Impact of Laparoscopic Nissen Fundoplication With Prosthetic Hiatal Closure on Esophageal Body Motility

Results of a Prospective Randomized Trial

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Hypothesis: Prosthetic crural closure does not adversely influence esophageal body motility. In most patients, postoperative increased dysphagia resolves spontaneously during the first months after surgery.

Design: Prospective randomized trial. We compared patients who underwent laparoscopic Nissen fundoplication with simple sutured hiatal closure and those who underwent laparoscopic Nissen fundoplication with prosthetic hiatal closure.

Setting: University-affiliated community hospital.

Patients: Forty consecutive patients who underwent laparoscopic Nissen fundoplication for gastroesophageal reflux disease.

Interventions: A 360° Nissen fundoplication with simple sutured crura (n=20; nonmesh group) vs the same procedure with posterior 1 × 3-cm polypropylene onlay mesh prosthesis (n=20; mesh group).

Main Outcome Measures: Recurrences; postoperative dysphagia rate; localization, length, and pressure of the lower esophageal sphincter (LES); results of 24-hour pH monitoring; esophageal body motility; peristalsis; and esophageal amplitude of contraction and interrupted waves.

Results: Preoperatively, both groups had pathological LES pressure and DeMeester scores. These values improved significantly (P<.01) after surgery and remained stable at 1 year after surgery. Patients in the nonmesh group had a significantly lower LES pressure 1 year after surgery compared with those in the mesh group. There were no significant differences in postoperative mean LES length (4.1 vs 3.8 cm), LES relaxation (93.4% vs 92.4%), and intrathoracic LES length (2.1 vs 2.1 cm). Patients in the mesh group had fewer simultaneous waves and interrupted waves 1 year after surgery, but the difference between groups was not significant. There were no significant differences in interrupted waves and amplitude of contraction between groups 1 year after surgery.

Conclusion: Laparoscopic Nissen fundoplication with prosthetic crural closure does not impair postoperative esophageal body motility compared with laparoscopic Nissen fundoplication with simple suture hiatal closure, although it is associated with a higher rate of short-term dysphagia.

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The primary goal of laparoscopic antireflux surgery (LARS) is to create an antireflux barrier by performing a fundoplication and hiatal closure. Gastroesophageal reflux disease (GERD) is frequently accompanied by the presence of hiatal hernia; therefore, most authors agree that routine crural closure has to be added to fundoplication in LARS or in large-hernia repair.1,2 The most common morphological complication after LARS for GERD or hiatal hernia is the postoperative migration of the intact fundic wrap into the mediastinum.3,4 This complication usually leads to recurrent or persistent GERD symptoms such as dysphagia, recurrent reflux, or a combination of both. To prevent postoperative intrathoracic wrap herniation, some authors have advocated the use of prosthetic materials for closure of the hiatal crura.5-8 Especially in LARS for large hiatal hernia repair but also for GERD, prosthetic hiatal closure can reduce the postoperative recurrence rate significantly.9,10 However, the use of prosthetic mesh for crural closure appears to cause some adverse effects. In a large nonrandomized study,11 we evaluated the outcome of LARS with mesh hiataloplasty by comparing patients who underwent LARS with simple sutured crural closure with patients who underwent LARS with a prosthetic hiataloplasty. Patients with mesh hiataloplasty had a significantly higher rate of postoperative dysphagia 3 months...
after surgery, which decreased spontaneously at the 1-year follow-up.

The aim of the present study was to reevaluate these findings thoroughly by performing a prospective randomized trial to clarify the following questions: (1) Does the use of prosthetic mesh for crural closure influence esophageal body motility? (2) Is prosthetic hiatal closure associated with a higher dysphagia rate? (3) If so, for what postoperative period does the higher dysphagia rate remain?

## METHODS

Forty patients with GERD (12 women and 28 men; mean age, 47.6 years [range, 24-68 years]) were allocated for laparoscopic 360° floppy Nissen fundoplication at our surgical unit. All patients had a long history of GERD symptoms (mean, 4.2 ± 3.1 years) and had been treated with proton pump inhibitors or histamine2-blocker medication at least 7 days before monitoring. After location during primary esophageal manometry, the pH electrode is placed 5 cm above the the upper border of the LES. Before and after surgery, all patients were classified using the following dysphagia score: able to eat solid food (1), able to eat semisolid food (2), able to swallow liquids only (3), and dysphagia for solids, semisolids and liquids (complete obstruction; 4).

