

## ORIGINAL ARTICLE

# A Randomized Trial of Low-Cost Mesh in Groin Hernia Repair

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## ABSTRACT

**BACKGROUND**

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The most effective method for repair of a groin hernia involves the use of a synthetic mesh, but this type of mesh is unaffordable for many patients in low- and middle-income countries. Sterilized mosquito meshes have been used as a lower-cost alternative but have not been rigorously studied.

**METHODS**

We performed a double-blind, randomized, controlled trial comparing low-cost mesh with commercial mesh (both lightweight) for the repair of a groin hernia in adult men in eastern Uganda who had primary, unilateral, reducible groin hernias. Surgery was performed by four qualified surgeons. The primary outcomes were hernia recurrence at 1 year and postoperative complications.

**RESULTS**

A total of 302 patients were included in the study. The follow-up rate was 97.3% after 2 weeks and 95.6% after 1 year. Hernia recurred in 1 patient (0.7%) assigned to the low-cost mesh and in no patients assigned to the commercial mesh (absolute risk difference, 0.7 percentage points; 95% confidence interval [CI], -1.2 to 2.6;  $P=1.0$ ). Postoperative complications occurred in 44 patients (30.8%) assigned to the low-cost mesh and in 44 patients (29.7%) assigned to the commercial mesh (absolute risk difference, 1.0 percentage point; 95% CI, -9.5 to 11.6;  $P=1.0$ ).

**CONCLUSIONS**

Rates of hernia recurrence and postoperative complications did not differ significantly between men undergoing hernia repair with low-cost mesh and those undergoing hernia repair with commercial mesh. (Funded by the Swedish Research Council and others; Current Controlled Trials number, ISRCTN20596933.)

*N Engl J Med* 2016;374:146-53.

DOI: 10.1056/NEJMoa1505126

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**R**PAIR OF A GROIN HERNIA IS ONE OF the most frequently performed surgical procedures worldwide, with approximately 20 million operations performed annually.<sup>1-3</sup> Groin hernia causes considerable illness and even death if left untreated, and its repair has been identified as a key intervention to reduce the burden of disease in low- and middle-income countries.<sup>1,4-9</sup> Surgery in general and groin hernia repair in particular have also been shown to be highly cost-effective, even in comparison with other prioritized health care interventions such as child vaccination and treatment of human immunodeficiency virus infection in such settings.<sup>10,11</sup> Resource constraints, however, restrict the capacity to provide sufficient surgical volume, which has resulted in a large burden of disease in low- and middle-income countries.<sup>4,5</sup>

Limited resources also influence the choice of surgical technique. In high-income countries, a synthetic mesh is used in almost all hernia repairs, because this type of mesh results in a significantly lower risk of recurrence than the risk with the older, sutured techniques.<sup>12-16</sup> Many commercial meshes are available for hernia repair. These commonly cost more than \$100 (in U.S. dollars) each. This cost limits the use of commercial mesh in many low- and middle-income countries, where an estimated 2.4 billion people live on less than \$2 (in U.S. dollars) per day, and a large proportion of health care costs are paid out of pocket.<sup>17,18</sup>

Mosquito meshes, which are similar to commercial meshes, are currently used in some places as a low-cost alternative in hernia repair.<sup>19-23</sup> Previous studies on the use of mosquito mesh in groin hernia repair have shown promising results with respect to tissue reaction, outcome, and cost-effectiveness.<sup>19,21-26</sup> However, data from randomized trials are lacking to inform the safety and long-term effectiveness of this practice. The aim of the current randomized trial was to assess the outcomes of groin hernia repair performed with the use of a low-cost lightweight mesh as compared with a commercial lightweight mesh in a low-income country in sub-Saharan Africa.

## METHODS

### STUDY DESIGN AND OVERSIGHT

This study was a double-blind, randomized, controlled trial comparing the use of a low-cost mesh with the use of a commercial mesh in the repair of a groin hernia in adult men. The study was carried out and analyzed in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines. No modifications to the design of the study were made during its conduct. The protocol is available with the full text of this article at NEJM.org. The first author assumes responsibility for the accuracy and completeness of the data and analysis and for the fidelity of this report to the study protocol.

