Arthrex® Bio and BioComposite™ Implants: Post-Op Complaint Analysis

Arthrex Research and Development

Objective

The use of biodegradable implants in orthopedic applications has, in rare instances, been attributed to local inflammatory responses. Polymer degradation that occurs too quickly may decrease the local pH at the surgical repair site, thereby increasing the activity of osteoclasts to resorb tissue and screw material, weaken the interface, and induce inflammation[1,2]. These inflammatory responses have been characterized by Weiler, et al. as "mild, nonspecific tissue responses with fibroblast activation and the invasion of macrophages, multinucleated foreign-body giant cells, and neutrophilic polymorpho-nuclear leukocyctes during [the polymer's] final stage of degradation.[3]" Reaction rates to polylactic acid (PLA) have been reported in literature to range from 0%[4,5,6] to 0.04%[7], 0.2%[8], 1.2%[9], 3.7%[10], and even as high as 16.2%[11] and 60%[12]. There are a multitude of variables affecting the rate of degradation, including implant and environmental factors[13], by-products of degradation, and inherent differences in composition from one medical device company's material to another. For this reason, specific complaint rate analyses should be investigated per medical device company and material. In this review, we provide post-op complaint rates for our biodegradable implants.

Methods and Materials

Arthrex reviewed all complaints received from June 2004 through March 2016 that were related to biodegradable and non-biodegradable implants. Our biodegradable implants include Bio (100% polymer) and BioComposite (polymer and ceramic). Our non-biodegradable implants include PEEK (polyetheretherketone) and metal. All complaints associated with inflammatory response or reaction were included in this analysis. Arthrex implant sales data were populated from June 2004 through March 2016.

Results

All data compiled from June 2004 through March 2016 is shown in Table 1. The following reaction rates were observed: Bio = 14 per million implants, BioComposite = 17 per million implants, PEEK = 8 per million implants, and the Metal = 13 per million implants.

Table 1

Material	Units Sold	Reactions	Reaction Rate
Bio	7,784,761	106	0.0014%
BioComposite	6,121,312	105	0.0017%
PEEK	2,447,892	20	0.0008%
Metal	7,621,823	98	0.0013%

*Data on file

Conclusion

The complaint data compiled for this review clearly demonstrates that the risk of inflammatory response or reaction is very low for both the biodegradable and non-degradable implants manufactured by Arthrex, Inc. Arthrex maintains that the safety and effectiveness of our carefully selected materials contribute to safe and successful patient outcomes.

References

1. Komarova, et al. *PNAS*. 2005; (102):2643-2648.
2. Hunt, et al. *KSSTA*. 2008; (16):655-660.
3. Weiler, et al. *Arthroscopy*. 2000; (16):305-321.
4. Barber, et al. *Arthroscopy*. 1995; (11):537-548.
5. Tan, et al. *Arthroscopy*. 2006; (22):716-720.
6. Frank, et al. *Am J Sports Med*. 2008; (36):1496-1503.
7. Burkhart. *Am J Sports Med.* 2005; (33):1768.
8. Bostman. *Clin Orthop Relat Res*. 2000; (371):215-227.
9. Bucholz, et al. *J Bone Joint Surg Am*. 1994; (76):319-324.
10. Cummins, et al. *Arthroscopy*. 2003; (19):239-248.
11. Anderl, et al. *European Cells Materials*. 2006; (12):51.
12. Bergsma, et al. *J Oral Maxillofac Surg*. 1987; (45):751-753.
13. Kontakis, et al. *Acta Orthop Belg*. 2007; (73):159-169.
14. Data on file, Arthrex Inc.