A review of the use of biological mesh products in modern UK surgical practice: a religious and cultural perspective

RM Koshy¹, EG Kane², C Grocock³

¹University Hospital Coventry and Warwickshire, Coventry, UK

²University of Liverpool, Liverpool, UK

³Royal Liverpool University Hospital, Liverpool, UK

ABSTRACT

INTRODUCTION The UK is an increasingly multicultural society. This change coincides with an increasing use of animal products in medicine and surgery and a change in the UK law of consent. The refusal of Jehovah's Witnesses to accept blood products is well known, but the use of animal products in surgery is a neglected topic. As society becomes more diverse and medicine becomes ever more advanced, there is increasing potential for a mismatch between what is medically possible and what is acceptable from a religious perspective.

METHODS Surgical products were identified by searching the literature and contacting manufacturing companies. Literature was identified by using PubMed and OVID (MEDLINE). Religious views were established by contacting national bodies for each group.

FINDINGS The views of common UK religious groups and the constituent parts of biological meshes are summarised in tables intended to be used as a reference during clinical practice. On an elective basis, the Islamic, Hindu, Sikh and Jain leaders contacted had strong views on avoiding animal derived products. The Christian and Jewish leaders contacted did not. All religious leaders contacted accepted the use of mesh derived from human tissue. All products, including those of porcine and bovine origin, were acceptable to all leaders contacted if the procedure was performed to save life. The highlighting of this issue should prompt earlier consideration and discussion in the surgical planning and the consenting process with all final decisions taken by both the surgeon and the individual patient.

KEYWORDS

Surgical mesh – Bioprosthesis – Religion – Islam

Accepted 23 March 2020

CORRESPONDENCE TO

Christopher Grocock, E: cgrocock@liv.ac.uk

Introduction

This work was prompted by a clinical case and the relative paucity of available literature to guide management. A 62-year-old man was admitted as an emergency. He had a longstanding incisional hernia after a previous laparotomy for a perforated duodenal ulcer. He had clinical symptoms and signs consistent with both obstruction and strangulation and, after initial assessment and plain films, he was reviewed by the consultant on call for general surgery. He was listed for emergency surgery and a laparotomy was performed. A midline incision confirmed the working diagnosis and an extensive small-bowel resection for infarction was required. The patient was otherwise fit and did not require organ support, with no soiling of the peritoneal cavity, so a single-stage resection, small-bowel anastomosis (from mid-jejunum to the terminal ileum) and abdominal wall reconstruction was performed. The

hernia was repaired using a modified Rives–Stoppa technique with porcine mesh.¹ There were no clinical postoperative complications but, on meeting the family, it became obvious that the patient was likely to be a Muslim. This prompted a review of the literature, discussion with a senior colleague and a family meeting in keeping with the General Medical Council's 'duty of candour'.

The UK is increasingly multicultural. Census data for England and Wales show that between 2001 and 2011, not only did the overall population increase, but so did overall numbers identifying as belonging to all religious groups. When these figures are calculated as percentages of the overall population (England and Wales only) the percentage size of all religious groups increased over this period, except for those identifying as Christian or Jewish. Of particular relevance to this case, those identifying as Muslim increased from 3% to 5% between these two time points.

Within each religious group, there is obviously a range of opinions and beliefs. While views are often influenced by those in authority within each faith group, the medical treatment that an individual chooses to accept or decline is for the individual to decide in conjunction with the responsible clinician.

It is not new for religious and cultural considerations to be considered in the provision and acceptance of healthcare. The non-acceptance of blood products by the vast majority of Jehovah's witnesses is well known, with the ethical dilemmas this can present commonly forming part of undergraduate medical training. There is often a separate section on standardised procedure consent forms specifically asking about transfusion or, increasingly, a separate form. This focus on acceptability (or otherwise) of human blood products is in stark contrast to the attention paid to the use of animal products during surgery.

