



Radiological assessment of the breast following enhancement with Macrolane: Managing the challenges

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ABSTRACT

Macrolane VRF®, a biodegradable, stabilized hyaluronic acid gel, was used for breast enhancement 2008–2012. Similar to permanent implants, the presence of Macrolane gel may interfere with interpretation of mammography. This short communication aims to provide a guide to the appearance of Macrolane on radiology examination (including mammography, ultrasound and magnetic resonance imaging) and aid selection of the most appropriate imaging modality to facilitate breast examination in women who have undergone Macrolane breast enhancement.

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1. Introduction

Macrolane VRF® (Q-Med AB, Uppsala, Sweden) is a biodegradable, stabilized hyaluronic acid gel indicated for use in volume restoration and contouring of body surfaces. Between May 2008 and April 2012, Macrolane was also marketed for breast enhancement. Typically, 100 mL Macrolane was injected in the space between the pectoralis fascia and the glandular tissue. The resorption rate varied between patients, but after 24 months, a mean of approximately 20% of the injected volume still remained in the breast [1]. Even after more than 4 years, small amounts of Macrolane were still visible on magnetic resonance imaging (MRI) or ultrasound in some patients [2]. The safety and performance of Macrolane in this indication has been documented [3–7]. Never-

theless, the breast enhancement indication was withdrawn by the manufacturer in April 2012 because of the potential for Macrolane to interfere with interpretation of mammograms for the purpose of breast cancer screening. This, in turn, may delay the diagnosis of breast lesions. Interference with interpretation of mammograms can also occur when imaging permanent breast implants [8].

Despite the withdrawal of the breast indication, several thousand women have already been treated. The possibility that some product could still be present in the breasts [7] prompts the need to disseminate knowledge on the product's appearance on radiological assessment of breasts following Macrolane treatment. To meet this need, a group of radiologists experienced in the imaging of this patient population and consultant plastic surgeons attended an expert meeting with the specific aim of discussing and describing the most appropriate imaging modalities for a woman treated with Macrolane in the breasts. This short communication summarizes data and images from radiological studies, as well as case experience of participating experts, to show the appearance of Macrolane on mammography, ultrasound and MRI.

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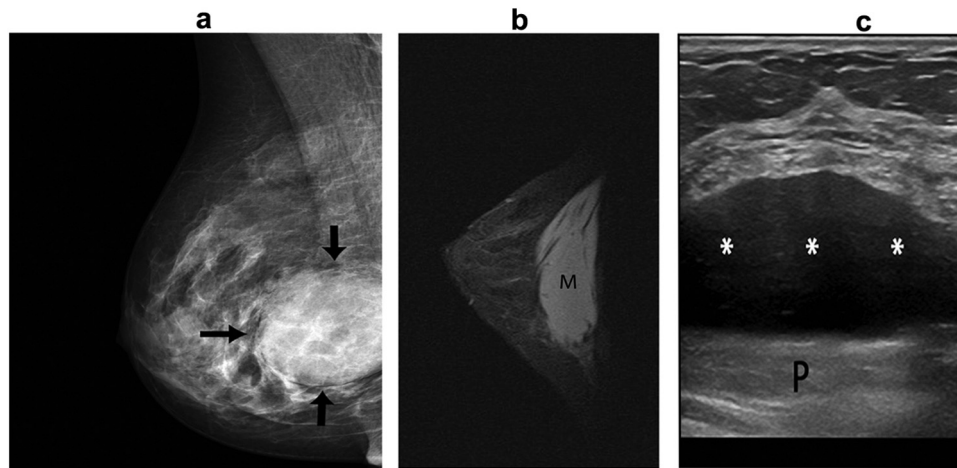


Fig. 1. (a) Appearance of Macrolane on digital mammography (right medio-lateral oblique [MLO] view): well-circumscribed mass (arrows) of low to medium density is seen. (b) Typical appearance of Macrolane (M) by MRI (using Sagittal Short T1 Inversion Recovery [STIR]) 12 months after treatment. (c) Typical appearance of Macrolane by ultrasound (transverse close to the nipple) 12 months after treatment. Macrolane (*) superficial to pectoralis muscle (P) and deep to breast gland.

