Arthrex® Bio and Biocomposite Implants: Post-op Complaint Analysis by Product Family

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 leukocytes during [the polymer's] final stage of degradation."[3] Reaction rates to polylactic acid (PLA) have been reported in literature to range from 0%,[4-6] to 0.04%,[7] 0.2%,[8] 1.2%,[9] 3.7%,[10] and even as high as 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. For this reason, specific complaint rate analyses should be investigated per medical device manufacturer 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 December 2019 that were related to biodegradable implants. Our biodegradable implants include bio (100% polymer) and biocomposite (polymer and ceramic) materials. All complaints associated with patient infection or reaction were included in this analysis. Arthrex implant sales data were populated from June 2004 through December 2019.

Results

All data compiled from June 2004 through December 2019 are shown in Table 1 and were broken down according to product family.

Table 1

Reaction Rates for Bio Implants by Product Family		
Product Family	**Reaction Rate (%)**	**Reaction Rate Per Million**
Bio-SwiveLock™ Anchor	0.0009	9
Bio-Corkscrew® Anchor	0.0020	20
Bio-PushLock™ Anchor	0.0011	11
Bio-SutureTak® Anchor	0.0004	4
Bio Total	0.0012	12
Reaction Rates for BioComposite Implants by Product Family		
Product Family	**Reaction Rate (%)**	**Reaction Rate Per Million**
BioComposite SwiveLock® Anchor	0.0010	10
BioComposite Corkscrew® Anchor	0.0007	7
BioComposite PushLock® Anchor	0.0005	5
BioComposite SutureTak® Anchor	0.0012	12
Biocomposite Total	0.0009	9

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 bio and biocomposite 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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