National Institute for Health and Clinical Excellence

845/1 – Breast reconstruction using lipomodelling after breast cancer treatment

Consultation Comments table

IPAC date: Friday 13 May 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	Breast cancer treatment involves a multidisciplinary approach which includes Surgery, Radiotherapy, Chemotherapy and Hormonal treatment. Life expectancy after breast cancer treatment has improved significantly and more younger women are diagnosed with breast cancer. The Mastectomy and Breast reconstruction audit shows that patients have significant side effects of treatment after Surgery, Chemotherapy, Radiotherapy and after other forms of reconstruction. Lipomodelling offers an opportunity to alleviate some of these side effects to patients.	Thank you for your comment. Section 1.3 of the guidance recommends that patient selection should be carried out by a breast cancer multidisciplinary team.
2	Consultee 2 NHS Professional	**1**	Appropriate recommendations. Â 1.4 - should also state only carried out by units with adequate governance, and capacity for longterm follow up.	Thank you for your comment. Section 1.1 of the guidance recommends that normal arrangements should be in place for clinical governance. Section 1.2 of the guidance states that NICE encourages long term data collection on this procedure. A section 2.5.3 will be added to the guidance to state that joint guidelines on lipomodelling are in development and these include a dataset for a proposed national audit.

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3	Consultee 1 NHS Professional	**2.1**	Primary Surgery in the form of Breast conserving surgery and Mastectomy produces scarring and some times neuropathic pain. Surgery also produces asymmetry and problems with contralateral procedures. Breast reconstruction with implants initially give good results but can produces capsule formation and asymmetry in a proportion of patients. Radiotherapy causes significant changes in the Breast including hardening of tissues, scarring and telangectasia. Lipomodelling with Adipose derived regenerative cells have a valuable role to play in reversing some of the side effects of treatment. Lipomodelling on its own is useful to correct defects and symmetrising.	Thank you for your comment. This is more detail than is normally included in the guidance document.
4	Consultee 2 NHS Professional	**2.1**	appropriate	Thank you for your comment.
5	Consultee 3 Patient	**2.1**	Traditional methods of reconstruction may not always be appropriate for the patient - implants after radiotherapy, common reconstruction methods causing long term mobility problems.	Thank you for your comment. Section 2.2.1 of the guidance states that lipomodelling can be used on its own or as an adjunct to other reconstruction techniques.
6	Consultee 4 British Association of Aesthetic Plastic Surgeons	**2.2.1 and 2.2.2**	Comments: There is no reliable evidence based on prospective controlled clinical trials to support that enriching fat graft with concentrate of adipose derived stem cells is advantageous and better than fat graft alone. Furthermore, there is legitimate concern about its safety to use in breasts with history of cancer, similarly due to lack of reliable evidence.The current suppliers of Cytori machine that is used for this purpose have in the past refused the surgeons, who agreed to use their equipment for free, to conduct controlled clinical trials to assess whether the technique is better than fat graft alone.	Thank you for your comment. The theoretical possibility of an increased rate of breast cancer recurrence is noted in sections 1.2, 2.2.2 and 2.4.5 of the guidance.

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7	Consultee 4 British Association of Aesthetic Plastic Surgeons	**2.2.1 and 2.2.2**	When approached to use the machine for a 'trial', I personally refused to use the equipment as I felt my clinical independence in assessing the technique would be compromised. The results from all those so called 'clinical trials' are unreliable. There is no doubt that there are therapeutic values from adipose derived stem cells, but if this technique is to be advocated in breast reconstruction after breast cancer, it is imperative that the procedure is only carried out as part of controlled clinical trials and only in specialist unit with full MDT facilities until such time when the true value, safety and the efficacy of the technique are established. It is also expensive and doubles the operating time in theatre.	Thank you for your comment. Section 1.3 of the guidance recommends that patient selection should be carried out by a breast cancer multidisciplinary team. Section 1.4 of the guidance recommends that the procedure should only be carried out by surgeons with specialist expertise and training in the procedure.
8	Consultee 1 NHS Professional	**2.2**	In my experience, the procedure is detailed as above, my patients undergo harvesting of the fat under general anaesthesia using the tumescent technique, the fat is washed and I use half the fraction in a device to concentrate ADRC. The ADRC is mixed with the other half of the fat and is used as a graft. The injection of the graft is done under local anaesthesia and sedation.	Thank you for your comment.
9	Consultee 2 NHS Professional	**2.2**	commencement of lipomodeeling may also be delayed after reconstruction to improve viability of fat transfer.	Thank you for your comment. None of the evidence presented to the Committee addressed this issue, and therefore, having considered the comment, the Committee decided not to change the guidance.

