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EDITORIAL

Implications of the Human Tissue Act (2004) on tissue storage for UK plastic surgeons

In September 2006, the UK Human Tissue Act,¹ which gained royal assent in 2004, came into effect. Covering all aspects of the use of human-derived tissue, it affects all Plastic Surgery units that have previously stored skin following the harvest of skin grafts, and other human tissue following trauma. This practice, in general, is no longer permitted under the new legislation and all plastic surgeons, trainees and allied health professionals must be aware of this. However, it does not preclude the storage of tissue for autologous use altogether and Plastic Surgeons should be aware of this also.

Plastic Surgeons have for many years harvested skin for use as autologous skin graft, and until now, the storage of harvested skin for delayed use has been a common practice.² This has changed in the UK, and throughout Europe, as new legislation (the Human Tissue Act (2004) and the European Union Cells and Tissue Directive³) intervenes. BAPRAS announced these changes on its website, stating only that this will have 'significant implications for units that store skin including skin autograft'.⁴ This article seeks to clarify the law and the implications thereof. Similarly, tissue from amputated body parts may also need to be stored temporarily before being used definitively, and this will also be addressed.

The current law in the UK

The Human Tissue Act (2004) has been formulated to improve regulation of how tissue and organs from the living and deceased are removed, stored and used. In the Act, this tissue is referred to as 'relevant material', and is defined as

"...material, other than gametes, which consists of or includes human cells...(and) do not include...hair and nail from the body of a living person"

Section 53, Human Tissue Act (2004)

One of the purposes of the Human Tissue Act was to create the Human Tissue Authority.⁵ This legislative body has issued 'Codes of Practice' that explain the exact nature of what is permitted under the new Act, and it is this body that oversees and regulates these practices.

European law also requires a 'Competent Authority' to regulate the EU Cells and Tissue Directive and again the Human Tissue Authority is that professional body.

The EU Cells and Tissue Directive is made up of three Directives, the parent Directive (2004/23/EC) that provides the framework legislation and two technical directives (2006/17/EC and 2006/86/EC), which provide the detailed requirements of the EU Cells and Tissue Directive. The Directives were fully implemented into UK law in July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations).⁶ These regulations extended the Human Tissue Authority's remit to include the regulation of procurement, testing, processing, storage, distribution and import/export of tissues and cells for human application. Establishments where these activities are carried out will normally need a licence under the Q&S Regulations.

These regulations also require that donors of tissues and cells undergo the biological tests set out in, and in compliance with the requirements of, Annex B of the Directions 001/2006.⁷ This states that donors of such tissue, including that which is to be for autologous use, must have tests for HIV (Anti-HIV-1,2), Hepatitis B (HBsAg and Anti HBc), Hepatitis C (Anti-HCV-Ab) and Syphilis if it is to be stored for longer than 48 h. Although the tests are necessary, a positive result will not prevent the storage of such tissue, as long as there are appropriate measures in place to store these tissues in isolated facilities to avoid cross-contamination with other stored tissue.

For an institution to carry out any practice that involves the procurement and storage of human-derived tissue for a 'scheduled purpose', it requires a licence from the Human Tissue Authority, as stated. There is a list of procedures that qualify as 'scheduled purposes'⁸ and transplantation is one of these.

Autologous skin transplantation

The harvest, storage and use of skin in autologous skin grafting falls under the remit of the Human Tissue Act (2004).

Neither the Human Tissue Act nor the EU Cells and Tissue Directive apply to autologous skin harvested from a donor site and applied to the same patient's wound in the same procedure. This practice does not require a Human Tissue Authority licence. However, there is a clear distinction between this and the delayed use of autologous skin grafts, which obviously requires that the tissue be stored and then be used in a second procedure.

Under the current legislation, such 'delayed skin grafting' is considered a form of transplantation. For the purposes of the Human Tissue Act, transplantation is defined as⁹:

'An implant of an organ, tissue or cells either from and into the same body or from one person to another.'

Thus, delayed autologous skin grafting is seen as autologous skin transplantation, and a Plastic Surgery unit that wishes to continue such practice will require a licence from the Human Tissue Authority to do so (but see below for further clarification).

As a result of these publicised legislative changes, many UK Plastic Surgery units have concluded that harvesting and storing skin for delayed use or storing excess harvested skin is no longer allowed without a Human Tissue Authority licence. Such practice has ceased more or less completely (anecdotal).

