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Short Communication

Prosthesis Contact Dermatitis with Long-Term Prosthetic Lining Usage

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Abstract

Limb loss is a multifaceted, significant issue that affects millions of civilians and veterans in the United States, primarily due to vascular disease and trauma. Over two million individuals in the United States have experienced limb loss, with a predicted expectation of that number doubling by 2050. Prosthetic devices are currently used by 1.7 million people living in the United States. The use of prosthetic limbs provides improved autonomy, mobility, and overall quality of life. Complications may arise throughout the trajectory of prosthetic limb usage, including epidermoid cysts, epidermal hyperplasia, follicular hyperkeratosis, allergic or irritant contact dermatitis, bullous diseases, ulcerations, and infections. While skin irritation can occur at any stage of using a prosthetic limb, there have been many cases where allergic contact dermatitis develops in the prosthetic lining after decades of use. When allergic contact dermatitis develops over time to certain materials comprising prosthetic limbs (e.g., polyurethane, urethane, polyethylene, latex, and silicone), alternative options are currently very limited. Additionally, the cost and lack of availability of alternative materials leave many patients forced to sacrifice their independence and mobility. Solutions to prosthesis contact dermatitis with long-term prosthetic usage must be addressed to allow continued autonomy and mobility for individuals experiencing limb loss.

Keywords: child abuse; imaging; bony fractures; review

Introduction

Contact dermatitis may be attributable to polyurethane, urethane, polyethylene, latex, and silicone being widely used for medical and non-medical purposes. Silicones are polysiloxane polymers with low allergenicity and high biocompatibility due to their physicochemical characteristics. Many of these materials are used in medical devices such as pacemakers, cochlear and breast implants, as well as cosmetology and household products (1, 2, 3). While silicone coatings are often utilized to avoid hypersensitivity to the metal parts of cochlear implants and pacemakers, there have been reports of hypersensitivity to the coating, which may mimic recurrent infections at the implant site (4, 5, 6). Similar cases have been presented with silicone breast implants (7, 8).

While skin irritation can occur at any stage of using a prosthetic limb, there have been many cases where allergic contact dermatitis develops from the prosthetic lining after decades of use. Plastic resins, cements, foam rubber cushions, and plastic-covered pads can all produce allergic sensitization over decades of use (Bowker, HK). Allergic contact dermatitis may occur from agents manufacturing the prosthetic device, lining, or socket. Delayed hypersensitivity may develop from multiple materials used in creating the prosthetic limb and lining. Allergic or irritant contact dermatitis may be contributed to by nickel, chromates, lanolin, rubber additives, dyes, varnishes, lacquers, resins, plastics, and rubbers used within the device. Additional known allergens in prosthetic materials include para-tertiary butylphenol formaldehyde, para-phenylenediamine, epoxy resins, and thioureas, amongst others (Lyon, C).

Contact dermatitis to prosthetic lining materials may occur with continuous use, and it can be challenging to diagnose. The patient may present with symptoms mimicking recurrent wound infection (So, S). Possibly, patch testing may adequately confirm the diagnosis of hypersensitivity in patients suspected of having atypical symptoms and contact dermatitis. This article will discuss prosthesis contact dermatitis with long-term usage and current recommendations for addressing the lack of alternative materials.

Discussion

Prosthetic limbs are currently used by nearly two million people in the United States. Limb loss significantly impacts civilians and veterans in the United States. Most limb loss occurrences are due to vascular disease or trauma. The number of Americans experiencing limb loss is expected to reach nearly four million individuals by 2050 (Amputee Coalition). Amputations are often the beginning of a lifetime of treatment by a dermatologist, prosthetist, and rehabilitation team. Prosthetic materials have irritant or allergenic effects leading to dermatological concerns, often requiring acute consults and continuous care.

Dermatologists frequently treat patients with amputations for skin problems that may result from wearing an artificial limb. As the skin is in constant contact with synthetic materials, such as silicone or plastic, a barrier arises since the skin is not well-suited for continuous contact with synthetic substances (Highsmith, M). Skin problems are currently one of the most common conditions affecting lower-limb prosthetic users, impacting approximately 75% of amputees using a lower-limb prosthesis (Highsmith, M). Amputees experience over 60% more dermatological complaints than non-amputees. Specifically, skin concerns may be attributable to prosthetic fit and alignment problems, but complications such as allergic contact dermatitis, bullous diseases, epidermal hyperplasia, epidermoid cysts, and follicular hyperkeratosis may also occur. Skin lesions are of tremendous importance in individuals experiencing limb loss due to the mental, social, and economic impact they may have on the amputee. Minor irritations are highly suggested to be dealt with early and viewed as a potentially dangerous symptom given the risk of the amputee having to trade in their prosthetic limb for crutches or a wheelchair due to skin irritation, eruption, or ulceration (Bowker, HK). Amputees may go for months or years without skin irritation or dermatologic complaints, but skin lesions can start to develop decades after continuous use.

