Evidence Navigator: Cholecystectomy

Systematic literature review & meta-analysis as of April 15, 2024

INTUITIVE

Purpose

The Evidence Navigator is a slide presentation representing a summary of the meta-analysis of the highest level of evidence available specific to a given procedure and published as of a particular date. It is created by the Global Evidence Management team within Global Access, Value and Economics (GAVE). It includes information that is available in the public domain. It is a systematic review and meta-analysis of the peer-reviewed literature based on a timeframe within which a literature search has been conducted according to a set of concise inclusion and exclusion criteria. The results of the meta-analysis are presented in the form of forest plots summarized for each outcome according to a comparator and surgical approach of interest. The summary results are reflective of a specific period in time and are subject to change with increasing literature. All of the robotic-assisted surgery procedures mentioned within the Evidence Navigator were performed using a da Vinci® surgical system.

Statistical analysis

All summary measures are shown as odds ratios, risk ratios or risk differences when describing binary outcomes, or as weighted mean differences or standardized mean differences when describing continuous outcomes. Weighting is based on the study sample size and variability of the outcome. A random effect model is used if heterogeneity is statistically significant, otherwise a fixed effect model is used. The Mantel Haenszel summary statistic is used for the overall results. The meta-analysis is performed with RevMan 5.4 (Review Manager, Version 5.4. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) or R software (R Foundation for Statistical Computing, Vienna, Austria.URL https://www.R-project.org/).

Interpretation notes

When the effect size is measured as a standardized mean difference (SMD), or a risk difference (RD), it is not possible to provide a quantitative conclusion. In such cases, a qualitative conclusion is given with reference to its statistical significance. In some instances, studies may contain some overlapping patient populations. A redundancy check is performed in order to minimize this overlap and bias due to over-reporting.

Glossary

RAS	robotic-assisted surgery
Lap	laparoscopic surgery
LOE	level of evidence
HTA	health technology assessment
RCT	randomized controlled trial
OR	odds ratio
MD	mean difference

WMD	weighted mean difference
RD	risk difference
SMD	standardized mean difference
95% CI	95% confidence interval
I^2	test statistic for heterogeneity
EBL	estimated blood loss
LOS	length of hospital stay

Evidence Navigator: Cholecystectomy Summary Slides

Systematic literature review & meta-analysis
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WHAT DOES THE LITERATURE SHOW?

Systematic literature review:
Da Vinci robotic-assisted cholecystectomy

Inclusion criteria

Robotic-assisted cholecystectomy performed with a da Vinci surgical system

January 1, 2010 – April 15, 2024

Level of Evidence 1b, 2b, 2c, 3b

RCT, large database, prospective and retrospective cohort studies (with n≥20 in each cohort)

Exclusion criteria

Not in English

Paper reports on a pediatric population

Publication is an HTA that was not published in a peer-reviewed journal

Alternate technique/approach (e.g. single-port)

No stratified analysis by study arm

Cholecystectomy data mixed with other procedures or benign/cancer data mixed

Original research study does not provide quantitative results for outcomes of interest

Original research publication includes redundant patient population and similar conclusions

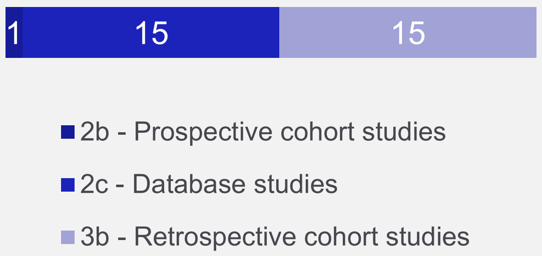
31 publications including:

Robotic-assisted patients: **135,710**

Laparoscopic patients: **6,172,677**

Open patients: **499,544**

Level of evidence



Systematic literature review key points:
Robotic-assisted vs. laparoscopic cholecystectomy