The 48-h rule

This, however, is a result of a misinterpretation of the new rules. In fact, the new legislation does allow storage of skin for use in autologous transplantation for up to 48 h, without the need for a Human Tissue Authority licence.

The Human Tissue Authority Code of Practice relating to transplantation⁹ clearly states that:

'Establishments which store tissue (not organs or part organs) for transplantation purposes are required to apply to the Human Tissue Authority for, and hold a licence for, the storage of such tissue unless they store for less than 48 h.'

Hence, if the harvested autologous skin graft is used within 48 h, a Human Tissue Authority licence is not needed. This is very important to know for those units that do not hold Human Tissue Authority licences and may still yet prove to be of benefit and applicable in certain clinical situations, such as in the following example:

A patient with multiple medical problems, on anticoagulants, has a large expanding pretibial haematoma. The patient is taken to the operating theatre and the haematoma is evacuated and the non-viable skin debrided.

Ideally the surgeon does not want to graft the resultant wound at this time, because of the risk of further

bleeding (and potential graft failure). However, the patient is not medically fit enough to have a second general anesthetic procedure. Traditionally, the surgeon would have harvested skin and stored it for use as a delayed graft to be applied on the ward without the need for a return trip to theatre.

What does the new law say?

As long as the harvested skin is used within 48 h, storage of skin for use as a delayed autologous graft is still permissible under the new legislation. Hence, a skin graft can be harvested at this time and stored until such a time within the next 2 days that the wound can be grafted.

One of the underlying principles behind the new Human Tissue Act is that of appropriate informed consent and, in such circumstances, all patients should be made aware that their skin will be stored for this period of time after being harvested, and their consent must be sought.

There will also be other clinical scenarios (for example, excess harvested skin could be stored temporarily if early graft inspections are planned; or skin could be stored after tumour excision using 'slow Mohs' micrographic surgery) where patients may benefit from delayed skin grafting. However, only if the harvested skin is to be used within 48 h will the Human Tissue Authority not require you to have a licence to do so. If the skin is to be stored for longer than 48 h, then the surgeon or hospital will require a Human Tissue Authority licence. It is important to be aware of these regulations as failure to comply could result in prosecution.

Amputated body parts

Another instance in which this legislation is important is that of amputated body parts and this also falls under the remit of the new Human Tissue Act.

In particular, the replantation of a traumatic digit amputation is a clinical scenario that the Plastic Surgeon will often face. If, for example, such a case was admitted out of office hours, replantation may not necessarily need to be carried out at that time, and surgery may be planned for the following morning. Here, the amputate would have to be stored for a period of hours before the reparative surgery takes place. Again, the 48-h rule applies for storage of this tissue, and as previously mentioned, appropriate informed consent for storage is necessary.

Summary

In general, if skin is to be stored for subsequent use in autologous skin grafting, a Human Tissue Authority licence is required in the UK. However, skin can be stored for use in delayed skin grafting for up to 48 h after harvest without such a licence. Delayed autologous skin grafting still has important clinical applications and, despite the recent changes in UK law, it is permitted within this time period.

Summary Box

- The Human Tissue Authority (HTA) regulates activity under the UK Human Tissue Act (2004) and The EU Cells and Tissue Directive (2004)
- To carry out any 'scheduled purpose' under the Human Tissue Act a HTA licence is required and this includes storage of human tissue for >48 h
- If tissue is stored for autologous use for <48 h a HTA licence is not required
- If tissue is stored for >48 h, the patient must be tested for Hepatitis B, Hepatitis C, HIV and syphilis (and if tests are positive, tissue must be stored appropriately)
- Appropriate informed consent must be obtained if any tissue is to be stored

Those institutions that have acquired Human Tissue Authority licences for the purpose of storing human tissue should be aware of the Quality and Safety Regulations that require specific biologic tests to be carried out when tissue is stored for over 48 h.

As the EU Cells and Tissue Directive comes into force throughout Europe the harvest and storage of skin for use in delayed grafting throughout the member states will be affected. We wait to see whether similar rules are used throughout these countries. EU directives can be influenced by local laws, and how they are interpreted can vary between member states and hence not all will have the same legislations.

With respect to the UK legislation, further information can be found by contacting the Human Tissue Authority (www.hta.gov.uk).

Conflict of interest

I have no competing interests to declare.

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