
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 polymorphonuclear leukocytes during [the polymer’s] final stage of degradation.”³ In literature, reaction rates to polylactic acid (PLA) have been reported to range from 0%^{4,5,6} to 0.04%,⁷ 0.2%,⁸ 1.2%,⁹ 3.7%,¹⁰ and 60%.¹¹ There are a multitude of variables affecting the rate of degradation, including implant and environmental factors,¹² by-products of degradation, and inherent differences in composition from one medical device company’s material to another’s. 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 October 2019 that were related to biodegradable and nonbiodegradable implants. Our biodegradable implants include bio (100% polymer) and biocomposite (polymer and ceramic materials). Our nonbiodegradable implants include PEEK (polyetheretherketone) and metal. All complaints associated with inflammatory responses or reactions were included in this analysis. Arthrex implant sales data were populated from June 2004 through October 2019.

Results

All data compiled from June 2004 through October 2019 are shown in Table 1. The following reaction rates were observed per million implants: Bio = 14, Biocomposite = 14, PEEK = 11, and Metal = 13.

Table 1.

Material	Units Sold	Reactions	Reaction Rate
Bio	8,784,189	122	0.0014%
Biocomposite	11,872,077	168	0.0014%
Nonmetallic or PEEK	4,126,117	44	0.0011%
Metallic	14,788,552	190	0.0013%

Conclusion

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



References

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