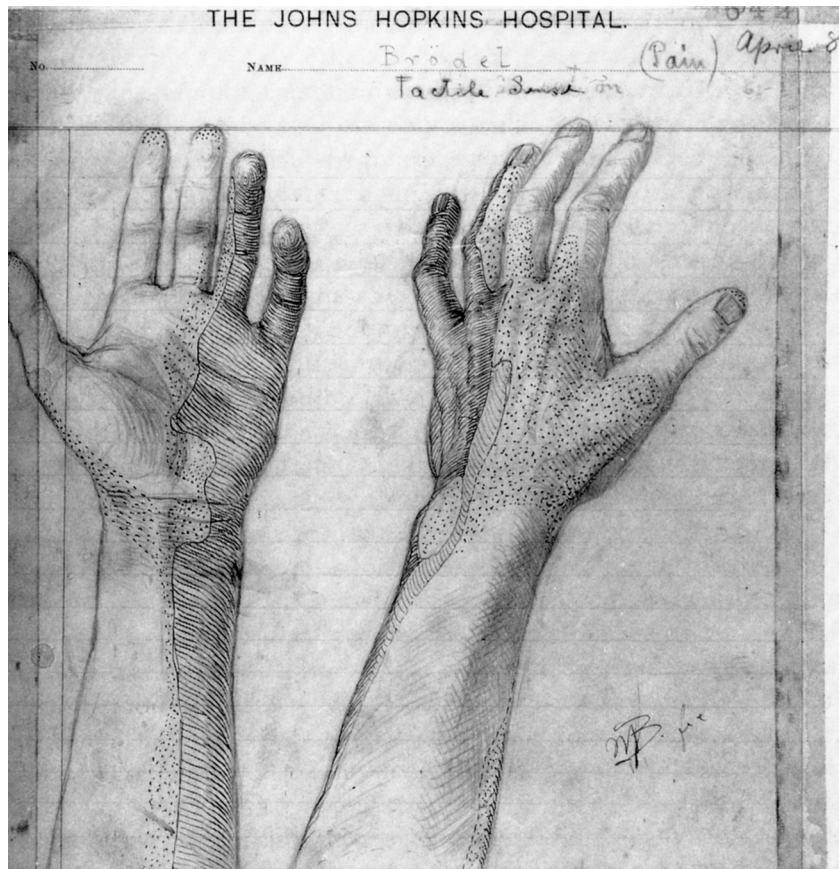
Bindal et al. report their initial experience using resorbable polylactic acid (PLA) anterior cervical fixation. The article summarizes both clinical and radiographic intermediate-term results on 24 patients, and compares this with a noncontrolled cohort of similar patients undergoing surgery with titanium plates. The conclusion reached is that the resorbable instrumentation was not associated with clinically significant complications, but radiographic parameters such as pseudarthroses and local kyphosis were more prevalent.

As an initial evaluation, one would be led to believe that the resorbable instrumentation is in fact inferior to the titanium implants, especially considering that the economic costs of these devices are somewhat similar. However, one could also argue that because the

study sample was small, the comparison groups not controlled, and the follow-up of too short a duration, that no definitive conclusions can be ascertained. Unfortunately, this is a discussion that emerges all too frequently in neurosurgical arenas where the pace of technological change is rapid and there exists powerful commercial interests, such as those in spinal surgery.

It is my belief that articles such as this one by Bindal et al. are actually highly informative and critical for the advancement of medicine. The honest assessment of any new technology, with particular attention directed to its potential shortfalls, is vital if we are to expand our surgical armamentarium but should not necessarily be viewed as an indictment of the devices being studied. I have personally used many varieties of resorbable anterior cervical plates and have found them to be effective. If critical attention is placed on the interbody graft carpentry and local osteobiological environment, then I am hopeful that future iterations of resorbable implants will become available as our knowledge of material science progresses. One only has to review the history of PLA materials to see how far we have come in preventing complications such as sterile abscess formation, which was rampant with PLA orthopedic implants a decade ago. In the future, it is likely that newer formulations, or even non-PLA materials, will also enter the arena and replace at least a subset of metallic fixation devices, providing us with more biomechanically and biologically appropriate implant materials for the human body.

Michael Y. Wang
Miami, Florida



Max Brödel's sketch of his left hand and arm indicating areas of hyperesthesia (dotted) and anesthesia (lines), April 8, 1899. Brödel suffered from a streptococcal infection following dissections of a deceased patient who died of a streptococcal infection and had four operations to abate the severe sepsis that followed. From Crosby RW, Cody J: *Max Brödel: The Man who put Art into Medicine*. New York, Springer-Verlag, 1991.