Favors robotic-assisted

- ↓ Conversions by **49%**
- ↓ Estimated blood loss by **7.65 mL**

Comparable outcomes

- ≈ Blood transfusion
- ≈ Bile duct leak
- ≈ Bile duct injury
- ≈ Bile duct obstruction
- ≈ Surgical site infection
- ≈ Length of hospital stay
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day mortality

Favors laparoscopic

- ↓ Operative time by **9.81 minutes**

Data collected: April 15, 2024

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: **Robotic-assisted vs. open* cholecystectomy**

Favors robotic-assisted

- ↓ Surgical site infections by **72%**
- ↓ Blood transfusion by **60%**
- ↓ Length of stay by **3.5 days**
- ↓ 30-day postoperative complications by **45%**
- ↓ 30-day mortality by **55%**

Comparable outcomes

- ≈ Bile duct injury
- ≈ 30-day readmissions
- ≈ 30-day reoperations

Favors open

Data collected:: April 15, 2024

*Limited data available on patients who underwent open surgery

Systematic literature review key points:
Robotic-assisted vs. laparoscopic cholecystectomy
Elective vs emergent / urgent

Elective (7 studies)

- ↓ Conversions by **89%**
- ↓ Estimated blood loss by **14.3 mL**
- ↓ 30-day readmissions by **52%**
- ≈ Bile duct injury
- ≈ Bile duct leak
- ≈ 30-day postoperative complication
- ≈ Length of stay
- ↑ Operative time by **10.37 minutes**

Emergent / Urgent (7 studies)

- ↓ Conversions by **43%**
- ↓ Estimated blood loss by **10.6 mL**
- ≈ Blood transfusion
- ≈ Operative time
- ≈ Length of stay
- ≈ Bile duct injury
- ≈ Surgical site infection
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day mortality

*Limited data available on all the other outcomes amongst patients who underwent elective or emergent/urgent cholecystectomy

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

Data collected: April 15, 2024

Evidence Navigator: Cholecystectomy Technical Slides

Systematic literature review & meta-analysis
as of April 15, 2024

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Cholecystectomy: Literature search methods

as of April 15, 2024

Monthly searches were conducted in PubMed, Scopus and Embase.

All citations were exported into a reference management system. Duplications were removed. Titles, abstracts and keywords were reviewed for literature review inclusion by Global Evidence Management team.

All robotic-assisted right colectomies performed with da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using R software.

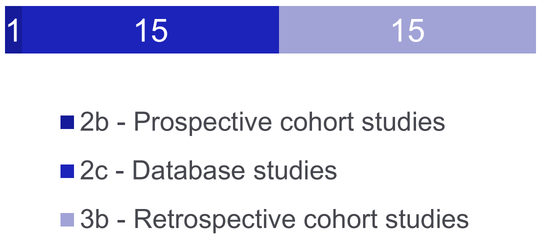
31 publications

135,710 patients who underwent RAS

6,172,677 patients who underwent laparoscopic surgery

499,544 patients who underwent open surgery

Level of evidence



Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N=45,378 library size at the time of search April 15, 2024
Inclusion criteria	
1. Robotic-assisted cholecystectomy procedure	Robotic cholecystectomy N = 424 (excluded N = 44,954)
2. Year ≥ 2010	Articles published ≥ 2010 N = 378 (excluded N = 46)
3. LOE = 1b, 2b, 2c, 3b	Articles with LOE= 1b, 2b, 2c N = 99 (excluded N = 279)
4. Study is an RCT, prospective or retrospective study or large database study with comparative cohorts (robotic-assisted vs lap and/or open surgery) and sample size N≥20	Comparator cohorts N = 70 (excluded N = 29)
Exclusion criteria	**N = 39 excluded publications:**
1. Not in English	N = 1 (EC#1)
2. Paper reports on a pediatric population	N = 2 (EC#2)
3. Publication is an HTA that was not published in a peer-reviewed journal	N = 0 (EC#3)
4. Alternate technique/approach (e.g., single-port)	N = 29 (EC#4)
5. No stratified analysis by study arm (e.g., combines results from robotic, laparoscopic, and/or open cohorts)	N = 1 (EC#5)
6. Cholecystectomy data mixed with another procedure/s	N =1 (EC#6)
7. Original research study does not provide quantitative results for the outcomes of interest	N = 4 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N = 1 (EC#8)

