

Yes Dear, That is the Logical Next Step

Stanley A. Brown, Katharine Merritt

Bay Hundred Biomaterials.

In celebration of the life of our dear friend Bill Hall and the SFB, we would like to share with you some of the events that led to our careers with the Society.

Fracture Healing: In the early 70's Stan was working with an orthopaedic surgeon, Dr. Mike Mayor, at the Dartmouth Hitchcock Clinic on the idea using plastic IM pins as insulators for electrical stimulation of fracture healing at the fracture site. In talking with those in the field and in writing proposals, the idea came to mind: "Would the fractures heal better just because the plastic pins are more flexible than bone?" The next step was studies with plastic and metal rods for fixation of fractures of the rabbit tibia (1).

The next logical step was plastic plates on canine femora for more control of rotation and apposition. This led to chopped carbon fiber composites for more strength and stiffness which could be heated and contoured.

Metal Allergy and Corrosion: In the early '70s, Kathy was working with another surgeon at Dartmouth Hitchcock, developing a test (LIF) for colon cancer. A patient of Dr. Mayor's presented with reversal of healing of the trochanteric osteotomy after THR, fracture of the wires, and bone resorption around the wires. "Could this be due to an allergic reactions to the wires?" The logical next question was: "Could Kathy's LIF test be used to test for metal allergy?" The answer was "yes" and this led to a series of clinical studies of metal allergy, and analysis of retrieved implants for evidence of corrosion.

But, "what to do about the patient?" Logically, we considered plastic sutures. After lab testing it was decided to remove the wires and fix the osteotomy with #8 Dacron (1).

To learn more about the reactions, we developed an *in vivo* model with metal screws in the rabbit humerus and injected the animals with metal salts to stimulate the immune system. At the 1980 WBC Kathy was asked "Why aren't you using corrosion products?" Her next logical step was: "Stan, can you make me some corrosion products?" He used a method developed to electrolytically dissolve metallic implants in histological specimens. "But the allergic reaction is to a metal-protein complex, here let me pour some calf serum into your test chamber." What a mess of foaming proteins, and what a mess of pits on the corrosion specimen. This led to a whole series of corrosion testing in saline and serum solutions and correlation with *in vivo* data on metal ion release in RBC, serum and urine. Calculations indicated that chromium was being released with a valence of +6 and was strongly bound to the red cells. "But implants don't corrode due to the application of 5 volt anodic potentials!" This led to a whole series of fretting corrosion experiments. To verify the cell binding of Cr+6, we fretted in cell culture. Chromium was in the fibroblasts, nickel was in the solutions. These fretting studies eventually led to the next step of the fretting of the bore and cone interface of modular THRs.

Implant Site Infections: After hearing a seminar on anaerobic infections, again back in the early '70s, Stan asked Kathy "How do you set up an anaerobic cell culture?" "Oh, you can pump it down with nitrogen, or throw in some chopped meat and iron filings." "Gee, that sounds like orthopaedic surgery." In studies of biomaterials and implant site infections, it was becoming known that multifilament sutures had a higher infection rate than monofilament ones. "Would the same apply to porous coating being developed for TJR fixation?" We found that the answer was "yes" for acute studies, but "no" if there was sufficient time for tissue ingrowth prior to contamination of the implant site. (1)

SFB 1993: As Cochairs of the 1993 SFB in Birmingham, we wanted to add something new to the program. During the 1991-2 meetings, we visited a lot of the commercial exhibits and enquired whether they would like to give a technical presentation in Birmingham. The reaction was overwhelming so we organized the first of what we called the Industrial Sponsors program.

At the time, abstracts were typed in two oversized columns, using typewriters, and glued to an oversized form which was mailed to the program committee – no internet. We were now using computers and we had laser printers which could print reduced fonts. So Stan and his students worked to figure out the printing settings for Mac and PC, to print the equivalent of an oversized form on standard 8 x 11 1/2" paper (2). This too, did turn out to be a logical next step.

Research at FDA: One major area we got into was reuse of single use devices (SUDs). We looked at effects on devices and materials, and residual ETO from resterilization. With the advent of TSE or mad cow disease, the CDC proposed autoclaving in sodium hydroxide or soaking in chlorine bleach, to decontaminate expensive reusable devices. Autoclave manufacturers said the warranties would be invalid if NaOH was used. The logical next step for us was to do the experiment; test different containment vessels for controlling the caustic vapors. Much like a cast iron Dutch oven, pans and lids were found to protect the autoclave from damage. As for the instruments, we did all the methods, and found some low cost instruments suffered in bleach. The big surprise was the damage done to gold plated handles on high cost instruments.

Conclusion: We have both retired. Or have we? Kathy has taken the logical next step to become a part time consultant. Its too soon to know about Stan. But what ever you do, ask good questions, take logical next steps, and come to SFB to share the results with us.

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References: 1. presented at SFB 1976. 2. Tra SFB XVI: 1, 1993