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Short Commentary

Dispelling the false narrative associated with polyurethane breast implants

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Introduction

In the contemporary digital era, the accessibility of online information has transformed the dissemination of medical knowledge. While this has facilitated intellectual advancement when sources are robust and appropriately interpreted, it has equally increased the risk of misinformation, scientific misinterpretation, and dissemination of inaccurate or misleading claims. These challenges are particularly evident in the ongoing discourse surrounding polyurethane-coated breast implants used in both aesthetic and reconstructive surgery.

Implant selection remains a nuanced clinical decision, guided by individual patient anatomy, clinical indication, and surgeon expertise, alongside important medico-legal considerations. A thorough understanding of the historical evolution and evidence base underpinning breast implant technology is therefore essential for informed clinical practice [1-6].

Background and controversy

Polyurethane-coated silicone breast implants have been in clinical use since the late 1970s, initially manufactured in Brazil (Silimed™) and subsequently in Germany (Polytech™). Recent legal determinations have confirmed patent ownership of the polyurethane coating technology, consolidating Silimed™ as the principal global manufacturer [7].

Since their introduction, polyurethane implants have been subject to recurrent controversy. Concerns have historically included potential carcinogenicity, risk of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), implant degradation, and technical challenges related to explantation. However, a critical appraisal of the literature demonstrates that many of these concerns are not substantiated by clinical evidence.

Early claims of carcinogenicity were derived from rodent studies involving high-dose oral exposure to Toluene Diamine (TDA), a degradation product of polyurethane in much smaller quantities. These findings in rodents have not been replicated in human studies and have been subsequently challenged on methodological grounds [8-10]. Importantly, there remains no credible clinical evidence linking polyurethane implant degradation products with malignancy in humans [11-14]. Despite this lack of evidence polyurethane implants are still not approved for use by the Food and Drugs Administration (FDA) in the USA or Canada.

Clinical performance and safety

The broader use of silicone in medical devices underscores a generally accepted safety profile, although not without recognised complications such as inflammatory responses following gel leakage [15-17]. Historical concerns regarding silicone implants similarly led to regulatory restrictions, which were later reversed following large-scale studies demonstrating acceptable safety outcomes [18].

Notably, no robust, independently controlled randomised trials have directly compared implant types, but generic risks associated with using different manufacturers silicone implants are well documented, including from the use of non-medical grade silicone as filler [19-22]. Nevertheless, cumulative

observational data consistently demonstrate favourable outcomes associated with polyurethane-coated implants. These include significantly reduced capsular contracture rates, lower reoperation rates, and high patient satisfaction [23-27].

Capsular contracture rates with polyurethane implants are reported to be less than 1% at five years, rising modestly to approximately 3% at ten years-substantially lower than rates observed with conventional silicone implants [20,25-27]. These outcomes are attributed to the unique bio-integrative properties of the polyurethane coating, which facilitates a three-dimensional collagen lattice and stable implant fixation [28].

Biological integration and degradation

Following implantation, fibroblast migration into the polyurethane matrix promotes tissue integration, resulting in a stable pseudo-synovial interface. Over time, the polyurethane coating undergoes gradual biodegradation, with minimal residual material detectable at approximately ten years post-implantation.

Degradation products, including TDA, are transiently detectable in urine but at levels comparable to environmental exposure in non-implanted individuals. There is no evidence to suggest that such exposure confers carcinogenic risk [11,14,29].

Contemporary risks

The incidence of BIA-ALCL associated with polyurethane implants remains exceedingly low and comparable to that observed with microtextured silicone implants [31-33]. Assertions of increased risk specific to polyurethane surfaces have not been consistently replicated and lack robust biological plausibility.

Similarly, breast implant illness has not been reported in association with polyurethane implants, raising the possibility of a protective effect conferred by the bio-integrative capsule.

Surgical considerations

Successful implantation of polyurethane devices requires meticulous surgical technique, including precise pocket preparation and avoidance of fluid accumulation. The conical shaped polyurethane implants manufactured by Silimed ™(Brazil) were preferred because produced better outcomes than anatomical or round implants [34]. These implants were voluntarily withdrawn from the EU in 2015. Optimal outcomes are achieved when implants are placed in a dry, appropriately sized pocket with full tissue contact, facilitating effective integration [35].

The use of drains is generally discouraged, as they may disrupt adherence and increase the risk of seroma formation. In revision procedures, complete capsulectomy is recommended to minimise complications and optimise implant performance.

Conclusion

Polyurethane-coated breast implants represent a clinically effective and well-supported option in both aesthetic and reconstructive breast surgery. Despite persistent misconceptions, the current body of evidence does not support claims of increased carcinogenicity or unacceptable risk.

On the contrary, these implants demonstrate superior outcomes in key clinical parameters, particularly capsular contracture and reoperation rates. It is incumbent upon clinicians to critically appraise the literature and provide patients with balanced, evidence-based information to counter prevailing misinformation.

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