While skin conditions are frequently noted due to pressure or friction of the prosthetic device or limb, the amputee's skin remains vulnerable to allergic contact dermatitis of materials used to manufacture the prosthetic device (Bowker, HK). Skin irritation can occur at any stage of using a prosthetic limb, and there have been many cases where allergic contact dermatitis develops from the prosthetic lining after decades of use. The prevalence and incidence of contact dermatitis on amputated limbs are unknown; however, in a study of 210 amputees, Lyon, and colleagues found 34% of their patients had skin problems (Lyon, C). Specifically, contact dermatitis represented more than one-third of all cases. Contact dermatitis is often seen in amputees who wear a prosthesis due to the skin lacking adaptability to heat, humidity, pressure, increased bacteria, occlusion, humidity, and friction (Rietschel, RL). Materials in the prosthesis itself or in the straps/attachments/liners may lead to contact dermatitis and produce a reactive allergic response. Many different allergens are culprits in prosthesis-induced allergic contact dermatitis. A few of the allergens that individuals experience sensitivities to are para-tertiary butylphenol formaldehyde, para-phenylenediamine, epoxy resins, and thioureas, amongst others (Lyon, C).

An individual using a prosthetic device may have an acute or chronic inflammatory skin reaction caused by an irritant or allergenic substance contained within the prosthetic limb lining. Irritant contact dermatitis can result when the skin directly encounters certain chemicals and irritants. Chronic irritant dermatitis is frequently seen in older amputees (Bowker, HK). Allergic contact dermatitis may occur from agents manufacturing the prosthetic device, lining, or socket. Delayed hypersensitivity may develop from multiple materials used in creating the prosthetic limb and lining. This type of hypersensitivity may result in intense itching, burning, and skin irritation. Allergic contact dermatitis may be contributed to by nickel, chromates, lanolin, rubber additives, dyes, varnishes, lacquers, resins, plastics, and rubbers used within the device.

Contact dermatitis is frequently seen in amputees wearing prostheses and presents as an erythematous weeping pruritic eruption. If the patient has repeated contact of the prosthesis with the skin, the allergic contact dermatitis will transform into a chronic dermatitis leading to lichenification, hyperpigmentation, and pruritus (Lyon, C). The area of contact dermatitis can either be localized or more diffusely spread. Prosthesis users will most commonly develop various skin rashes and lesions on the amputated limb directly under the prosthetic device when the device is in direct contact with the skin or with prolonged use of the device in direct contact with the skin (Sood, A). Irritant contact dermatitis and allergic contact dermatitis are two of the most common dermatologic concerns impacting prosthetic users. Both occur when the skin is exposed to a material creating irritation and aggravation to the skin barrier. If contact dermatitis is left untreated, it can lead to chronic inflammation, cellular damage, and carcinogenesis (Highsmith, M). Prosthetic users are encouraged to seek dermatologic care and patch testing if they have a lesion that refuses to heal with conservative treatment.

Prosthetic device users may opt to use a device with a hard socket, or they may choose to use a soft prosthetic liner. A hard socket is made of a rigid material and the limb can be placed directly into the socket (Bowker, HK). This design may be used if the limb has healthy, thick skin and ample soft tissue to cover any bony prominences (Bowker, HK). In contrast to a hard socket, soft prosthetic liners act as a physical barrier and cushion between the soft tissue at the distal aspect of an amputated limb and the rigid prosthetic device (Klute, G.K.). These liners are specifically designed to fit inside the prosthetic socket (Bowker, HK). The utility of these liners is two-fold: Not only do they protect the soft tissue as it articulates with the prosthetic device, but they also work to dampen pressure during activities such as ambulation. This type of liner is ideal for users who have thin and sensitive skin, or those who may have sharp, bony prominences at the site of amputation (Bowker, HK).