PREOPERATIVE DEMOGRAPHICS OF PATIENTS

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Mesh</th>
<th>Nonmesh</th>
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<td>10</td>
</tr>
<tr>
<td>&gt;5</td>
<td>9</td>
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<tr>
<td>No. of hiatal sutures, mean</td>
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<td>2.0</td>
</tr>
<tr>
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<tr>
<td>Preoperative DeMeester score, mean</td>
<td>53.4</td>
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</table>

Abbreviation: LES, lower esophageal sphincter.

## ESOPHAGEAL MANOMETRY

Stationary pull-through esophageal manometry was performed using a water-perfused polyvinyl catheter (Medtronic Inc, Minneapolis, Minn) with side holes connected to an external transducer assembly. The catheter combines 5 capillary tubes 0.8 mm in diameter with side openings at 5 different levels. The tubes are radially spaced 3 cm apart for esophageal body motility study. After an overnight fast, the catheter is introduced transnasally until all 5 holes are in an intra-abdominal position, which is noted by a pressure increase on inspiration. For identification of the high-pressure zone of the lower esophageal sphincter (LES), the catheter is withdrawn across the cardioesophageal junction. The catheter is withdrawn 1 cm at a time. The following values are noted: (1) distal border of the LES, (2) respiratory inversion point, and (3) upper border of the LES.

From these measurements, LES overall length, intra-abdominal length, and pressure are determined. For assessment of esophageal body motor function, the most distal pressure transducer is located 1 cm above the upper border of the LES. With this method, the pressure response throughout the whole esophagus can be obtained by swallowing. The response to 10 wet swallows (each 5 mL of water) is then recorded. Amplitude, duration, number of peaks, and esophageal activity of contractions after each swallow are measured at each level of the esophageal body. The esophageal contraction waves after a swallow are classified as peristaltic, simultaneous, or interrupted. Esophageal dysmotility was defined as an amplitude of less than 30 mm Hg in the lower segments in response to wet swallows and peristalsis of greater than 40% of simultaneous contractions in wet swallows.

## SYMPTOMATIC EVALUATION

Preoperatively, the subjective value of postoperative dysphagia was measured using a simple verbal rating scale subdivided into none, mild, moderate, and severe. In addition, after surgery, all patients were classified using the following dysphagia score: able to eat solid food (1), able to eat semisolid food (2), able to swell liquids only (3), and dysphagia for solids, semisolids and liquids (complete obstruction; 4).

## SURGICAL TECHNIQUE

All patients of both groups underwent laparoscopic 360° floppy Nissen fundoplication in a standardized manner by 2 laparoscopic experienced surgeons (F.A.G. and R.P.) as described recently. In the nonmesh group, the hiatal crura were closed using 1 to 4 simple nonabsorbable interrupted sutures, depending on the size of hiatal defect (Figure 1). In the mesh group, the hiatal crura were primarily closed with simple sutures and additionally reinforced with a 1 × 3-cm polypropylene mesh (Figure 2).
FOLLOW-UP

At the day of discharge, the extent of dysphagia was evaluated using the scoring system as described in the “Symptomatic Evaluation” subsection. Standardized follow-up occurred 6 weeks, 3 months, and 1 year after surgery. All 40 patients were available for complete follow-up. Routine EGD at our surgical unit or by a local gastroenterologist was performed 6 weeks after surgery. At 3 months and 1 year after surgery, esophageal manometry, 24-hour pH monitoring, cinematographic radiography (barium swallow), and evaluation of dysphagia were performed. In all patients who were referred to our unit in the meantime with any kind of persistent or recurrent signs of GERD symptoms during follow-up, routine EGD and cinematographic radiography were performed.

STATISTICS

We used commercially available software (SPSS program; SPSS Inc, Chicago, Ill) for statistical analysis comparing baseline differences between the surgical groups and treatment results using tests as appropriate. A P value <.05 was considered statistically significant. Data are reported as mean, mean±SD, range, or percentage.

