Oxidation of Silicone Elastomer Finger Joints

Sanjiv H. Naidu, MD, PhD

From the Department of Orthopaedic Surgery and Rehabilitation, Penn State College of Medicine, Hershey, PA.

Purpose: We analyzed the oxygen content of 19 retrieved implants and 6 packaged implants to further understand the mechanism of degradation of silicone elastomer finger joints while *in vivo*.

Methods: Nineteen Swanson (Wright Medical Technology, Arlington, TN) silicone elastomer finger joints were retrieved at revision surgery at an average of 7 years of use. Six packaged and expired implants (5 years after the expiration date) along with the retrieved implants were studied with an elemental analyzer for the total percentage (by weight) of oxygen content.

Results: The retrieved implants showed a mean total oxygen content of 0.41% ± 0.35%, whereas each of the packaged specimens showed less than 0.1% total oxygen content. Eight of the 19 retrieved implants remained unoxidized. There was no correlation between implant fracture and the oxygen content of the retrieved implants.

Conclusions: Our results suggest that silicone elastomers are oxidized *in vivo*. Although such oxygen embrittlement may have implications in compromising silicone elastomer material mechanics during *in vivo* use, our data indirectly suggests that mechanical factors also have an important role in the final fracture of the silicone elastomer implant. (J Hand Surg 2007; 32A:190–193. Copyright © 2007 by the American Society for Surgery of the Hand.)

Key words: Silicone, elastomer, arthroplasty, prosthetic, oxidation.

In the past 4 decades silicone elastomers have become the standard for small-joint replacement arthroplasty of the fingers; today there is some controversy that the silicone elastomer finger joint material degrades during *in vivo* use.[1–6] The mechanism of degradation of the silicone elastomer material in the finger joints is addressed incompletely in the literature.

Although Carmen and Mutha[1] showed a positive correlation between lipid absorption and the time of exposure of silicone heart poppets, Swanson and Lebeau[2] and Pfleiderer et al[3] found no correlation between the amount of lipid uptake and the condition of the finger joints removed or the time in use. Weightman et al[4] reported that discoloration of silicone rubber as a result of lipid absorption is accelerated by flexural stresses. The yellowing of the implant hypothetically was attributed to the lipid absorption.

A more rigorous approach was adopted by Ward and Perry,[5] only to be refuted later by Naidu et al[6] using dynamic mechanical analysis. Although Ward and Perry[5] showed marked alterations in the silicone elastomer viscoelastic properties in pseudo-extracellular fluid over a 4-month period, Naidu et al,[6] in an *in vivo* rabbit knee model, definitively showed that 4 months of implantation and *in vivo* use did not alter the finger joint silicone elastomer viscoelastic properties. Both studies, however, focused on the short-term exposure with implants.

It also is well known that elastomer aging by oxidation leads to inferior fatigue crack propagation and fissuring of elastomers in general. One percent oxygen by weight within the elastomer bulk can degrade the elastomer fatigue propagation by 2-fold.[7] Although silicone rubbers traditionally have been considered resistant to oxidation, our hypothesis was that oxidative aging of silicone elastomer implants occurs during *in vivo* use.

Materials and Methods

Nineteen Swanson (Wright Medical Technology, Arlington, TN) silicone elastomer metacarpophalangeal finger joint implants were retrieved from 6 patients during revision surgery for recurrence of deformity and pain (Table 1). The implants were retrieved from 3 men

Table 1. Retrieval Analysis of Silicone Finger Joints

Implant No.	Time in Use, y	Diagnosis	Finger	Patient Age, y (M/F)	Failure Mode	Oxygen, %
MDR2	6	RA	Index	62 F	UHR	0.79
MDR3	6	RA	Middle	62 F	UHR	<0.10
MDR4	6	RA	Ring	62 F	UHR	<0.10
MDR5	6	RA	Small	62 F	UHR	0.25
SHL5	5	TR	Small (PIP)	55 F	DIS	1.04
EML2	10	RA	Index	80 F	DSW	<0.10
EML3	10	RA	Middle	80 F	F	0.81
EML4	10	RA	Ring	80 F	RHW	0.42
EML5	10	RA	Small	80 F	UHR	0.70
HSL2	7	RA	Index	71 M	F	0.62
HSL3	7	RA	Middle	71 M	F	1.06
JJL2	7	RA	Index	73 M	F	<0.10
JJL3	7	RA	Middle	73 M	F	0.51
JJL4	7	RA	Ring	73 M	F	0.19
JJL5	7	RA	Small	73 M	F	0.50
JHR2	8	RA	Index	71 M	F	<0.10
JHR3	8	RA	Middle	71 M	UHR	<0.10
JHR4	8	RA	Ring	71 M	F	<0.10
JHR5	8	RA	Small	71 M	F	<0.10

RA, rheumatoid arthritis; UHR, ulnar hub rupture secondary to ulnar deviation deformity, and compressive and shear forces at the ulnar hub of the implant; TR, trauma; PIP, proximal interphalangeal joint; DIS, dislocated implant; DSW, distal stem wear at hub-stem junction both on the palmar and dorsal surface without complete fracture, but with obvious crack initiation; F, distal stem fracture at the junction of the implant hub and the distal stem; RHW, radial hub wear.

and 4 women, with an average age of 69 years. The mean *in vivo* length of use for each implant was approximately 7 years. At the time of retrieval there was no gross evidence of silicone synovitis,[8] which usually is characterized by hard yellowish tissue with little surrounding fluid. Six packaged and expired implants (5 years after package expiration date) that were stored effectively at atmospheric pressure, along with the retrieved implants, were sectioned and weighed.

Oxygen analysis was performed with an elemental analyzer (Perkin Elmer 2400 CHN; Shelton, CT).[9] Briefly, the entire system consists of 4 major zones: the pyrolysis zone, the gas control zone, the separation zone, and the detection zone.

In the pyrolysis zone, the weighed samples encapsulated in tin vials are inserted and pyrolyzed. In the presence of argon or helium, the volatile oxygen is converted into carbon monoxide (CO) by high temperature and contact with a platinized carbon reagent. The carrier gas then sweeps the CO and other byproduct gases into the gas control zone; gases then are separated by frontal chromatography, and the CO then is passed through a thermal conductivity detector system. The oxygen content then is obtained as a weight percentage of the original sample. An oxygen content greater than 0.2% was considered significant. One sample *t* test was used to determine statistical significance. The Fisher exact test was used to examine the implant fracture incidence between the oxidized and unoxidized retrieved implants.

Results

The retrieved implants were yellowed, deformed, and fractured (Figs. 1–3). The fragmentation of the ulnar

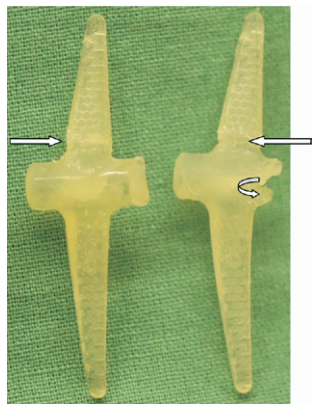

Figure 1. Solid left and right arrows point to the area of distal stem-hub junction wear where the stress is concentrated during *in vivo* use. Although the implant initially was designed to flex at the hub, it is clear from these retrieved specimens that all flexion-extension occurs distal to the hub. Curved right arrow points to the area of ulnar hub rupture, consistent with the ulnar deviation forces at the metacarpophalangeal joints of a rheumatoid hand.