Ethical approval for the study was granted by the institutional review board at the School of Biomedical Sciences, Makerere University, and by the Uganda National Council for Science and Technology. All participants provided written informed consent. A thumbprint was used for patients who could not write their names.

### PATIENTS AND STUDY SETTING

Adult men ( $\geq 18$  years of age) with a primary, unilateral, reducible groin hernia, an American Society of Anesthesiologists classification score (a measure of physical status for patients undergoing surgery) of less than 3 (on a scale of 1 to 6, with higher values indicating more severe disease), and the ability to give informed consent were eligible for inclusion. Exclusion criteria were femoral hernia, obvious substance abuse, and confirmed or suspected coagulopathy.

Recruitment was carried out in several villages in eastern Uganda. All persons who came to the recruitment sessions were offered a clinical examination by a physician. Information on noneligible persons was not collected. The surgery was performed at the Kamuli Mission Hospital, a 160-bed private not-for-profit hospital, in Kamuli District, Uganda.

Uganda, located in eastern Africa, is a low-income country that is ranked 164 out of 187 countries with respect to social and economic development, according to the Human Development Index.<sup>27</sup> The annual per capita gross domes-

tic product is \$657 (in U.S. dollars), and the per capita health care expenditure is \$59.<sup>28,29</sup> Of the 37 million inhabitants, almost 40% live in poverty on less than \$1.25 (in U.S. dollars) per day.<sup>30</sup> Most people live in rural settings; Kamuli, a typical rural district, is located approximately 120 km from the capital city, Kampala.<sup>31</sup>

#### PROCEDURES AND MATERIALS

All patients included were operated on by one of the four senior surgeons (two Ugandan and two Swedish) who participated in the study. The anterior mesh technique according to Lichtenstein,<sup>13</sup> performed under local anesthesia, was used for all patients. The local anesthesia consisted of an equal mix of lidocaine (10 mg per milliliter) and ropivacaine (7.5 mg per milliliter). During the first 10 operations, the surgeons worked together to confirm that the same surgical and anesthetic techniques were practiced on all patients. A prophylactic oral dose of 1.5 g of floxacillin (flucloxacillin) was administered before surgery. The aim was to perform the surgery on an outpatient basis. Patients with clinically significant postoperative problems, those with very large scrotal hernias (with associated increased risk of bleeding), and those who underwent surgery late in the afternoon stayed until the next day.

Patients in the intervention group received a low-cost mesh composed of 100% polyethylene produced by Amsa Plastics (Karur, India). The mechanical properties of this mesh, which normally serves as a mosquito net, are similar to those of widely available commercial surgical meshes.<sup>21</sup> The control group received a commercial 100% polypropylene mesh (Parietene Light), manufactured by Covidien. Both were lightweight meshes (the low-cost mesh weighed 38.0 g per square meter, and the commercial mesh weighed 53.7 g per square meter), and the pore size was similar in the two meshes (1.5 mm and 1.9 mm, respectively). Each low-cost mesh costs less than \$1 (in U.S. dollars), whereas a commercial mesh costs \$125 (in U.S. dollars) when bought in Uganda.

Nurses working in the operating theater prepared the low-cost mesh before use. First, they washed it with water and a mild detergent. Thereafter, they cut it into pieces 10 cm by 15 cm in size, packed the pieces individually, and auto-

claved them at 121°C for 20 minutes. A previous study showed that this method achieved adequate sterility, with minimal structural changes to the mesh.<sup>32</sup>

Equipment for the surgeries was donated or provided at a reduced cost by Östersund Hospital, Capio S:t Göran's Hospital, IBBAB-Instrumenta, Mölnlycke Health Care, Covidien Sweden, Stille, Textilia, and OneMed. These entities had no role in the conception, design, or conduct of the study or in the analysis or interpretation of the data.

#### RANDOMIZATION AND BLINDING

The operation list and the order of the patients were determined on the day before surgery. On the day of surgery, patients were assigned to each surgeon consecutively, according to the predetermined order. Randomization was performed by a nurse after the surgeons had taken their next patient to the operating room. A computer-based program was used to randomize the sequence of treatment groups in blocks of four and six. Thereafter, the surgeon, but not the patient, was informed of which mesh would be used. The two physicians performing the follow-up did not participate in the randomization or in the surgeries, and they were unaware of the study-group assignments.