RESULTS

All procedures could be completed laparoscopically with no intraoperative complications in either surgical group. There was no significant difference in mean operating time between groups (mesh group, 59 minutes; nonmesh group, 55 minutes). There were no significant differences between groups regarding demographic data such as age, sex, weight, or height (Table). Preoperative and postoperative evaluation of symptomatic outcome, upper gastrointestinal tract endoscopy, esophageal manometry, and 24-hour pH monitoring were performed in all patients.

ESOPHAGOGASTRODUODENOSCOPY

Preoperatively, 3 patients (15%) in each group had a histologically verified Barrett esophagus. All patients in both groups presented with a hiatal hernia at preoperative EGD. A small hiatal hernia (<5 cm) could be detected in 11 patients in the mesh group (35%) and in 10 patients in the nonmesh group (50%). In 9 patients in the mesh group (45%) and 10 patients in the nonmesh group (50%), hiatal hernia was larger than 5 cm.

At the 6-week follow-up examination, no patient in either surgical group showed any signs of recurrent hiatal hernia and/or intrathoracic wrap migration.

CINEMATOGRAPHIC RADIOGRAPHY

During the complete follow-up, no patient in either group showed pathological findings on cinematographic radiography, especially signs of postoperative intrathoracic wrap migration.

ESOPHAGEAL MANOMETRY: LES

Mean LES Length

Figure 3 shows the mean LES length in both groups. Preoperatively, the mean LES length is similar in both groups (mesh group, 2.0 cm; nonmesh group, 2.0 cm). The LES length increased significantly (P<.01) at 3 months (mesh group, 3.6 cm; nonmesh group, 3.8 cm) and 1 year (mesh group, 4.1 cm; nonmesh group, 3.8 cm) after surgery and was comparable in both groups.
Mean Intra-abdominal LES Length

The proportion of the LES within the abdomen showed no significant differences between the surgical groups. Despite a significant increase ($P < .05$) from preoperative values (mesh group, 1.1 cm; nonmesh group, 0.9 cm) to postoperative values at 3 months (mesh group, 2.2 cm; nonmesh group, 2.5 cm) and 1 year (mesh group, 2.1 cm; nonmesh group, 2.1 cm), a significant difference between groups was not detected (Figure 4).

LES Pressure

Preoperatively, the mean LES pressure was pathological and similar in both groups (mesh group, 3.6 ± 1.8 mm Hg; nonmesh group, 3.1 ± 1.7 mm Hg). At the 3-month follow-up, the LES pressure improved significantly ($P < .01$) to 12.9 ± 4.8 mm Hg in the mesh group and 12.0 ± 4.0 mm Hg in the nonmesh group. At the 1-year follow-up, a significant difference between groups was found (Figure 5). In mesh group patients, the LES pressure remained stable at 13.9 ± 4.9 mm Hg; in nonmesh group patients, the LES pressure decreased to 8.9 ± 3.7 mm Hg ($P < .01$).

Mean LES Relaxation

The mean LES relaxation was almost complete in both groups (mesh group, 99.7%; nonmesh group, 99.3%). After surgery, the mean LES relaxation decreased to 87.4% in the mesh group and to 92.2% in the nonmesh group (both, $P < .05$). At 1 year after surgery, LES relaxation increased again and was comparable in both groups (mesh group, 93.4%; nonmesh group, 92.4%) (Figure 6).

ESOPHAGEAL MANOMETRY: ESOPHAGEAL BODY MOTILITY

Amplitude of Contractions in Wet Swallows

Mesh Group. In the mesh group, the postoperative mean amplitude of contractions in wet swallows showed a significant improvement in all 5 esophageal levels compared with preoperative values ($P < .05$). At the 1-year follow-up, this improvement remained constant in all esophageal segments but level 5. In level 5, the amplitude at first increased from a preoperative level of 52.3 mm Hg to 63.6 mm Hg at 3 months, but again decreased to 61.9 mm Hg at 1 year (Figure 7).