Cholecystectomy publications: N = 31

Robotic-assisted vs. laparoscopic cholecystectomy

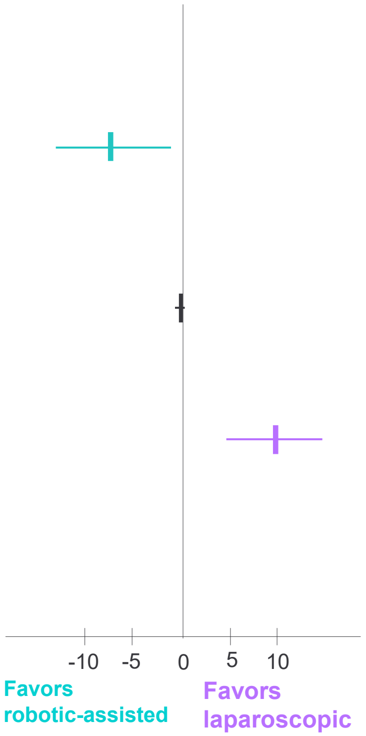
Summary as of April 15, 2024

- Significant difference favoring robotic-assisted surgery
- No significant difference; comparable outcomes
- Significant difference favoring laparoscopic surgery

Compared to laparoscopic cholecystectomy, the evidence for **robotic-assisted cholecystectomy using the da Vinci surgical system** demonstrates:

- Significantly less estimated blood loss by an average of 7.65 mL
- Comparable length of hospital stay
- Significantly longer operative time by an average of 9.81 minutes

Weighted Mean Difference (WMD) 95% CI



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect Size WMD, 95%CI	P-value
Cholecystectomy Continuous Variables (to April 15, 2024)				
EBL, mL[3,8,9,10,30,31]				
Subtotal	1228	1104	-7.65 [-13.74 ; -1.56]	**p=0.01**
Random, Heterogeneity: $p<0.01$; $I^2=70\%$				
LOS, days[2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,20,21,22,24,25,28,29,30,31]				
Subtotal	65771	655164	-0.19 [-0.47 ; 0.09]	p=0.18
Random, Heterogeneity: $p<0.01$; $I^2=98\%$				
Operative Time, min[3,5,7,8,9,11,12,14,15,20,28,29,20,31]				
Subtotal	14918	60437	9.81 [4.41 ; 15.2]	**p<0.01**
Random, Heterogeneity: $p=0$; $I^2=96\%$				

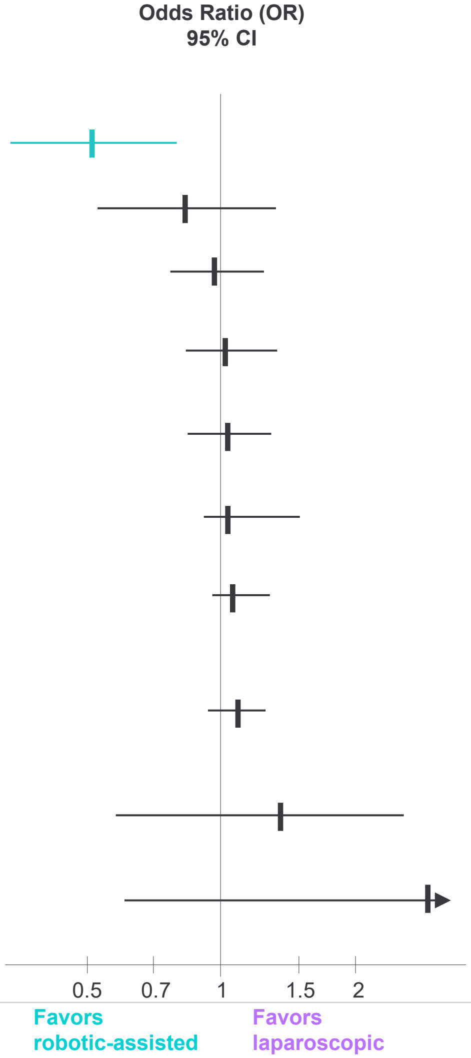
Robotic-assisted vs. laparoscopic cholecystectomy