What has changed in the last few years is that the Montgomery case has transformed the law of consent for those practising in the UK. The ruling has changed practice from one where clinicians provide information which they feel to be 'reasonable' (Bolam) to one where the clinician must provide all information that a 'reasonable patient would expect to know'. While it has yet to be legally tested, the use of a product to which a patient may object on religious or cultural grounds is almost certainly encompassed by the Montgomery ruling.

Animal products have been used in surgery for decades. 'Catgut' was the traditional absorbable suture of choice for many general surgeons until it was banned over concerns regarding bovine spongiform encephalopathy. Porcine heart valves have been used for over forty years,² and animal products are routinely used in the majority of common drugs prescribed in primary care.³ In a hospital setting, commonly used animal derived medications include low molecular weight heparins, insulin and pancreatic enzyme replacement therapy. Biological meshes are commonly used in hernia repair and abdominal wall reconstruction with some haemostatic products used to promote local coagulation during surgery also containing material derived from animals.

The census data show that UK society is becoming ever more religiously diverse. Medical science is advancing and as more animal-based treatments become available, there is the potential for a mismatch between what is medically possible and what is acceptable from a religious (and perhaps cultural) point of view.

The primary aim of this review is to summarise the views of the most common religious and cultural groups as well as the constituent parts of currently available biological meshes. This will permit the surgeon to select the most suitable product for each individual case. A secondary aim is to highlight this potential problem so that the effect of culture and religion are considered earlier in the treatment pathway and issues are pre-empted, planned for and discussed, in keeping with the Montgomery ruling, whether this be on an elective or an emergency basis.

Methods

The clinical case prompted a literature review and online searching of the manufacturer's product information to identify available biological meshes and their key constituents to find an alternative product for the patient. In time, this was supplemented by discussion with company employees. These data are summarised in Table 1.

A PubMed search was performed using the terms 'mesh', 'biological', 'porcine', 'Islam' OR 'Muslim'. The search was repeated using OVID (MEDLINE) using the same search terms. The references listed in any identified publication were interrogated. The identified literature is summarised in the following section.

After the patient had been discharged home, the authors contacted representatives of the major religious groupings within the UK to ascertain their views. The outcomes are shown in Table 2.

Findings

The authors identified commercially available alternatives for the patient described above. The most useful summary of available products was found in Baylon *et al.*⁴

The most common animal to have its tissue incorporated into third-generation mesh products is the pig. Of the commercially available products identified, 15 were porcine, 5 were bovine based and a further 6 use tissue derived from humans. Two synthetic meshes were also identified. Each mesh has its own characteristics giving it varying utility in a specific clinical context. Identified available products are shown in Table 1.

The literature search performed to answer the highlighted clinical dilemma yielded surprisingly few results that related to religious (and cultural) views on the use of animal products in medical treatment. An updated search was repeated as part of this work. A total of five papers were identified and these are described below in alphabetical order.⁵⁻⁹ Two are written by UK authors, only one of which was available at the time of this clinical case. Single papers were identified from a Danish, a United States and an Australian group.

Easterbrook and Maddern was published in 2008.⁵ It lists examples of several surgical products containing animal material, but the most unique part of the paper was the section on religious views. The paper concentrated on Judaism, Islam and Hinduism, both looking at religious writings and contacting religious authorities. This paper was available at the time of the highlighted clinical case and summarises the views of the religious faiths. In summary, it found that porcine-based surgical implants were generally acceptable to those of Jewish faith; porcine material should be avoided for followers of the Islamic faith, but may be acceptable if the circumstances involved life and death and there was no other alternative available. Bovine material was found not to be acceptable to Hindus. At the time the paper was reviewed, the authors noted the

section on Islam, but the paper contained a caveat that some Islamic scholars resisted the use of porcine material, with a non-animal alternative being preferred. The paper also suggested that the decision on whether to use animal material in surgery should be taken by the individual, after consultation with a cleric if desired.

