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Early clinical experience of hyaluronic acid gel for breast enhancement

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Summary *Background:* An increasing number of women are seeking minimally-invasive procedures to enhance the shape and volume of their breasts. Early, limited use of Macrolane™ suggests it is a promising agent for non-surgical breast enhancement.
Objective: To assess the safety and efficacy of Macrolane™ in non-surgical breast enhancement.
Methods: A prospective report of 194 women presenting for non-surgical breast enhancement at London Bridge Plastic Surgery between November 2007 and August 2009.
Results: Safety: Adverse events were reported in a total of 21.1% of patients. Minor adverse events (12%) were mainly confined to product migration, lumpiness, scar pigmentation and breast pain. All events were of mild to moderate intensity and resolved promptly without any additional treatment. Major adverse events (8.7%) included infection, capsular contracture, early resorption and product removal. *Efficacy*: Efficacy of treatment was assessed by patients using the five-point Global Esthetic Improvement Scale (GEIS). Patient satisfaction with treatment was consistently high with a mean score $\geq$3.3 at all time points during follow-up. Patient-assessed GEIS indicated that some degree of improvement was seen by all (100%) patients at all time points up to and including 12 months irrespective of whether they had been re-treated. At the time of analysis, follow-up data are available for 45% of patients at 12 months, with 19% of all patients presenting for re-treatment with Macrolane™ to date and 5.7% going on to have breast implants.
Conclusion: This review represents the largest European clinical experience with Macrolane™ for breast enhancement. It shows that Macrolane™ can provide satisfactory improvement in breast shape. It is associated with high patient satisfaction, and provides a long-lasting result. Follow-up to data have been adequate to identify early complications; however, further follow-up is required to monitor long-term outcomes. The impact of HA on breast cancer remains inconclusive to date.

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Introduction

Breast augmentation is the most common surgical procedure amongst women in the US; over 350,000 women had surgery for breast implants in 2008.[1] Approximately half of these women seek breast augmentation to correct severe asymmetry, congenital micromastia, tubular breast deformity and Poland's syndrome; the remainder request treatment for purely cosmetic reasons.[1] Within this latter group of women, dissatisfaction with breast shape and size is the main motivation for surgery, especially after having children.[2,3]

Surgery statistics do not reflect the true level of dissatisfaction with breast shape or size. According to a poll conducted by one of the leading manufacturers of breast implants,[4] one in five women is severely self-conscious about her breasts, three-quarters (77%) would like to improve their breast size or shape; and two-thirds (64%) would consider breast augmentation. Interestingly, the majority of women surveyed (75%) only desire a one-cup size increase.

Despite this widespread unhappiness amongst women regarding the size or shape of their breasts, surprisingly few opt for surgery. When considering the number of procedures performed each year in the UK (26,852)[5] in the context of the total eligible female population (17.65 million working female population aged 16–59),[6] less than one percent of women choose to have surgical breast augmentation, leaving a large proportion seeking improvement untreated. Factors contributing to this reluctance include fear of surgery or long-term effects, concerns about safety and worry that the breast will look unnatural or change body symmetry.[7]

In all areas of cosmetic surgery, there is a growing trend towards minimally-invasive procedures and breast augmentation has not escaped this shift in emphasis. Recent interest has focused on the use of injectable fillers as a potential treatment option. For plastic surgeons, going from injecting 1 or 2 mL of product into the face to injecting 200 mL into the breast requires absolute confidence in the safety of the product. The limited long-term data on the safety and efficacy of the semi-permanent or permanent fillers that have been used in facial aesthetics and body contouring to date have failed to inspire that confidence. In contrast, clinical data on the safety and efficacy of non-animal stabilised hyaluronic acid (NASHA™; Q-Med AB, Uppsala, Sweden) is extensive.[8-13] NASHA™ is currently used to treat a number of clinical indications, including osteoarthritis, faecal incontinence and vesicoureteral reflux (VUR) in children. Its safety in these indications is not only well-documented[14] but also includes up to 12 years of follow-up in paediatric patients with VUR with no evidence of any persistent adverse effects.[8–11,15–17] In facial aesthetics, NASHA™ has been used to treat over 11 million patients over 14 years with minimal adverse effects.[12,13,18]

The safety and efficacy of NASHA™ in breast shaping was first reported in Japan by Inami et al.[19] The authors describe favourable results in 1100 patients using a gel formulation indicated for facial aesthetics (Restylane® SubQ [Q-Med AB, Uppsala, Sweden]) with a low incidence of minor, short term side effects, such as swelling, pain and hardness. Data from small studies in both Europe and Japan[20,21] confirm that a NASHA™ gel (Macrolane™ [Q-Med AB, Uppsala, Sweden]), specifically developed for use in body contouring and volume restoration and injected into the same retromammary space as permanent implants are placed, is well-tolerated with no serious adverse events. The data also show that Macrolane™ is associated with high levels of patient satisfaction for up to six months following treatment.[20,21] Longer-term safety and efficacy of Macrolane™ has been described by Hedén et al.[20] Although only involving small patient numbers ($n = 16$) the authors reported satisfactory cosmetic results, lasting for at least 18 months in the majority of patients, and that treatment was well tolerated.

This independent prospective report summarises the efficacy and safety of Macrolane™ in breast shaping in 194 patients seeking non-surgical treatment to improve the shape or size of their breasts.

Patients and methods

Patient selection

All patients included for treatment underwent detailed physical assessment. Only patients seeking a 1–1½ cup size increase, who did not want surgery and had no evidence of breast pathology, were considered for treatment. In addition, they had to have good skin tone, a skin thickness of greater than 2 cm and minimal ptosis (ptosis <II). Any woman who was pregnant or lactating was excluded from treatment.

Screening

Patients aged below 40 years with no identified risk factors for breast cancer were not required to have mammography; however those women aged over 40 years or with risk factors for breast cancer, as determined by national screening guidelines, were required to undergo a mammogram within one year of treatment.

Preparation

Patients were required to avoid taking aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) for 14 days prior to treatment and advised of the need to take the day off work following treatment. In accordance with all surgical and non-surgical procedures, the patients were required to provide informed consent.

Pre–operative

Photographs of both breasts were taken (five in total). All patients received prophylactic antibiotics (500 mg ciprofloxacin) prior to treatment. Each breast was infiltrated with 40 mL of local anaesthetic (100 mL saline; 20 mL 2% lidocaine; 20 mL bupivicaine 0.5%; 0.5 mL adrenaline; 5 mL sodium bicarbonate).