

- Title** Assessment of the safety and conditions for conducting autologous fat grafting in reconstructive, restorative and cosmetic breast surgery
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- Reference** ISBN number : ISBN 978-2-11-139054-6, link to full report in French : http://www.has-sante.fr/portail/jcms/c_1778570/fr/evaluation-de-la-securite-et-des-conditions-de-realisation-de-lautogreffe-de-tissu-adipeux-dans-la-chirurgie-reconstructrice-reparatrice-et-esthetique-du-sein?xtmc=&xtcr=5

Aim

The medical questions of this assessment mainly relate to the safety of the autologous fat grafting procedure in the breast and may be grouped into 3 major areas: intraoperative and postoperative complications and oncological safety, radiological changes and their impact on patient care, and the conditions for conducting this procedure.

Results

Currently, literature analysis does not permit drawing formal conclusions on the safety of the autologous fat grafting procedure in the breast (complications and oncological safety), regardless of the indication concerned (cosmetic, restorative or reconstructive surgery, with or without breast cancer history), due to too few studies identified (n=4), their intermediate level of evidence (non-comparative non-randomized prospective studies with a short follow-up of patients) and their heterogeneity.

However, it can be noted that the rates of immediate complications reported are relatively low (0% to 4% of procedures) and that the appearance of radiological changes is fairly common, such as after any breast surgery (up to 40% of procedures). None of the studies identified demonstrates an oncological risk following this procedure.

The position of the working group consulted during this evaluation is that autologous fat grafting in the breast is an effective and simple procedure that entails a low risk of complications. The lack of relevant data regarding the oncological safety of this procedure is acknowledged, however, which leads the working group to propose a specific framework for this technique, in agreement with existing guidelines. Recommendations have therefore been issued on several points, including contraindications to the technique, the content of preoperative and postoperative assessments, qualifications of the health professionals involved, facility for the procedure, protocols for the technique and patient information sheets.

Conclusions

Given that the autologous fat grafting technique has spread into clinical practice and there is no negative signal

regarding the safety aspects of this procedure, HAS believes, subject to compliance with the methods for use of this technique, the operating conditions proposed by the members of the working group and the implementation of postoperative patient follow-up, that autologous fat grafting is a possible surgical method in restorative, reconstructive and cosmetic breast surgery, beyond symmetrization of the contralateral breast after surgery for breast cancer.

Methods

The assessment method used in this report includes :

- a critical analysis of clinical studies identified by a systematic review for the period from January 2003 to October 2014;
- collecting a reasoned position from a working group;
- consulting the Office national d'indemnisation des accidents médicaux [National Board for Compensation for Medical Accidents] and a mutual insurer of health professionals (MACSF group).

Thus, the conclusions of the assessment are based on the data collected. These conclusions are reviewed by the National Commission for the Assessment of Medical Devices and Health Technologies and then validated by the HAS Board.

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