Nonmesh Group. Preoperatively, the mean amplitude of contractions in wet swallows was pathological in levels 3 to 5 and improved significantly during follow-up to normal values at the 1-year follow-up ($P < .05$). In level 4, after primary improvement from a preoperative value of 32.2 mm Hg to 46.8 mm Hg at 3 months, the amplitude decreased minimally to 45.3 mm Hg at 1 year. In level 5, the amplitude increased significantly from a preoperative value of 23.7 mm Hg to 47.9 mm Hg at 3 months, but then decreased to 38.1 mm Hg at 1 year ($P < .05$) (Figure 8).

Esophageal Peristalsis: Simultaneous Waves

Mesh Group. In general, no pathological simultaneous waves were found in the mesh group. Simultaneous waves
were detected only in levels 2 and 5. In level 2, the mean percentage of simultaneous waves was 10% and decreased completely at both postoperative examinations. In level 5, the preoperative value of 10% recurred at the 1-year follow-up (Figure 9).

Nonmesh Group. In levels 1 and 2, no pathological values could be detected. In level 3, 30% simultaneous waves were found 1 year after surgery. In level 4, preoperative values of 30% remained stable at 3 months after surgery and decreased to 20% at 1 year. In level 5, preoperative 20% simultaneous waves decreased completely at 3 months and 1 year postoperatively (Figure 10).

Esophageal Peristalsis: Interrupted Waves

Mesh Group. Generally, the preoperative percentage of interrupted waves was nonpathological in all esophageal levels. In level 2, the preoperative value of 50% increased to 80% at 3 months after surgery, but then decreased completely at 1 year. Levels 1 and 5 showed no interrupted waves in all examinations. In level 2, 80% interrupted waves were detected at 3 months; in level 3, 10% interrupted waves were found at 3 months (Figure 11).

Nonmesh Group. Postoperative interrupted waves only could be detected in levels 2 and 5. In level 2, the preoperative percentage of 30% decreased to 20% at the 1-year follow-up. In level 5, the preoperative percentage of 30% at first decreased completely at 3 months, but then increased to 50% at 1 year after surgery (P < .05) (Figure 12).

24-HOUR pH MONITORING

The mean DeMeester score in both surgical groups improved significantly from a preoperative 66.1 ± 11.7 to 7.5 ± 3.1 at 3 months and 8.9 ± 2.2 at 1 year after surgery in the mesh group and from a preoperative 53.4 ± 9.9 to 8.8 ± 1.9 at 3 months and 7.0 ± 1.8 at 1 year after surgery in the nonmesh group (P < .01). A significant difference between surgical groups was not found (Figure 13).

SYMPTOMATIC OUTCOME

Preoperatively, 1 patient in the mesh group (5%) and 2 patients in the nonmesh group (10%) reported mild to moderate dysphagia. Postoperatively, a significant difference in the subjective extent of dysphagia was found.
between surgical groups. At the time of discharge (1 week postoperatively), 4 patients in the mesh group (20%) had dysphagia of grades 1 to 2, whereas 1 patient in the nonmesh group (5%) had dysphagia of grade 1 at this time ($P < 0.05$). At the 6-week and 3-month follow-ups, this ratio was almost unchanged. At 6 weeks, 4 patients in the mesh group (20%) had dysphagia of grades 1 to 2 in contrast to 2 patients in the nonmesh group (10%) ($P < 0.05$). Three months after surgery, the overall dysphagia rate decreased to 15% (n = 3) in the mesh group and to 5% (n = 1) in the nonmesh group ($P < 0.05$). At the 1-year follow-up, this significant difference disappeared because the dysphagia rate became equal in both surgical groups at 5% (n = 1 in each group) (Figure 14).

**COMMENT**

Laparoscopic antireflux surgery has proved to be a successful treatment alternative to lifelong medical treatment of GERD. During the past few years, several studies have shown that LARS is a safe and effective procedure with good long-term symptom relief and a significant improvement of patients’ quality of life, especially in patients with anatomical morphological causes for GERD symptoms. However, despite these good results, it has been shown that LARS can also fail in a small percentage of patients and result in persistent or recurrent GERD symptoms. The underlying morphological causes of recurrent GERD symptoms like dysphagia, recurrent reflux, or a combination of both are multifarious. In many cases, postoperative dysphagia is the result of too tight or complete hiatal closure during the laparoscopic antireflux procedure. Inadequate or too loose hiatal closure will lead to postoperative hiatal disruption or hiatal insufficiency with consequent recurrent hiatal hernia and/or intrathoracic migration of the fundic wrap. In particular, the intrathoracic wrap migration has been the most frequent morphological complication after LARS and has been described as the most common complication leading to revision surgery after failed LARS.