Summary as of April 15, 2024

Significant difference favoring robotic-assisted surgery | No significant difference; comparable outcomes | Significant difference favoring laparoscopic surgery

Compared to laparoscopic cholecystectomy, the evidence for **robotic-assisted cholecystectomy using the da Vinci surgical system** demonstrates:

- 49% less likely to have a conversion to open surgery
- Comparable bile duct obstruction rate
- Comparable surgical site infection rate
- Comparable mortality rate within 30-days of surgery
- Comparable blood transfusions rate
- Comparable reoperations rate within 30-days of surgery
- Comparable readmissions rate within 30-days of surgery
- Comparable postoperative complications rate within 30-days of surgery
- Comparable bile duct injury rate
- Comparable bile duct leak rate



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size OR 95% CI	P-value
Cholecystectomy Binary Variables (to April 15, 2024)				
Conversions, n [3,4,5,7,8,9,10,11,12,16,17,19,22,26,28,30,31]				
Subtotal	44158	830372	OR: 0.51 [0.33 ; 0.79]	p<0.01
Random, Heterogeneity: p<0.01; I²=90%				
Bile Duct Obstruction, n[3,5,16,31]				
Subtotal	11392	41964	OR: 0.83 [0.52 ; 1.35]	p=0.46
Fixed, Heterogeneity: p<0.01.18; I²=39%				
Surgical Site Infection, n [4,5,8,9,12]				
Subtotal	14070	38036	OR: 0.97 [0.76; 1.24]	p=0.80
Fixed, Heterogeneity: p=0.62; I²=0%				
Mortality 30-day, n [1,3,4,5,8,12,13,25]				
Subtotal	60078	3301695	OR: 1.01 [0.88 ; 1.15]	p=0.93
Fixed, Heterogeneity: p=0.63; I²=65%				
Blood transfusions, n [4,5,8,12,16,30]				
Subtotal	15065	69002	OR: 1.03 [0.88 ; 1.21]	p=0.71
Fixed, Heterogeneity: p=0.61; I²=0%				
Reoperations 30-day, n [4,5,7,8,30]				
Subtotal	10911	10887	OR: 1.04 [0.81 ; 1.34]	p=0.75
Fixed, Heterogeneity p=0.87; I²=0%				
Readmissions 30-day, n [3,4,5,6,8,9,12,16,20,25,26,28,30,31]				
Subtotal	18056	162332	OR: 1.07 [0.98 ; 1.17]	p=0.12
Fixed, Heterogeneity: p=0.03; I²=47%				
Postoperative Complications 30-day, n [1,2,3,5,12,13,16,17,18,24,25,31]				
Subtotal	102630	4572137	OR: 1.13 [0.97 ; 1.31]	p=0.12
Random, Heterogeneity: p<0.01; I²=97%				
Bile Duct Injury, n [3,5,7,9,10,11,12,16,18,30]				
Subtotal	40459	1069928	OR: 1.39 [0.66 ; 2.93]	p=0.39
Random, Heterogeneity p<0.01; I²=86%				
Bile Duct Leak, n [3,8,30,31]				
Subtotal	532	746	OR: 3.00 [0.60 ; 14.96]	p=0.18
Fixed. Heterogeneity p=0.80; I²=0%				