Eriksson *et al* is the closest work to this publication and was the most practical use at the time of the illustrated case.⁶ It was published by a Danish group in 2013 and focused on the views on the major religious groups, gathering data via a validated questionnaire. The one significant difference in the results gleaned was that in

Table 1 Summary of 'biological' or third-generation mesh products

Name	Company	Porcine	Bovine	Human	Synthetic
Biodesign	Cook	Small Intestine Submucosa			
Cellis	Elemental Healthcare	Dermis			
CollaMend	Bard Davol	Dermis			
Egis	Raise Healthcare	Dermis			
ENDURAGen	Stryker	Dermis			
FortaGen	Organogenesis	Small Intestine Submucosa			
FortaPerm	Organogenesis	Small Intestine Submucosa			
Fortiva	RTI Surgical	Dermis			
Insuregraf	SK Bioland	Dermis			
InteXen	American Medical Systems	Dermis			
Permacol	Medtronic	Dermis			
Strattice	Allergan	Dermis			
XCM Biologic	Johnson and Johnson	Dermis			
XenMatrix	Bard Davol	Dermis			
Zenapro	Cook	Small Intestine Submucosa plus polypropylene			
Peri-Guard	Baxter		Pericardium		
SurgiMend	Integra LifeSciences		Dermis		
Tutomesh	RTI Surgical		Pericardium		
Tutopatch	RTI Surgical		Pericardium		
Veritas	Baxter		Pericardium		
AlloDerm	Allergan			Dermis	
AlloMax	Bard Davol			Dermis	
Cortiva	RTI Surgical			Dermis	
Dermaspan	Zimmer Biomet			Dermis	
Epiflex	DIZG			Dermis	
Flex HD	Johnson and Johnson			Dermis	
BIO-A	Gore				Polyglycolic acid and trimethylene carbonate
TIGR	Novus Scientific				Copolymers of glycolide, lactide and trimethylene carbonate

Table 2 Summary of views expressed by UK religious authorities

Source of mesh	Religious groups in England ^a					
	Christians	Muslims	Hindus	Sikhs	Jains	Buddhists
Bovine	✓	✓	✗	✗	✗	✗
Porcine	✓	✗	✗	✗	✗	✗
Human	✓	✓	✓	✓	✓	✓

^a These views are for elective surgery. In an emergency, all UK religious leaders contacted said that life takes precedence over religious prohibitions.

Eriksson *et al*, Buddhists were accepting of all animal and human material, whereas the results of the current review indicated that only human material would be acceptable. In Eriksson *et al*, Christians, Hindus and Sikhs would only use human derived implants if donor consent had been given. Attitudes to consent were not formally reassessed as part of this work. Eriksson *et al* limited themselves to elicit the view of the major religions. The current study is also interested in a more practical extension, confirming the contents of each available product, facilitating product selection for the individual patient.

Jenkins *et al* was published by a US-based group in 2010.⁷ It gives the most in depth analysis of the views of smaller Christian religious groups and other religious groupings more commonly found in the US and rarely found in the UK. Views were sought from Catholics, Methodists, Baptists, Lutherans, Jehovah's Witnesses, Church of Jesus Christ of Latter-Day Saints, Seventh Day Adventists and Evangelicals. Representatives of Judaism, Islam, Buddhism, Hinduism, Scientologists, People for the Ethical Treatment of Animals and veganism were also contacted. None of the Christian-orientated groups had objections to the use of animal material in surgery. There were concerns raised regarding the use of aborted fetal tissue in medicine, but that is beyond the scope of this review.

In Jenkins *et al*, the experts contacted suggested that there were no restrictions on the use of animal- or human-based products in Judaism or Islam. The Buddhist authority stated that while the use of products derived from animals was not forbidden, Buddhist teachings may lead many individual Buddhists to reject their use. Allogenic material would be acceptable to Buddhists. Hindus would also normally avoid the use of animal but not human products.