To prevent or minimize the rate of postoperative intrathoracic wrap migrations, some authors have advocated the use of prosthetic materials for hiatal reinforcement. The use of prosthetic patches for reinforcement of the hiatal crura has proved to be an efficient method for prevention of postoperative intrathoracic wrap migration, especially in patients with large hiatal hernia or paraesophageal hernia. In a recent trial by Frantzides et al.
72 patients were prospectively randomized to laparoscopic Nissen fundoplication with simple sutured hiatal closure (n=20) or laparoscopic Nissen fundoplication with prosthetic hiatal closure (n=20). After a mean follow-up of 3.3 years, the postoperative hernia recurrence rate was significantly higher in the nonmesh group (22% vs 0%). In a study by Basso et al., 65 consecutive patients underwent laparoscopic Nissen fundoplication with simple sutured hiatal closure and had an intrathoracic wrap migration rate of 13.8% for a mean follow-up period of 48.3 months. Therefore, the authors used a 3 x 4-cm polypropylene mesh for hiatal closure in another 67 patients and reduced the postoperative intrathoracic wrap migration rate to 0% for a follow-up period of 22.5 months.

Like other investigators, postoperative intrathoracic wrap migration has been the most frequent morphological complication after LARS in our clinical practice. This common complication has also led us to the use of a 1 x 3-cm polypropylene mesh for reinforcement of the hiatal crura. In a nonrandomized study, we compared 361 patients with GERD who underwent laparoscopic fundoplication with simple sutured hiatal closure and a group of 170 patients who underwent laparoscopic fundoplication with prosthetic hiatal closure using a 1 x 3-cm polypropylene mesh. After a complete postoperative follow-up of 1 year, we found a significant difference in the occurrence of postoperative intrathoracic wrap migration, i.e., 6.1% in the nonmesh group vs 0.6% in the mesh group. Despite these good results, we also saw a significantly higher rate of postoperative dysphagia in the patients who underwent prosthetic hiatal closure. At the 3-month follow-up examination, 35.3% of patients who had the mesh prosthesis had postoperative dysphagia compared with 19.8% of patients undergoing simple sutured hiatal closure. Nevertheless, at the 1-year follow-up, 95% of patients in both groups were free of dysphagia, and the dysphagia rates were equal in both groups and comparable to preoperative values (4.9% vs 4.4%).

To verify these results thoroughly, we performed a prospective randomized trial to determine the morphological reasons for this higher dysphagia rate in our patients. Therefore, we prospectively randomized 40 patients to laparoscopic Nissen fundoplication with simple sutured hiatal closure (n=20) or laparoscopic Nissen fundoplication with simple sutures in addition to a 1 x 3-cm polypropylene mesh (n=20). Complete follow-up data of both groups for 1 year after surgery were evaluated, with the main focus on data of esophageal manometry and esophageal body motility.

The preoperative rate of dysphagia in both groups showed no significant difference in this trial, but again, a significant difference in the postoperative dysphagia rate could be detected at follow-up examinations; i.e., at the 3-month follow-up, patients in the mesh group had a constantly higher rate of dysphagia than those in the nonmesh group. At 1 and 6 weeks after surgery, a postoperative dysphagia rate of 20% was found in the mesh group, which decreased to 15% at the 3-month follow-up. However, as shown in our previous study, no significant difference between groups could be found at the 1-year follow-up. Almost 95% of patients of both groups were free of dysphagia, and the 1-year follow-up dysphagia rate was equal (5% in each group).

Obviously, prosthetic hiatal closure is associated with a higher postoperative dysphagia rate for short-term and midterm follow-up, but the rate decreases and becomes comparable to the dysphagia rates of patients who underwent simple sutured hiatal closure for long-term follow-up.