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10	Consultee 3 Patient	**2.2**	Whilst traditional lipomodelling has proved fat resorption and necrosis it is seeming that adipose-derived stem cell methods have overcome these problems. Â I had this treatment 13 months ago involving only an overnight stay in hospital with a very quick recovery time - mainly just external wound healing and a little bruising in the liposuction site. Â I was delighted with the result and have experienced no deterioration over the past 13 months. Â My scarring has also vastly improved. Â I have no longer term effects from the treatment.	Thank you for your comment.
11	Consultee 5 NHS Professional	**2.2**	the number of procedures could potentially be reduced by cell enriched fat injection techniques	Thank you for your comment. Section 2.2.2 of the guidance states that patients subsequently undergo treatment (typically 2–4 sessions).
12	Consultee 6 Manufacturer	**2.2**	The adipose-derived stem and regenerative cells are thought to increase graft survival. This may decrease the need for repeat sessions.	Thank you for your comment. Section 2.2.2 of the guidance states that patients subsequently undergo treatment (typically 2–4 sessions).
13	Consultee 1 NHS Professional	**2.3**	In my series of 30 patients, 85% of patients reported good to excellent results. Predominant comments were about the softness and natural look and feel of the breast. My indications were for primary breast reconstruction after radiotherapy, correction of implant based reconstructions, correction of asymmetry, correct complications and asymmetry after autologous tissue transfer and congenital abnormalities.	Thank you for your comment.
14	Consultee 3 Patient	**2.3**	I must report an excellent outcome from adipose-derived stem cell enriched fat lipomodelling.	Thank you for your comment.
15	Consultee 1 NHS Professional	**2.4**	Out of the 30 patients I have had so far, I have had no loco regional recurrence of breast cancer. There was no increase in metastases compared to other group of patients.	Thank you for your comment.

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16	Consultee 4 British Association of Aesthetic Plastic Surgeons	**2.4**	Comments: Complications rates, by and large, are technique dependent, including harvesting, processing and grafting of the fat. Therefore, adequate training under supervision is vital before introducing the technique for the first time.	Thank you for your comment. Section 1.4 of the guidance recommends that the procedure should only be carried out by surgeons with specialist expertise and training in the procedure.
17	Consultee 1 NHS Professional	**2.5**	Three out of my 30 patients have had fat necrosis, out of which one needed aspiration of a fat cyst. Two of the fat necrosis settled after 3 months. There has been no increase in calcifications or interference in mammographic follow up for the past 2 years and 6 months. However, this technique requires training for both harvesting the fat and re injection of the graft, if the fat is injected inappropriately it could cause dystrophic calcification and could interfere in imaging as shown in some of the older studies. So training is a key issue for this technique. I am happy to participate in the advisory group for this procedure.	Thank you for your comment. Section 1.4 of the guidance recommends that the procedure should only be carried out by surgeons with specialist expertise and training in the procedure.
18	Consultee 3 Patient	**2.5**	I experienced no problem with subsequent mammogram imaging.	Thank you for your comment.
19	Consultee 3 Patient	**General**	I am one of the trial patients to receive adipose-derived stem cell lipomodelling (March 2010).	Thank you for your comment.
20	Consultee 5 NHS Professional	**General**	I havre been trailing Cytori fat injection system	Thank you for your comment.
21	Consultee 2 NHS Professional	**General**	limited provision of consumables for research purposes, to use lipoharvested tissues for other tissue engineering research applications.	Thank you for your comment.

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22	Consultee 7 Specialist Adviser	**General**	I only have experience of the Breast Reconstruction Audit, which as you say is now closed. I have not been involved in the National Cancer Registry or National Breast Cancer Audit, but it is unlikely that these will capture this data. Before asking the committee to reconsider, we should question what a National Lipomodelling Database will be used for: Research - Many units, like my own, will be in the process of or already have set up studies to monitor these patients. The protocol for entry into these studies will be rigorous and will include consent forms specifically detailing the potential risks. With time, high quality data will therefore emerge from these studies with in-depth analysis. A national study would of course be more powerful but would only provide data on cancer recurrence, it would also be extremely costly and complicated to administer. That said, if there were to be an increased chance of breast cancer recurrence then it might only get picked up in a national study, as the numbers needed are high because recurrence rates are so low.	Thank you for your comment. Section 1.2 of the guidance states that NICE encourages long term data collection on this procedure. Section 1.3 of the guidance states that patient selection should be carried out by a breast cancer multidisciplinary team. A section 2.5.3 will be added to the guidance to state that joint guidelines on lipomodelling are in development and these include a dataset for a proposed national audit.

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23	Consultee 7 Specialist Adviser	**General**	Safety - Entry onto a register would include a consent which would provide an opportunity to detail the additional specific risks. More importantly perhaps would be the fact that if data did emerge regarding an increased risk of breast cancer recurrence, then we would be able to inform and track this group more accurately from a register. However this would also be possible at a local level from coding data. Resource management and tracking of availability / trends in breast cancer reconstruction across the UK- This has been one of the major outcome benefits of the National Breast Reconstruction Audit but I don't feel strongly that this data is needed for lipomodelling, which is obviously not in routine use in all breast units as yet. Hence, whilst it would be ideal to set up a national register, I feel that it is not essential. If NICE do not recommend such a register then they should at least recommend rigorous follow up of these patients and that patients should only be treated within the setting of an MDT. Perhaps NICE should also await the guidelines that are due to be produced by the combined group from ABS, BAPRAS and BAAPS on lipomodelling in breast surgery, before concluding their analysis?	Please see response above.