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Long-term Complications of Gluteal Augmentation Using Aquafilling Filler: A Case Report

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Abstract

The interest in gluteal augmentation using minimally invasive techniques has been increasing rapidly. Despite the fact that Aquafilling filler was described as biocompatible with human tissues, the number of associated complications has been rising. We present an exceptional case of a 35-year-old female patient, who suffered major long-term complications in association with Aquafilling filler injections in the gluteal region. The patient was referred to our center with signs of recurrent inflammation and severe pain focusing on the left lower extremity. A computed tomography (CT) scan showed multiple, communicating abscess formations all the way from the gluteal region to the lower leg. Therefore, an operative debridement was accomplished in the operating theater.

Keywords

- aesthetic surgery
- ► buttock
- ► polyacrylamide

Finally, this report emphasizes the severity of possible long-term complications when using Aquafilling filler especially in larger areas. Furthermore, the oncogenicity as well as toxicity of polyacrylamide, the core material of Aquafilling filler, remains uncertain, which is why further research is urgently required.

Introduction

The interest in gluteal augmentation, especially using minimally invasive techniques, has been rapidly increasing over the recent years. 1-3 Whereas most filler materials, used for breast and gluteal augmentation, have been associated with a high risk of complications, Aquafilling filler, produced by BIOTRH s. r. o., Prague, Czech Republic, has been described as biocompatible with human tissues, offering stable results for up to 8 to 10 years. However, the number of associated complications after injections of Aquafilling filler, composed of 98% sodium chloride solution and 2% copolyamide, has

been rising as its usage has been increasing exponentially in clinics.4

Here, we present an exceptional case of a 35-year-old female patient, who suffered major long-term complications after receiving Aquafilling filler injections in the gluteal region.

Case Report

In July 2022, a 35-year-old female patient presented at the emergency room due to fever up to 38.5°C and severe, persistent pain on the left thigh as well as lower leg

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Fig. 1 Preoperative photo of the 35-year-old patient presenting with fever and persistent pain on the thigh and lower leg.

(**Fig. 1**). The patient declared that similar symptoms have been occurring repeatedly for years. However, those were always treated successfully with a conservative approach. Approximately 6 years ago, the patient underwent a buttock augmentation using silicone implants and with a time interval of 6 months additional Aquafilling filler injections (300–400 mL on each side) in the gluteal region only. The patient had no relevant comorbidities.

After severe symptoms appeared in July 2022, primary care was performed by a family doctor, who arranged an empirical antibiotic treatment (amoxicillin, which was switched to azithromycin due to the lack of improvement). However, this time the patient's health status did not improve under the medication. Therefore, the patient presented at the emergency room. During physical examination, besides fever, purulent skin defects with inflammatory signs on the left leg were reported by the attending dermatologist. After the patient was hospitalized, a sonography was performed, which showed multiple sharply defined masses from the buttock all the way to the lower leg. Throughout hospitalization, the patient was ongoingly treated with empirical intravenous antibiotic medication (clindamycin 600 mg three times a day) and local, antiseptic covers. However, due to persisting inflammation, she was subsequently presented at our plastic surgery outpatient clinic.

Here, for a better surgical debridement planning, a computed tomography (CT) scan of the leg was performed and showed the following results: a straight filiform formation of multiple, subcutaneous abscesses starting from the

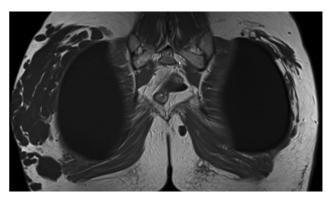


Fig. 2 CT scan of the gluteal region showing multiple subcutaneous abscess formations.

gluteal area affecting the thigh, knee, and lower leg all in continuation (>Fig. 2). After the examination, an operative exploration and debridement was accomplished in the operating theater. Multiple incisions from the buttock all the way to the lower leg were performed intraoperatively to remove the abscesses completely. Fortunately, no direct contact with the implant was detected. Intraoperatively, a wound swab culture enabled the detection of the germ Streptococcus anginosus, which showed sensitivity to the given antibiotic medication. In addition, drains were inserted to remove further fluid from the area. The histopathological evaluation of the surgically removed tissue demonstrated an acute and chronic inflammatory reaction with foreign body granuloma formation. Several areas showed cystic configurations including mucoid liquids and a reactive change of synovial lining cells, which induced a CD68-positive reaction according to the immunohistochemical evaluation. These results are consistent with Aquafilling filler-associated foreign body granuloma.

After surgery, the patient's health status improved rapidly and the wounds were irrigated with Lavasorb (Fresenius Kabi AG, Bad Homburg, Germany) for 4 days, after which the drains were removed. Lastly, the patient was discharged from the hospital with ongoing oral antibiotic treatment (clindamycin 600 mg three times a day) 6 days after surgery. During the follow-up examination ~2 months after surgery, slight wound healing problems without any further complications were detected (**Fig. 3**).

Discussion

During the last decade, Aquafilling filler has become a popular option for breast and gluteal augmentation. The manufacturer has claimed that the product differentiates itself from the polyacrylamide hydrogel (PAAG) filler. However, according to a nuclear magnetic resonance analysis of copolyamide and PAAG fillers, both fillers seem to be similar in terms of composition, which explains the parallelism regarding the complications. In addition, a retrospective study, including 146 patients receiving Aquafilling filler injections in their breast (n=136), buttock (n=6), and breast and face (n=4), summarizes the clinical features of complications. Accounting for 83.6% of the patients, induration and masses were by far the



Fig. 3 Postoperative photo of the patient \sim 2 months after surgery showing signs of a wound healing disorder.

most common complications, followed by pain (76%), firmness (36%), and asymmetry (15%). Even though severe complications are less common, they are associated with irreversible deformities often requiring complex reconstruction surgeries after removal of the filler. Also, the study illustrated an enormous variety of the initial onset of complications, ranging from 5 months to 12 years (average, 38.5 ± 10.2 months). Furthermore, due to the incomplete encapsulation and inert consistency of Aquafilling filler, migration has been observed especially in areas where routes to other regions exist.⁴ To this day, there are no established guidelines for the removal of large quantities of permanent gluteal filler. According to the suggested algorithm by Elahi et al, aspiration techniques can lead to satisfactory results; however, infectious cases should always be treated with a direct approach.⁶

This case report is an excellent example of an exceptional long-term complication of Aquafilling filler, which shows the

migration of the product all the way from the buttock to the lower leg, causing communicating abscesses and inflammation. Not to mention, the oncogenicity as well as toxicity of polyacrylamide, the core material of Aquafilling filler, remains uncertain.4

The lack of knowledge concerning the risks and effects on the surrounding tissue should provoke serious thoughts and concerns on state approval of new filler material.

Conclusion

Finally, this report emphasizes the severity of possible longterm complications when using Aquafilling filler especially in larger areas such as the gluteal region. The similarity concerning the composition as well as complications to the prohibited PAAG filler is the reason why multiple studies are critically questioning the safety of Aquafilling filler injections. Additionally, because of the unknown toxicity as well as oncogenicity of polyacrylamide, further research is urgently required.

Ethics Approval

This article including human participants is in accordance with the ethical standards of the national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Conflict of Interest None declared.

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