Rodger and Blackshaw was published in 2019.⁸ Written by a UK research team, it is a significant addition to the literature. It illustrates the extent of the use of animal products in many drugs, implants and dressings (principally from an anaesthetic perspective) and focuses on the law and ethics of disclosure. In addition to a religious perspective, it also considers the views of vegans. The authors point out that it would be difficult to give a genuinely vegan or animal-free anaesthetic. Common medications frequently contain animal material with no legal requirement for

contents with no therapeutic action to be listed on the packaging.

Shiwani (2011) is a *BMJ* editorial highlighting the problem of inadequate labelling and clinician's low level of knowledge regarding the exact contents of mesh products.⁹ It highlights the likelihood that many Jews, Muslims and Hindus may have had meshes containing animal-derived material placed during hernia repair without being fully informed. At the time of the case described in the introduction, this publication confirmed that there may be a problem, but did not assist the authors to find a practical solution.

Religious views expressed by UK religious leaders who responded as part of this study are summarised in Table 2. In summary, the religious leaders contacted stated that Muslims would normally avoid the use of porcine tissue. There could be a discussion on an individual basis if there was no other alternative. The contacted leaders from the Buddhist, Sikh, Hindu and Jain religions had no objection to the use of mesh products derived from human tissue but did not sanction the use of tissue from pigs or cows. Jewish and Christian leaders had no difficulty with the use of human or animal tissue in surgery. If the procedure were an emergency, all the contacted leaders agreed that the patient's life takes precedence over religious belief and all products in Table 1, irrespective of origin, would be acceptable.

Conclusion

The case which prompted this review was resolved by the identification of a synthetic alternative (Gore Bio-A) and a family meeting. As the case had been an emergency, the patient's view was that the Islamic emphasis on the sanctity of life outweighed the prohibitions on porcine tissue. He went home two days later without having his mesh exchanged or a clinical complication.

The available literature demonstrates that many clinicians do not always know the exact constituents of the products that they use in clinical practice, nor do they know the views of different religions (or at least the views of religious leaders) as to what is and is not commonly acceptable in either an elective or an emergency context.

There is a spectrum of belief in any religion and by highlighting this issue, surgeons should increasingly consider and discuss the use of animal products with an individual patient as part of the preoperative planning and consenting process, particularly in light of the Montgomery ruling.

References

1. Stoppa R, Louis D, Verhaeghe P *et al*. Current surgical treatment of post-operative eventrations. *Int Surg* 1987; **72**: 42–44.
2. Angell WW, Angell JD. Porcine valves. *Prog Cardiovasc Dis* 1980; **23**: 141–166.
3. Tatham KC, Patel KP. Suitability of common drugs for patients who avoid animal products. *BMJ* 2014; **348**: g401.
4. Baylón K, Rodríguez-Camarillo P, Elías-Zúñiga A *et al*. Past, present and future of surgical meshes: a review. *Membranes (Basel)* 2017; **7**: 47.
5. Easterbrook C, Maddern G. Porcine and bovine surgical products: Jewish, Muslim, and Hindu perspectives. *Arch Surg* 2008; **143**: 366–370.
6. Eriksson A, Burcharth J, Rosenberg J. Animal derived products may conflict with religious patients' beliefs. *BMC Med Ethics* 2013; **14**: 48.
7. Jenkins ED, Yip M, Melman L *et al*. Informed consent: cultural and religious issues associated with the use of allogeneic and xenogeneic mesh products. *J Am Coll Surg* 2010; **210**: 402–410.
8. Rodger D, Blackshaw BP. Using animal-derived constituents in anaesthesia and surgery: the case for disclosing to patients. *BMC Med Ethics* 2019; **20**: 14.
9. Shiwani MH. Surgical meshes containing animal products should be labelled. *BMJ* 2011; **343**: d4625.