Some of the most common materials used to construct hard sockets are high- and low-density polyethylene, polypropylene, unsaturated polyester resin, epoxy resin, and vinyl ester resin (Quintero-Quiroz, C.). Although the current literature has few documented cases of allergic contact dermatitis to prostheses, the materials used to make these devices have been implicated in confirmed allergic reactions. For example, a case study documented an allergic reaction to a splint made of polyethylene that was used for de Quervain tenosynovitis. After two days of exposure, the patient developed a pruritic, erythemato-squamous, oedematous plaque at the site of contact, and subsequent patch testing confirmed allergic contact dermatitis (De Mateo, J.A.). Another study documented four patients who reacted to polyester resins found in car repair cements/putties. The allergic contact dermatitis was confirmed using the cements found at the patient's workplace, as well as standard polyester cements used in a patch test series (Aalto-Korte, K.). Additionally, a review of the North American Contact Dermatitis Group database documented 250 patients who had allergic contact dermatitis to epoxy resins after occupational exposure (Xiong, M.).

Common materials used to construct soft liners include polyurethane, urethane, polyethylene, latex, and silicone (Quintero-Quiroz, C.). A study investigated a contact dermatitis outbreak in individuals who worked at a vehicle equipment factory and were exposed to polyurethane foam. Seven of the workers were diagnosed with allergic contact dermatitis (Kiec-Swierczynska, M.). Another study of 167 patients found that 2.4% had a type IV hypersensitivity to natural latex found in rubber products (Gottlober, P.). Although latex allergies are typically associated with type I reactions, it is important to note that latex can also induce allergic contact dermatitis. Case reports have also documented allergic contact dermatitis to silicone found in positive airway pressure (PAP) masks. A 42-year-old male developed allergic contact dermatitis to his PAP mask after one month of use. The patient had similar reactions to other masks, and patch testing ultimately confirmed the reaction was to silicone and propylene glycol (Rath, S.). Similarly, another case report documented a 57-year-old man who developed allergic contact dermatitis to silicone in his PAP mask and to the frame of his plastic reading glasses (Prasad, A.).

When approaching a suspected case of allergic contact dermatitis in the setting of prosthetic device use, it is essential first to obtain a thorough history. For example, the patient's history may reveal a recent repair of their prosthetic device. In those cases, the patient's reaction may be towards the various cements and substances used to repair the prosthetic and not the original prosthetic material (Bowker, HK). In such an event, simply replacing the patient's damaged prosthesis with a new device should resolve their reaction. However, if the reaction occurs in the absence of any precipitating exposures, the current alternatives for lining materials are limited.

It is of utmost importance to study the materials used in the manufacture of prosthetic devices in order to understand and treat the cause of dermatitis. Plastic resins, cements, foam rubber cushions, and plastic-covered pads can all produce allergic sensitization over decades of use (Bowker, HK). When contact dermatitis is diagnosed in a patient with a prosthetic limb, the contactant must be identified in order to avoid future dermatological issues that may lead to decreased mobility and independence. Specifically, patch tests can be utilized to pinpoint the specific substance leading to the allergic contact dermatitis. Due to the fact that patch testing with strong concentrations of known irritants will be highly likely to react on any skin, substances must be diluted according to guidelines and previously-developed recommendations to prevent false-positive reactions (Bowker, HK). Removal of the suspected contact allergen is curative, and patch testing often identifies any offending agents post acute process. Patch testing remains imperative for patients experiencing allergic or irritant contact dermatitis related to their prosthetic limb. Patients should be patch tested with the standard allergen series as well as with materials from their own prosthesis. Additional patch testing with extended series of plastic additives, adhesives, tapes, and liner materials would also be indicated if initial patch-testing results are negative (Lyon, C).

Diagnostic approaches to hypersensitivity reactions include patch testing and delayed intradermal testing. Patch tests are applied to the upper back, arms, or abdomen on unaffected skin. This is done using chambers that contain the allergen that are secured to the skin with a hypoallergenic tape. These patches are left for 48 hours and then the skin is inspected 48 hours later. Reactions for the allergens are graded on a spectrum ranging from negative to +++ strong reaction (Dermnet).

With an intradermal test, the provider injects possible allergens into the epidermis via a small needle. After 15 minutes, any wheals or discolored spots are measured with a ruler. If the skin test is negative for any medication, there is a second intradermal test stage. During the second stage, a stronger solution of the allergen is inserted. After 10 minutes, any reactions are measured again (Cleveland Clinic). Immediate allergic reactions are mediated by the IgE class of antibodies. These reactions typically occur 15 to 20 minutes after allergen exposure. IgE binds to mast cells and basophils, which contain histamine granules that are released and cause inflammation during the reaction. Otherwise known as type I hypersensitivity reactions, these can be seen in asthma, allergic rhinitis, allergic dermatitis, food allergy, and anaphylactic shock (Justiz-Vaillant, AA). Skin prick testing can be used as an initial test for medication allergies and can be followed up with intradermal testing. A lancet is used to prick the skin with a small amount of different possible allergens near an allergen label marker. This is done with a positive control that contains a histamine solution (which causes a wheal) and a negative control that contains a saline solution (causes no wheal). After 15 minutes, any wheals or discolored spots are measured with a ruler (Cleveland Clinic).

