440 consecutive immediate, implant-based, single-surgeon breast reconstructions in 281 patients: a comparison of early outcomes and costs between SurgiMend fetal bovine and AlloDerm human cadaveric acellular dermal matrices

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The study compared costs and consequences of acellular dermal matrices in breast reconstructive surgery. The author concluded that fetal bovine acellular matrices (SurgiMend) was preferable to human cadaveric acellular matrices (AlloDerm) due to its complication profile, price, sterility and handling characteristics. The study was transparently reported but excluded potentially relevant interventions and had potential for bias due to study design. The study should not be used to draw firm conclusions about the cost-effectiveness of SurgiMend compared to AlloDerm.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The study compared costs and complications of acellular dermal matrices in breast reconstructive surgery.

Interventions
Fetal bovine acellular dermal matrices (SurgiMend) were compared to human cadaveric acellular dermal matrices (AlloDerm) in breast reconstructive surgery after mastectomy. Patients had immediate implant-based breast reconstruction surgery by a one-stage process where the breast implant was inserted immediately or a two-stage process where a tissue expander was used before insertion of a permanent breast implant.

Location/setting
USA/Secondary Care

Methods
Analytical approach:
The cost-effectiveness analysis was based on a retrospective cohort study of 281 patients (440 breast reconstruction) with surgeries performed by a single surgeon between 2005 and 2010. The study had variable follow-up depending on whether patients had a one-stage or two-stage procedure. The study perspective was not stated explicitly.

Effectiveness data:
The primary measure of effectiveness was complications experienced by patients post surgery. Complications were monitored for the period between exchange of tissue expanders and permanent implants for two-stage procedures or for a minimum of three months from implant placement for one-stage procedures. Complications included infection, seroma, haematoma, major necrosis (requiring excision in the operating room), minor necrosis (addressed in office) and breast implant removal.

Patients were compared at baseline for demographic differences including age, body mass index, pre-operative bra size and medical risk factors (such as diabetes, hypertension, coronary arterial disease, smoking, chemotherapy and radiation therapy). There were 222 SurgiMend patients (351 breast reconstructions) and 59 AlloDerm patients (89 breast reconstructions).

Monetary benefit and utility valuations:
Not relevant.
Measure of benefit:
The measures of benefit were clinical effectiveness outcomes.

Cost data:
Only the cost of the acellular matrices was included. SurgiMend acellular matrix costs were derived from a review of invoices for the participating study hospitals. AlloDerm acellular matrix costs were derived from a review of costs used in other published studies. All costs were from 2010 and assumed an 8” by 16” common acellular matrix size.

Analysis of uncertainty:
Differences in patient characteristics and complications after surgery were analysed for statistical significance using p-values.

Results
The authors found no statistically significant patient demographic differences between the two cohorts.

There was no statistically significant difference between the interventions in total complications (p=0.66) but there were some statistically significant differences in individual complications. AlloDerm patients were more likely to have seroma (15.7% of patients versus 8.6% for SurgiMend, p=0.04). SurgiMend patients were more likely to have necrosis of any kind (11.1% versus 3.4%, p=0.03) and more likely to have minor necrosis (8.8% versus 1.1%, p=0.01), but not more likely to have major necrosis (p=0.99).

Costs for SurgiMend were $22/cm and for AlloDerm were $30/cm. If each arm of the study had 440 breast reconstructions then for the whole study SurgiMend matrices would be $450,560 less expensive if only the cost of the acellular matrix was included.

Authors’ conclusions
The author concluded that SurgiMend was preferable to AlloDerm due to its complication profile, price, sterility and handling characteristics.

CRD commentary
Interventions:
The author indicated that many other types of acellular matrices were in use but only two were selected for this study. The two selected for the study were well described but inclusion of only two of many interventions was not sufficient to reach firm cost-effectiveness conclusions.

Effectiveness/benefits:
Effectiveness data were derived from a single surgeon who had decided to switch from AlloDerm to SurgiMend and came from a case-series. The preference of the surgeon for SurgiMend could introduce bias. Case-series study designs have greater potential to introduce bias than more rigorous study designs such as randomised controlled trials. This specific case-series was highly unbalanced in the allocation of patients between interventions (59 AlloDerm patients and 222 SurgiMend patients). Because the author decided to switch treatments, with SurgiMend following AlloDerm, there may be a learning advantage built into the SurgiMend results.

Additionally, the outcomes presented did not account for some elements that may be important to patients, such as self-confidence after reconstruction and quality of life.

Costs:
A full cost-effectiveness analysis should include costs excluded from this analysis. Excluded costs included costs of the procedures, costs to treat complications and other medical costs that may be incurred after breast reconstruction by the patients that are related to the reconstruction. Costs for SurgiMend were derived from the hospitals where the surgeon performed reconstruction, which was appropriate. Methods for selecting the sources and selection criteria for the costs for AlloDerm were not described so it is unclear whether the costs were representative for the study setting.

Analysis and results:
The results were well reported but the study design was not a thorough cost-effectiveness analysis and the sample size
for AlloDerm was small.

The author gave a list of reasons why SurgiMend was preferable to AlloDerm; these all appeared valid but should be the subject of further study. The author's discussion highlighted that acellular matrices were safe for use in breast reconstruction and preferred by surgeons but did not provide any evidence that any specific acellular matrices were superior.

Concluding remarks:
The study was reported transparently but limitations of study design, potential for bias and exclusion of potentially relevant comparators make validation of the study results problematic. The study should not be used to draw firm conclusions about the cost-effectiveness of fetal bovine acellular matrices compared to human cadaveric acellular matrices.

Bibliographic details

PubMedID
23629076

DOI
10.1097/PRS.0b013e3182865ab3

Original Paper URL
http://journals.lww.com/plasreconsurg/Abstract/2013/05000/440__Consecutive__Immediate__Implant__Based_.6.aspx

Indexing Status
Subject indexing assigned by NLM

MeSH
Acellular Dermis; Adult; Animals; Breast Implants /economics; Breast Neoplasms /economics /surgery; Cadaver; Cattle; Collagen /therapeutic use; Female; Hospital Costs /statistics & numerical data; Humans; Mammaplasty /economics /methods; Middle Aged; Postoperative Complications /economics /prevention & control; Retrospective Studies; Tissue Expansion Devices /economics; Treatment Outcome

AccessionNumber
22013031714

Date bibliographic record published
15/08/2013

Date abstract record published
10/01/2014