INTUITIVE

Robotic-assisted vs. open cholecystectomy

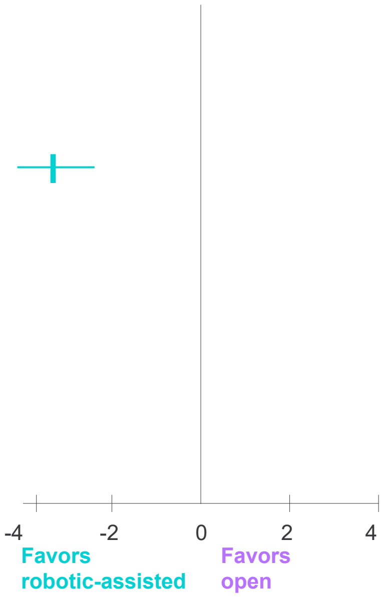
Summary as of April 15, 2024

Significant difference favoring robotic-assisted surgery | No significant difference; comparable outcomes | Significant difference favoring open surgery

Compared to open cholecystectomy, the evidence for **robotic-assisted cholecystectomy using the da Vinci surgical system** demonstrates:

- Significantly shorter hospital length of stay by an average of 3.51 days

Weighted Mean Difference (WMD) 95% CI



Outcome	Robotic-assisted, n	Open, n	Effect Size WMD, 95%CI	P-value
Cholecystectomy Continuous Variables (to April 15, 2024)				
LOS, days [4,5]				
Subtotal	2462	2461	-3.51 [-4.49 ; -2.53]	**p<0.01**
Random, Heterogeneity: p<0.01; I²=95%				

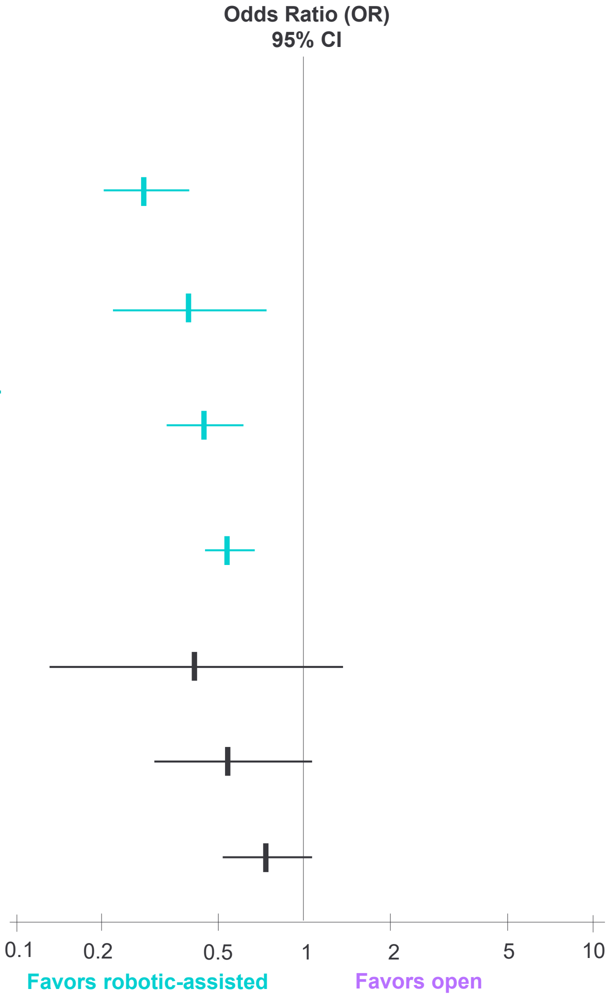
Robotic-assisted vs. open cholecystectomy

Summary as of April 15, 2024

■ Significant difference favoring robotic-assisted surgery ■ No significant difference; comparable outcomes ■ Significant difference favoring open surgery

Compared to open cholecystectomy, the evidence for **robotic-assisted cholecystectomy using the da Vinci surgical system** demonstrates:

- 72% less likely to experience surgical site infections
- 60% less likely to experience blood transfusion
- 55% less likely to experience mortality within 30-days of surgery
- 45% less likely to experience postoperative complications within 30-days of surgery
- Comparable bile duct injury rate
- Comparable readmissions within 30-days of surgery
- Comparable reoperations within 30-days of surgery