Skin issues are very common amongst amputees and need to be treated promptly as skin breakdown following allergic or irritant contact dermatitis can lead to infection, cancer, osteomyelitis, or even debridement or surgery. Additionally, it is crucial to detect contact dermatitis accurately, as the condition is often confused with a surgical site infection (SSI). According to a recent study, misdiagnosing contact dermatitis as an SSI can even result in a secondary SSI, proving to be dangerous and putting patients at further risk for complications (So, S). Cool or cold compresses, anti-itch lotions, and topical corticosteroids may be therapeutic in treating allergic contact dermatitis. All documented skin allergies should be carefully noted on a patient's allergy list in order to ensure repeated exposure does not result from future manufactured devices. Additionally, the patient may be at harm if continuously exposed to a documented skin allergy that has the potential to eventually develop into a systemic allergic reaction.

The cost and lack of availability of alternative materials forces many patients to sacrifice their independence and mobility. When allergic contact dermatitis develops over time to certain materials comprising prosthetic limbs (e.g., polyurethane, urethane, polyethylene, latex, and silicone), alternative options are currently very limited in terms of finding substitute prosthetic linings.

Prosthetic linings play a role in not only function, but also comfort and stability for the prosthesis user. While alternatives to improve comfort exist, such as those using thermoplastic materials, gel-based liners, moisture-wicking and antimicrobial fabrics, 3D-printed liners or vacuum-assisted liners (to improve fit), there are a multitude of challenges in their adoption. Specifically, there are increased barriers to accessibility with regard to affordability. The cost of a single prosthetic liner can quickly escalate into the hundreds, if not thousands of US dollars, depending on the liner's complexity, the materials used, and the manufacturing process (with alternative liners often costing more than the mainstream due to them not being produced in-bulk for healthcare facilities). In fact, the estimated lifetime costs of a prosthesis user with unilateral lower limb amputation can range from $500,000 to almost $2 million (Highsmith, M). In addition, purchasing a liner from a more reputable brand will incur higher costs, with the assumption that a more reputable brand is less likely to cause an allergic reaction, which is not always true (Brack, R).

Furthermore, adaptations to current liners, or alternative liners, not only pose concerns about cost, but also long-term durability and time-to-market integration, due to the multilevel steps of regulatory approvals and clinical trials required (Harmon, S). Additionally, these materials may be a culprit in allergic or irritant contact dermatitis in the future, indicating a need for further research and development of alternative hypoallergenic materials.

Using a prosthetic limb allows patients to resume normal daily activities and return to work. Given the fact that contact dermatitis accounts for one-third of dermatoses in amputee patients wearing prostheses, it is imperative to address solutions to prosthesis contact dermatitis (Munoz, C). Furthermore, the fact that some amputees only start exhibiting symptoms of allergy or irritation months to years post-implementation, contact dermatitis with long-term prosthetic usage must be prioritized in order to allow continued autonomy and mobility to individuals experiencing limb loss.

As the number of individuals with limb loss increases, it is critical that manufacturers of products designed for prosthetic devices begin devoting significant resources to identifying and offering a wider range of alternative materials. The impact on the healthcare system, the workplace, and the quality of life of wearers of prosthetic devices with debilitating skin conditions is too significant, and the manufacturer processing time too long, to delay allocating time and money to research. Without immediate action, the challenges faced by amputees with an array of largely preventable skin conditions will pose a significant challenge to dermatologists and constitute a threat to mobility for amputees that had been successfully living with their prosthetic limb for years to decades throughout their life.

Conclusion

Nearly two million Americans are affected by limb loss in the United States primarily due to vascular disease and trauma. Amputees are provided with limited options in regard to prosthetic limbs, linings, and devices to use for increased mobility. After months, years, or even decades, these devices may eventually lead to allergic or irritant dermatitis due to the composition of the manufactured materials. Polyurethane, urethane, polyethylene, latex, and silicone are only a few of the known products that may cause irritation and dermatological concerns with long-term use. Prosthetic materials have irritant or allergenic effects, and few alternatives currently exist for amputees who are experiencing moderate to severe dermatosis from their prosthetic limb materials. Further development and enhancement of alternative options for patients experiencing limb loss must be prioritized in order to allow amputees to continue having independence, mobility, and autonomy.

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