#### STUDY OUTCOMES

The primary outcomes of the study were hernia recurrence at 1 year and postoperative complications. Hernia recurrence was defined as a recurrent palpable hernia on examination on the same side as the repair. Postoperative complications were assessed at a 2-week follow-up visit and included hematoma, infection, seroma, impaired wound healing (wound not completely closed at 2 weeks), severe pain, urinary retention, or any serious adverse event. Secondary outcomes were measures of groin hernia symptoms or chronic pain, self-assessed health status on a scale from 0 (worst imaginable health) to 100 (best imaginable health), and patient satisfaction with the result of the operation at 1 year. The degree of pain due to groin hernia in the preceding week was assessed with the use of the Inguinal Pain Questionnaire, a validated tool that is commonly used for research purposes; scores range from 1 (no pain) to 7 (severe pain requiring immediate medical attention).<sup>33</sup> Detailed definitions of the

primary and secondary outcomes are provided in Table S1 in the Supplementary Appendix, available at NEJM.org.

#### DATA COLLECTION

Patients were interviewed and examined on recruitment, the evening before surgery, and at follow-up 2 weeks and 1 year after the surgery with the use of questionnaires developed for the study. The questionnaires collected information on demographic information, medical history, and hernia symptoms. The interviews and physical examination focused specifically on the primary and secondary outcome measures. Physical examination was performed in order to detect hernia recurrence and postoperative complications. Each patient was examined by two physicians who were unaware of the study-group assignments. Treatment of complications was offered, when needed, at no cost to the patients.

#### STATISTICAL ANALYSIS

We calculated that a sample size of 150 patients in each group would give the study 80% power, at a significance level of 5%, to detect an absolute between-group difference of 5 percentage points in the rate of hernia recurrence at 1 year (0% in the group assigned to the commercial mesh and 5% in the group assigned to the low-cost mesh). The projection of a 0% recurrence rate at 1 year in the commercial-mesh group was based on a Cochrane review and a meta-analysis comparing mesh repair with sutured repairs, which showed a 0.9% risk of recurrence after mesh repair (range of follow-up duration, 3 weeks to 6 years).<sup>14,15</sup> Recurrences often occur later than 1 year after surgery, and therefore a 0% recurrence rate at 1 year was a reasonable estimate.<sup>34</sup>

We analyzed data according to the group to which participants were randomly assigned; the analysis did not include persons who were determined after randomization to be ineligible. One interim analysis was performed after 163 patients had been enrolled and followed for at least 2 weeks (60 of whom had been followed for 1 year).

Continuous and ordinal variables are presented as means and standard deviations, and binary variables as numbers and percentages. Two sample t-tests were used for continuous variables, and Pearson's chi-square test, Fisher's

exact test, or an exact binomial test were used for counts, as appropriate. Two-sided P values of less than 0.05 were considered to indicate statistical significance. Two-sided 95% confidence intervals for the outcomes were calculated according to the method of Jeffreys.<sup>35</sup> All calculations were performed with the use of Excel 2013 (Microsoft), SPSS software (IBM), and MATLAB 2014 (MathWorks).