Outcome	Robotic-assisted, n	Open, n	Effect size OR 95% CI	P-value
Cholecystectomy Binary Variables (to April15, 2024)				
Surgical Site Infection, n [4,5]				
Subtotal	2737	2737	OR: 0.28 [0.20; 0.40]	p<0.01
Fixed, Heterogeneity: p=0.65; I²=0%				
Blood Transfusion, n [4,18]				
Subtotal	2737	2737	OR: 0.40 [0.22 ; 0.74]	p<0.01
Random, Heterogeneity: p=0.10; I²=63%				
Mortality 30-day, n [4,5]				
Subtotal	2737	2737	OR: 0.45 [0.34 ; 0.60]	p<0.01
Fixed, Heterogeneity: p=0.19; I²=41%				
Postoperative Complications 30-day, n [5,18]				
Subtotal	27138	266735	OR: 0.55 [0.46 ; 0.66]	p<0.01
Random, Heterogeneity: p=0.01; I²=84%				
Bile Duct Injury, n [5,18]				
Subtotal	27138	266735	OR: 0.42 [0.13 ; 1.38]	p=0.15
Random, Heterogeneity: p<0.01; I²=92%				
Readmissions 30-day, n [4,5]				
Subtotal	2737	2737	OR: 0.55 [0.29 ; 1.05]	p=0.07
Random, Heterogeneity: p<0.01; I²=93%				
Reoperations 30-day, n [4,5]				
Subtotal	2737	2737	OR: 0.75 [0.53 ; 1.07]	p=0.11
Fixed, Heterogeneity: p=0.55; I²=0%				

Robotic-assisted vs. laparoscopic cholecystectomy

Weighted estimates based on 31 studies

Meta-analysis covering period January 1, 2010 – April 15, 2024

This study analyzed continuous variables using weighted means and categorical variables using weighted rates with fixed or random effects models. This method gives more influence to studies with higher weights, providing a more accurate estimate of central tendency when combining results from multiple studies.

Outcomes that favor RAS

Conversions	2.6% vs 6.3%
Estimated blood loss	14.8 ml vs 22.5 ml

Comparable outcomes

Blood transfusions	1.9% vs 1.9%
Bile duct leak	1.5% vs 0.6%
Bile duct injury	0.7% vs 0.5%
Bile duct obstruction	0.7% vs 0.7%
Surgical site infection	1.3% vs 1.3%
Length of hospital stay	2.0 days vs 2.3 days
30-day postoperative complications	13.3% vs 12.0%
30-day readmissions	5.7% vs 5.7%
30-day reoperations	1.4% vs 1.4%
30-day mortality	1.2% vs 1.4%

Outcomes that favor Laparoscopic

Operative time	97.0 min vs 87.1 min

Disclaimer: The number of studies used to calculate the weighted estimates for each outcome varies

Robotic-assisted vs. open cholecystectomy

Weighted estimates based on 3 studies

Meta-analysis covering period January 1, 2010 – April 15, 2024

This study analyzed continuous variables using weighted means and categorical variables using weighted rates with fixed or random effects models. This method gives more influence to studies with higher weights, providing a more accurate estimate of central tendency when combining results from multiple studies.

Outcomes that favor RAS

Surgical site infection	2.1% vs 7.0%
Blood transfusion	3.4% vs 8.9%
Length of stay	3.0 days vs 6.5 days
30-day postoperative complications	19.8% vs 30.8%
30-day mortality	4.3% vs 8.2%

Comparable outcomes

Bile duct injury	0.7% vs 2.0%
30-day readmissions	10.5% vs 18.7%
30-day reoperations	2.3% vs 3.1%

Outcomes that favor Open

Disclaimer: The number of studies used to calculate the weighted estimates for each outcome varies

Cholecystectomy: bibliography

April 15, 2024

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Disclosures

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(US) Serious complications may occur in any surgery, including da Vinci surgery, up to and including death. Serious risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques which could result in a longer operative time and/or increased complications. For summary of the risks associated with surgery refer to www.intuitive.com/safety.

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The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence), except for radical prostatectomy which was evaluated for overall survival, or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

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