Until now, few data were available regarding the influence of prosthetic material for hiatal closure on esophageal motility and/or the LES as a reason for postoperative dysphagia. Impaired esophageal body motility and/or high LES pressures are morphological causes of dysphagia. In the present study, all patients of both groups had pathological LES pressure but esophageal body motility test results within the reference range. At 3 months postoperatively, a significant increase of the mean LES pressure was found in both groups, with no significant differences between the mesh group and the nonmesh group. One year after surgery, nonmesh group patients had a significantly lower LES pressure compared with mesh group patients. A significant difference in LES length or relaxation between groups could not be detected.

Preoperatively, the values of esophageal body motility testing showed values within the reference range in both surgical groups. The limit to pathological values for the amplitude of contractions in wet swallows was fixed at less than 30 mm Hg in the lower esophageal segment. Preoperatively, values completely within the reference range were found in all 5 esophageal segments for patients in the mesh group, and marginal reference values were found in levels 3 and 5 in the nonmesh group. Postoperatively, the amplitude improved significantly in both surgical groups to 1 year after surgery; however, overall values of the nonmesh group were lower at follow-up but did not fall below the limit of pathological values. Preoperative and postoperative esophageal peristalsis showed nonpathological values regarding simultaneous waves in both groups. Patients in the mesh group presented 10% simultaneous waves in level 5 at 1 year postoperatively; patients in the nonmesh group had 30% simultaneous waves at level 3 and 20% at level 4, which correlates with reference values. A significant difference between the groups was not detected.

We found comparable results regarding interrupted waves in esophageal peristalsis. Preoperative and postoperative data showed marginal reference values in both groups except for those for level 5 in the nonmesh group; preoperative 30% interrupted waves decreased completely at the 3-month follow-up, but increased significantly to 50% at the 1-year follow-up.

In general, these results show that patients with prosthetic hiatal closure have comparable results in esophageal manometry and body motility studies to those of patients who underwent simple sutured hiatal closure. Actually, patients in the nonmesh group have lower values in esophageal body motility, regardless of their lower rate of postoperative dysphagia. As our data show, prosthetic hiatal closure does not significantly impair esophageal body motility and, accordingly, the postoperative...

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higher dysphagia rate is not the result of mesh-related impaired esophageal body motility.

The high postoperative dysphagia rate remains at short-term follow-up but seems to be transient. Certainly, postoperative short-term dysphagia is the result of the rapid incorporation of polypropylene mesh and the tendency of this material to develop early postoperative adhesions with subsequent ingrowth of the hiatal crura, which normalizes during longer postoperative periods. Despite these results, further investigations are needed to clarify the morphological causes of this transient dysphagia and to evaluate the postoperative dysphagia rate for longer follow-up.

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Previous Presentations: This study was presented at the First European Endoscopic Surgery Week and the 11th International Congress of the European Association for Endoscopic Surgery, June 17, 2003; Glasgow, Scotland; and as a poster at the 45th Annual Meeting of the Society for Surgery of the Alimentary Tract, Digestive Disease Week; May 17-18, 2004; New Orleans, LA. This study was published as an abstract in Gastroenterology. 2004; 126(4):309. Abstract M1888.

REFERENCES

commitment to bridging the gap between academic surgery in the United States and Kenya.

There have been numerous reports recently examining disparities in health care administered in the United States. These disparities may not be as stark when comparing health systems on a global scale. Kenya has a life expectancy just over half that of the United States. With an approximate 80% literacy rate, the majority of the population earns less than a $1 a day, and the total health per capita expenditure is only $65.2 Compare this to the United States, where the average salary is $36,764 and total health care expenditure is $57,112.3

This provides a forum for discussing global health disparities among many others. The mark of a progressive society will always remain its ability to maintain concern for the disadvantaged portions of that society. As global satellite imaging and technology draw communities closer together, then so must our attention turn to the health of the rest of the world. There may be no better way to do this than by using, creating, and developing channels of education and training. In a clinical arena dominated by outcomes research, a commitment to improving the standards of surgical practice and care of the surgical patient may now assume a global definition. It is the belief of the foundation that a global surgical network can readily be established purely from volunteerism. But although it constitutes volunteerism for most surgeons, for some it may remain a justifiable act of personal obligation.

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