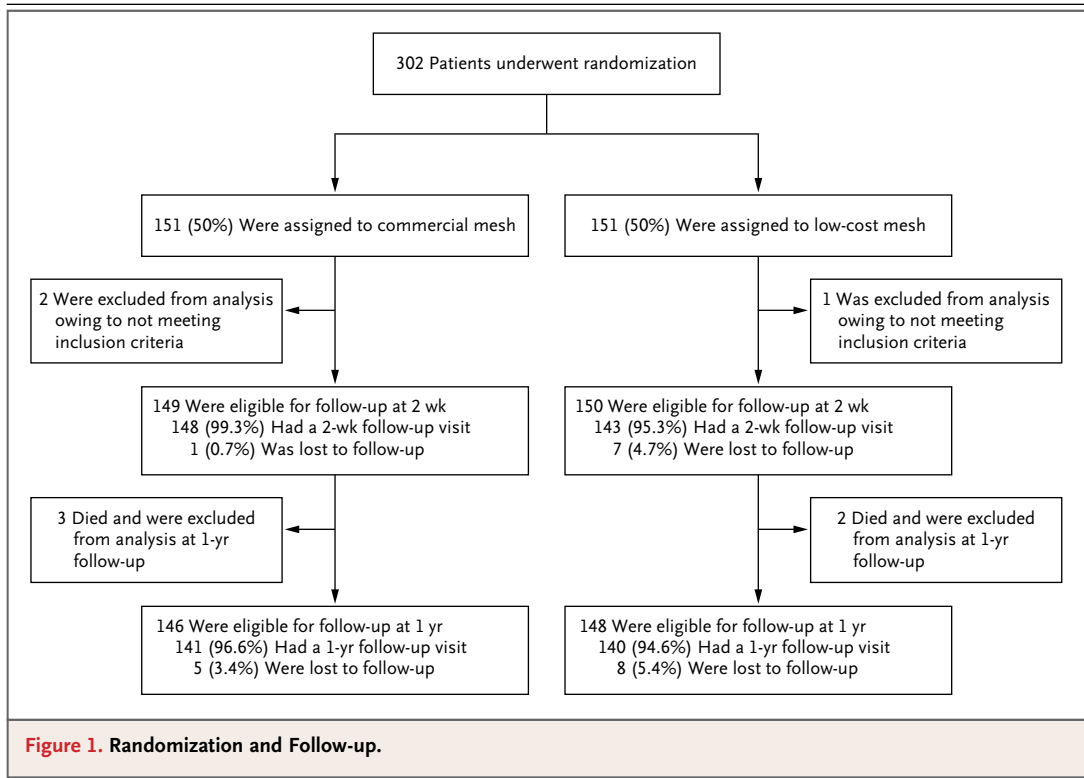
## RESULTS

From February 2012 through October 2013, a total of 302 patients were enrolled and underwent randomization (Fig. 1). Operations were carried out during three 2-week periods. No patient had to be switched from local to general anesthesia. Three patients who had been enrolled erroneously (1 patient assigned to the low-cost mesh and 2 assigned to the commercial mesh) were not followed. The baseline characteristics of the patients were similar in the two groups (Table 1).

Two weeks postoperatively (range, 10 to 34 days; mean, 18.1 days), 291 of 299 patients (97.3%) were seen for the follow-up interview and physical examination. There was one severe adverse event — a postoperative death of a patient assigned to the low-cost mesh. This case was investigated in detail. An autopsy had not been performed before burial occurred (in the study setting, autopsies are rare), and clinical information was insufficient to assign a cause of death; the information that was available is included in the Supplementary Appendix.

After 1 year (range, 379 to 1051 days; mean, 492), 281 of 294 patients (95.6%) were seen for the interview and physical examination; 13 (4.4%) were lost to follow-up. The time from surgery to follow-up was similar in the two groups ( $P=0.35$ ). Four deaths, all of unknown cause, occurred after the 2-week follow-up: 1 patient assigned to the low-cost mesh died at 543 days postoperatively, and 3 patients assigned to the commercial mesh died at 82 days, 552 days, and 642 days postoperatively. Information obtained from interviews with relatives of the patients is provided in the Supplementary Appendix.

A recurrence of hernia occurred in 1 patient (0.7%) assigned to the low-cost mesh and in no patients assigned to the commercial mesh (abso-



**Table 1. Preoperative Characteristics of the Study Participants.\***

Characteristic	Low-Cost Mesh (N=150)	Commercial Mesh (N=149)
Age — yr	45.1±17.6	46.4±17.8
ASA classification score of 1 — no. (%)†	132 (88.0)	132 (88.6)
Body-mass index‡	21.5±2.5	20.8±2.2
Scrotal hernia — no. (%)	58 (38.7)	59 (39.6)
Smoker — no. (%)	12 (8.0)	15 (10.1)
IPQ score§	3.4±1.3	3.4±1.2
Self-assessed health status score¶	59.5±16.4	58.2±18.0

\* Plus-minus values are means ±SD. There were no significant differences (at P<0.05) between the two groups with respect to any of the baseline characteristics, except with respect to body-mass index, for which P=0.02.

† An American Society of Anesthesiologists (ASA) classification score of 1 (on a scale of 1 to 6, with higher values indicating more severe disease) indicates that the patient has no systemic disease.

‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.

