Arthrex Bio and BioComposite Implants: Postoperative Complaint Analysis

Arthrex Orthopedic Research

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 poly-lactic acid (PLA) have been reported in the literature to range from 0%[4-6] 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], byproducts 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 manufacturer and material. In this review, we provide postoperative complaint rates for our biodegradable implants.

Methods and Materials

Arthrex reviewed all complaints received from June 2004 through March 2024 that were related to biodegradable and nonbiodegradable implants. Our biodegradable implants include Bio (100% polymer) and BioComposite (polymer and ceramic). Our nonbiodegradable 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 2024.

Results

All data compiled from June 2004 through March 2024 are shown in Table 1. The following reaction rates were observed: Bio= 13 per million implants, BioComposite= 11 per million implants, PEEK= 10 per million implants and metal= 13 per million implants.

Table 1.

Material	Units Sold	Reactions	Reaction Rate
Bio	9,121,370	123	0.0013%
BioComposite	19,179,963	220	0.0011%
PEEK	6,650,243	67	0.0010%
Metal	26,675,671	340	0.0013%

Conclusion

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

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