

Protocols

Use of autologous fat grafting in reconstruction following mastectomy and breast conserving surgery: An updated systematic review protocol



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ABSTRACT

Introduction: Use of autologous fat grafting (AFG) for breast reconstructive surgery is gaining acceptance, but concerns regarding its efficacy and safety remain. We present a protocol for a systematic review that aims to update the findings since our previous systematic review on a number of outcomes of AFG.

Methods: The systematic review has been registered a priori (UIN: reviewregistry308). All study designs, including randomised controlled trials, cohort studies, case-controlled studies and case reports/series, reporting original data, on women undergoing AFG for breast reconstruction following mastectomy or breast conserving surgery, will be included. Six categorical outcomes will be assessed: oncological; clinical; aesthetic/functional; patient-reported; process; and radiological.

The search strategy will be devised to investigate 'fat grafting and breast reconstruction'. Electronic databases will be searched, 01 April 2014 to 21 August 2017: PubMed, MEDLINE®, EMBASE, SCOPUS, CINAHL, PsychINFO, SciELO, The Cochrane Library, including the Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effect (DARE), the Cochrane Methodology Register, Health Technology Assessment Database, the NHS Economic Evaluation Databases and Cochrane Groups, ClinicalTrials.gov, Current Controlled Trials Database, the World Health Organisation (WHO) International Clinical Trials Registry Platform, UpToDate.com, NHS Evidence and the York Centre for Reviews and Dissemination. Grey literature will be searched. Two trained, independent teams will screen all titles and abstracts, and relevant full texts, for eligibility. Data will be extracted under standardised extraction fields into a preformatted database.

Ethics and dissemination: The systematic review will be published in a peer-reviewed journal and presented at national and international meetings within fields of plastic, reconstructive and aesthetic surgery, and surgical oncology. The work will be disseminated electronically and in print. Brief reports of the review and findings will be disseminated to interested parties through email and direct communication. The review aims to guide healthcare practice and policy.

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1. Introduction

Breast cancer is the most common cancer in UK females, with over 50,000 new diagnoses each year in the UK [1]. The vast majority of women diagnosed with breast cancer subsequently undergo surgery with curative intent, either mastectomy or breast conserving surgery (BCS). Increasingly there is a trend towards BCS over mastectomy. Surgery is often combined with radiotherapy or chemotherapy or hormonal treatments in efforts to minimise likelihood of recurrence.

Autologous fat grafting (AFG) is a technique gaining popularity for both reconstructive and/or cosmetic indications. It involves harvesting the patient's own adipose tissue, from distant sites, and implanting this tissue to the breast. There are several advantages to this approach: the fat harvested is often in ample supply; the patient's own tissue is used; harvesting procedures generally result in minimal donor site morbidity or cosmetic disturbance; foreign body or complicated flap procedures are avoided; procedures can be performed as a day case; AFG can rejuvenate breast skin which antagonises the effects of ageing and radiotherapy [2–4].

There are several disadvantages to consider with AFG [5–9]. Obtaining consistently good cosmetic and reconstructive results,

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with lasting volume, has been a challenge. Fat is implanted into a loose and poorly vascularised space after BSC or mastectomy, which puts it at risk of necrosis. Necrotic fat can instigate an inflammatory reaction resulting in fibrosis, cyst formation, calcification or local infection [10–13]. In 1987 the American Society of Plastic and Reconstructive Surgeons (ASPRS) Ad Hoc Committee on New Procedures therefore prohibited use of AFG to the female breast [14]. Since then, there has been effort to develop techniques to improve graft take and fat maintenance [4,14]. ‘Structural fat grafting’ [10] where small aliquots of fat are transplanted through multiple tunnels in a multi-layered and multidirectional way can maximise adipocyte contact with host tissue and hence survival and incorporation [11], and has been shown to be efficacious [15]. The scarring and calcifications that can result from AFG might mask detection of breast cancer on mammography. In one sample as many as 16.7% of patients showed microcalcification clusters after AFG [16]. The ASPS, however, have stated there appears to be no interference with breast cancer detection [13]. There are additional concerns are that adipocytes transplanted into areas of previous malignant change may directly stimulate the formation of cancer [5]. Adipocyte tissue is increasingly recognised as an endocrine organ, rich in mesenchymal stem cells (MSCs) [4]. Adipocyte derived stem cells (ADSCs) have potential to differentiate into cells including chondrocytes, osteocytes, myoblasts, and secrete angiogenic factors [17]. Promotion of angiogenesis in a tumour bed post mastectomy or BSC is of substantial oncological concern. Adipocyte tissue has an integral role in breast cancer progression and in metastasis [6]. In animal studies engrafted MSCs were less able to regulate growth patterns which could predispose to cancer [7,8]. Due to the significant potential harmful effects of AFG, in 2009 the American Society of Plastic Surgeons (ASPS) stated fat grafting was not strongly recommended by the Fat Grafting Task force due to limited scientific data on safety and efficacy [13].