§ Scores on the Inguinal Pain Questionnaire (IPQ) range from 1 (no pain) to 7 (severe pain requiring immediate medical attention).

¶ Scores for self-assessed health status were on a scale that ranged from 0 (worst imaginable health) to 100 (best imaginable health).

lute risk difference, 0.7 percentage points; 95% confidence interval [CI], -1.2 to 2.6), and any postoperative complication occurred in 44 patients (30.8%) and 44 patients (29.7%), respectively (absolute risk difference, 1.0 percentage point; 95% CI, -9.5 to 11.6) (Table 2). Hematoma or swelling in the groin or scrotum was the most common postoperative complication in each group, followed by impaired wound healing and superficial infection. There were no significant differences between groups in groin symptoms, patient satisfaction, and self-assessed health status (Table 3).

**DISCUSSION**

In this randomized trial comparing low-cost mesh with commercial mesh for use in hernia repair in Uganda, the rate of hernia recurrence at 1 year did not differ significantly between the group that received the low-cost mesh and the group that received the commercial mesh, and the rates were very low overall (0.7% and 0%, respectively). We also found no significant dif-

**Table 2. Primary Outcomes and Mortality among the Study Participants.\***

Outcome	Low-Cost Mesh (N=143)	Commercial Mesh (N=148)	Absolute Difference percentage points (95% CI)	P Value
	no. of patients (%)			
Primary outcomes				
Hernia recurrence	1 (0.7)	0	0.7 (−1.2 to 2.6)	1.0
Any postoperative complication	44 (30.8)	44 (29.7)	1.0 (−9.5 to 11.6)	1.0
Distribution of postoperative complications				
Hematoma or swelling in groin or scrotum	35 (24.5)	35 (23.6)	0.8 (−9.0 to 10.7)	1.0
Superficial infection	4 (2.8)	6 (4.1)	1.3 (−5.6 to 3.1)	0.38
Seroma	1 (0.7)	0	0.7 (−1.2 to 2.6)	1.0
Impaired wound healing	5 (3.5)	8 (5.4)	1.9 (−6.8 to 3.0)	0.29
Severe pain	2 (1.4)	0	1.4 (−0.9 to 3.7)	1.0
Other complication	2 (1.4)	4 (2.7)	1.3 (−4.8 to 2.2)	0.34
Death†	2 (1.4)	3 (2.0)	0.6 (−3.9 to 2.6)	1.0

\* Hernia recurrence was assessed at the 1-year follow-up visit, and postoperative complications were assessed at the 2-week follow-up visit. CI denotes confidence interval.

† All deaths during the study were investigated through interviews with relatives of the patients; the details obtained are shown in the Supplementary Appendix. No other severe adverse events were reported during the study.

**Table 3. Secondary Outcomes — Groin Symptoms, Self-Assessed Health, and Patient Satisfaction.\***

Outcome	Low-Cost Mesh (N=140)	Commercial Mesh (N=141)	Absolute Difference percentage points (95% CI)	P Value
	no. (%)†			
Lesser degree of groin symptoms than preoperatively — no. (%)†	138 (98.6)	139 (99.3)	0.7 (−3.5 to 2.1)	1.0
Maximum IPQ score during previous week‡	1.3±0.7	1.3±0.7	0.0 (−0.2 to 0.2)	0.66
Distribution of IPQ scores — no. (%)‡				1.0
Score of 1: no pain	116 (82.9)	114 (80.9)	2.0 (−7.1 to 11.0)	
Score of 2 or 3: pain that does not interfere with daily activities	21 (15.0)	21 (14.9)	0.1 (−8.3 to 8.5)	
Score of 4 or 5: pain that interferes with daily activities	3 (2.1)	6 (4.3)	2.1 (−6.4 to 2.2)	
Self-assessed health status§				
Score	84.2±14.8	85.4±14.4	1.2 (0.3 to 2.1)	0.48
Difference from preoperative score	25.1±21.7	26.8±21.3	1.7 (0.6 to 2.8)	0.37
Patient satisfied with result of surgery — no. (%)†	137 (97.9)	138 (98.6)	0.7 (−4.1 to 2.7)	1.0

\* Plus-minus values are means ±SD. The outcomes were assessed at the 1-year follow-up visit.