2. Rationale for development of recommendations

2.1. Ability to adequately visualize breast tissue using different imaging modalities following Macrolane treatment

Macrolane comprises 98% water and 2% hyaluronic acid and, as a consequence, has an appearance similar to water on all imaging modalities (see Fig. 1a–c for examples). On mammography, Macrolane can be seen as an area of increased density. On ultrasound, it can appear cyst-like, with anechoic features [9] or, in some cases, can contain punctate internal echoes described by Pienaar et al. [10] as ‘the sparkly lake sign’. Macrolane is clearly visible on MRI, appearing as areas of low T1/high T2 signal, without contrast enhancement and similar in appearance to cysts. These lesion-like cysts do not enhance with intravenous gadolinium, therefore facilitating their differentiation from the malignant masses that are enhanced.

The Instruction for Use for Macrolane emphasised that the implant should be placed in a position that would minimize the risk of adverse effects and aid radiological evaluation. Ideally, Macrolane was to be placed as a single, implant-like deposit in the retroglandular space (see Figs. 2 and 3). Depending on the site of placement of Macrolane, the product has different appearances on mammography (see Fig. 4a and b). Diagnostic problems may arise if multiple deposits of Macrolane are present in the breast tissue because it may be difficult to differentiate Macrolane from breast lesions. Diagnostic problems may also arise because the gel can mask breast lesions, including cancer.

2.2. Concerns regarding use of mammography to visualize Macrolane

The use of mammography for breast cancer screening has limitations depending on the age group and breast density. A number of studies have looked at the sensitivity and specificity of mammography in different age groups and show that, in younger patients, and in those with particularly dense breast tissue, breast cancer is more difficult to detect using mammography [11]. It has been recommended that women with dense breasts should have whole breast ultrasound performed routinely to complete the screening procedure [12].

The adoption of digital mammography has led to superior image resolution and the opportunity to magnify or invert images, as well as to improve the detection of cancer in women with dense

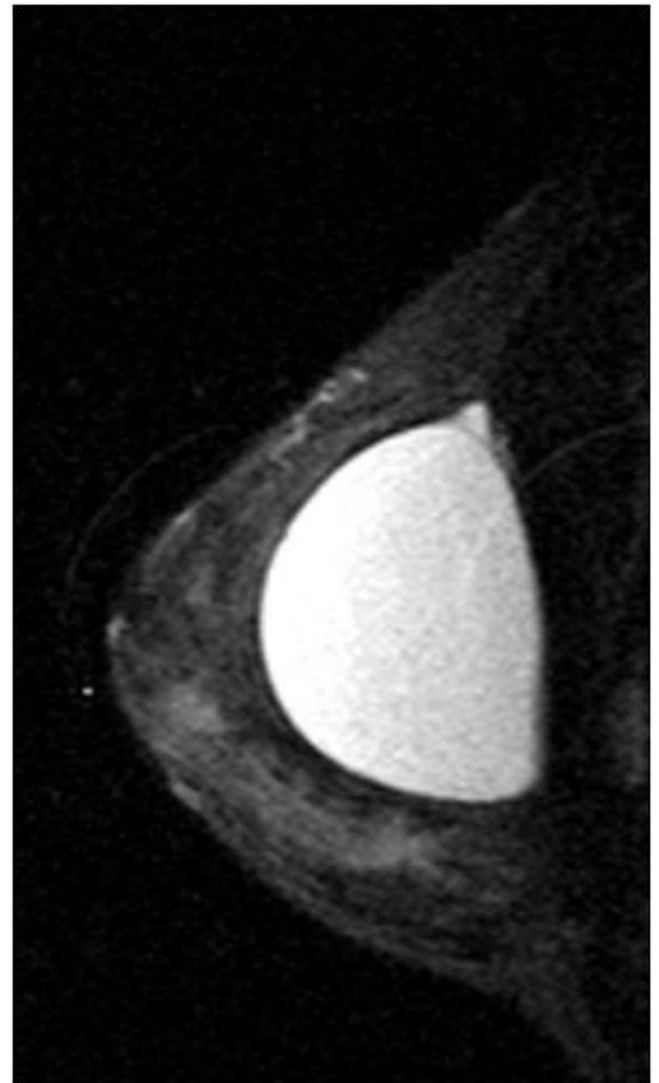


Fig. 2. Typical appearance of Macrolane following placement as a single implant (12 months post-treatment) on MRI (sagittal STIR).

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