The potential advantages of AFG has stimulated significant interest. It is essential to verify whether potential benefits of AFG outweigh the potential risk. In 2014 we conducted a systematic review [18] analysing the outcomes along the six dimensions of oncological, clinical, aesthetic/functional, patient-reported, process and radiological. The results of this review revealed significant heterogeneity on studies reporting on AFG outcomes in terms of techniques, patient population, indications and definitions, which precluded a meta-analysis of results. Importantly findings indicated no evidence that AFG promoted cancer recurrence or primary cancer, overall complications were low and most patients and clinicians were satisfied with the results. However, most studies included were of poor quality. Since 2014 there has been growing interest and use of AFG techniques for breast reconstruction. A basic search of the SCOPUS database for “fat grafting” and “breast reconstruction” (Fig. 1). Since the start of January 2017 to the start of August 2017, the SCOPUS search revealed that 54 articles had since been published in this area. As the use of AFG in breast reconstructive surgery is a rapidly developing area, an up-to-date systematic review and meta-analysis is needed.

2. Objectives

The primary objective is to perform an up-to-date comprehensive systematic review of AFG for breast reconstruction to determine the safety efficacy and radiological outcomes.

2.1. Primary objectives

The primary objective is to determine outcomes of AFG for breast reconstruction in women following mastectomy or BCS along 6 dimensions:

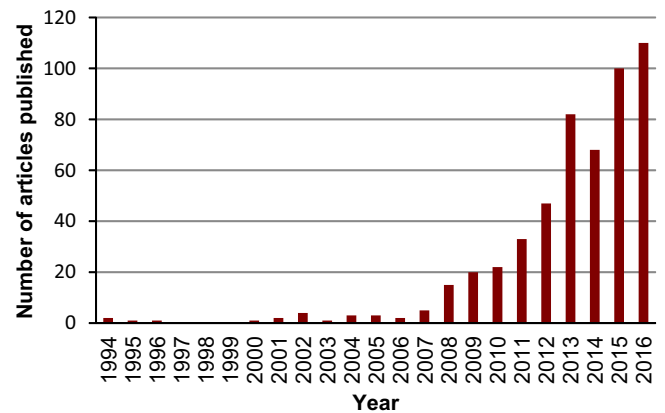


Fig. 1. Number of articles published per year and indexed by SCOPUS under the search term “fat grafting” AND “breast reconstruction”.

- (1) Oncological.
- (2) Clinical.
- (3) Aesthetic/functional.
- (4) Patient-reported.
- (5) Process.
- (6) Radiological.

2.2. Secondary objectives

The secondary objectives include

- (1) Determine optimal methods of AFG including fat harvesting, preparation and injection.
- (2) Determine the indications of AFG.
- (3) Refine the patient selection for AFG.

3. Method

This systematic review will be conducted in line with recommendations specified in the Cochrane Handbook for Intervention Reviews V.5.1.0 and is AMSTAR compliant [19] and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [20]. This protocol has been developed a priori, and the systematic review has been registered a priori on the Research Registry® (UIN: reviewregistry308, www.researchregistry.com). The methodology will closely follow that used in the systematic review and meta-analysis in 2015 for maximum comparability [18].

4. Criteria

The following inclusion and exclusion criteria will be used to minimise heterogeneity with previous reviews and address research questions

5. Types of studies included

All original research studies, levels 1–5 of the Oxford Centre for Evidence-Based Medicine [21] (randomised controlled trials (RCTs), cohort studies, case-controlled, case series, case reports) reporting on one or more of the outcomes of interest, will be included. Unpublished data and reports will also be considered if the methodology and data are accessible. Duplicate articles, cost-effectiveness studies, studies not reporting on primary data (review articles, editorials, discussions, commentaries, letters) and studies not reporting on the indication for AFG, will be excluded.

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