† Data were missing for one patient in the commercial-mesh group.

‡ Scores on the Inguinal Pain Questionnaire (IPQ) range from 1 (no pain) to 7 (severe pain requiring immediate medical attention).

§ Scores for self-assessed health status were on a scale that ranged from 0 (worst imaginable health) to 100 (best imaginable health). The difference from the preoperative score is for patients with data available both before surgery and at 1 year.

ference between the groups in the rate of postoperative complications (30.8% and 29.7%, respectively).

Our findings are consistent with those of previous observational studies that have shown similar outcomes with respect to postoperative complications and hernia recurrence among patients who underwent groin hernia repair with the use of low-cost mesh and those who underwent the procedure with the use of commercial mesh; our findings are also consistent with clinical experience from large-scale use of low-cost mesh.<sup>21,36</sup> Because groin hernia is a very common condition and its repair is one of the most commonly performed surgical procedures worldwide and because the cost of commercial mesh is prohibitive in many low- and middle-income countries, the findings of this study could have broad relevance for the care of these patients.<sup>1,4-6,37</sup>

The recurrence rate of 0.7% with low-cost mesh is consistent with recurrence rates reported with commercial mesh in high-income countries.<sup>38</sup> Hematoma or swelling in the groin or scrotum was documented more frequently than has been reported in high-income countries (5.6 to 16%).<sup>12</sup> A likely explanation is that more than a third of the study participants had a scrotal hernia, which is associated with an increased risk of diffuse bleeding and swelling. None of the hematomas were incised or drained. Superficial infection was uncommon, occurring in 3.4% of the study participants; the incidence was similar to rates of documented postoperative infection in Western countries.<sup>16</sup> These findings, together with the observation that the vast majority of patients in the two study groups were satisfied with the result of their operation, suggest that high-quality surgical care for hernia can be provided in areas in which resources are limited.

Limitations of our trial should be noted. First, the results should not be generalized to any available low-cost mesh or to settings that do not have procedures in place to ensure safety. The use of this alternative mesh requires correct preparation, including sterilization.<sup>22</sup> Preparation and distribution of the mesh to surgical facilities must be carefully monitored, and fa-

cilities must incorporate training and education of surgeons and staff and quality assessment in order to minimize adverse events. The meticulous attention to these details in the current study is not routine in the general health care system in most countries. Second, the inclusion criteria for this study resulted in a population that is not representative of the average patient with groin hernia in sub-Saharan Africa. In some hospitals in this part of the world, more than 40% of hernia repairs are performed on an emergency basis, and more than 20% of the patients undergoing hernia repair are women. In addition, most hernia repairs are performed by nonsurgeons.<sup>3,4,39</sup>

Third, owing to cost and feasibility issues, the current study used a superiority design, and thus the findings cannot be interpreted to show noninferiority of low-cost mesh repair to commercial mesh repair. Given the relatively small sample size in this trial, we had limited power to detect differences between groups in the rate of hernia recurrence; however, recurrence was very uncommon in both groups at 1 year. Finally, our study had only 1 year of follow-up, and recurrence rates would be expected to increase over time; further follow-up is needed to assess longer-term rates of recurrence, chronic pain, and patient satisfaction.

In summary, this study showed that a low-cost mesh can be used in hernia repair with excellent clinical outcomes that do not differ significantly from those achieved with commercial mesh. These results support the use of low-cost mesh for hernia repair in resource-scarce settings, after appropriate training of the staff performing the procedures.

Supported by the Swedish Research Council; the Department of Public Health and Clinical Medicine, Unit of Research, Education, and Development, Östersund, Umeå University; the Swedish Medical Society; Capio Research Foundation; Rotary Sweden; the Church of Sweden, Östersund; and Karolinska Institutet.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Mr. Keith Nyende, Dr. Joseph Wakonta, Ms. Rosette Nume, and Mr. Michael Waiswa for their dedicated work in the field; Ms. Ewa Nordin for preparatory work and logistics, as well as the hospital staff at Kamuli Mission Hospital; Dr. Henrik Holmberg, Dr. Lars Söderström, Dr. Johan Svensson, and Ms. Hilda Edlund for assistance with statistical analysis; and Professor Andrew Kingsnorth for his support and for providing us with the low-cost mesh used in the trial.

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