

Single Site Surgery – SSS: an intermediate step towards No (visible) Scar Surgery or the next Gold Standard in Minimally Invasive Surgery?

M.M. Lirici

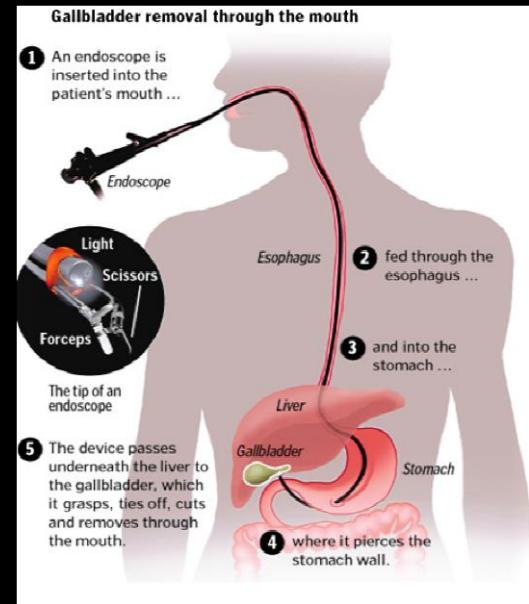
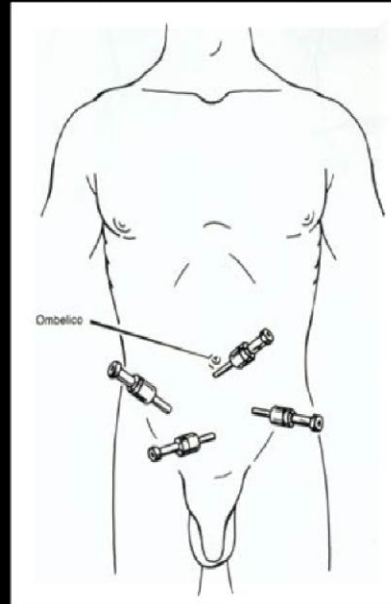
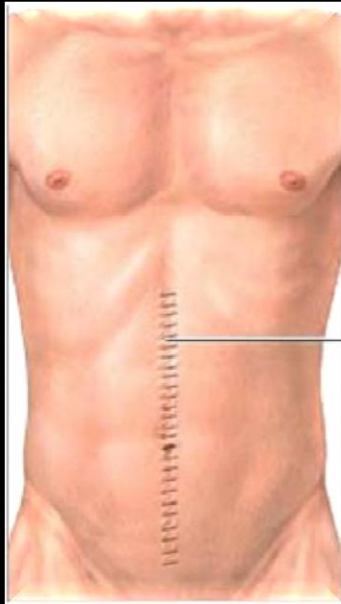
SIMPOSIO NOTES

**Current Clinical Applications
and Future Perspectives**

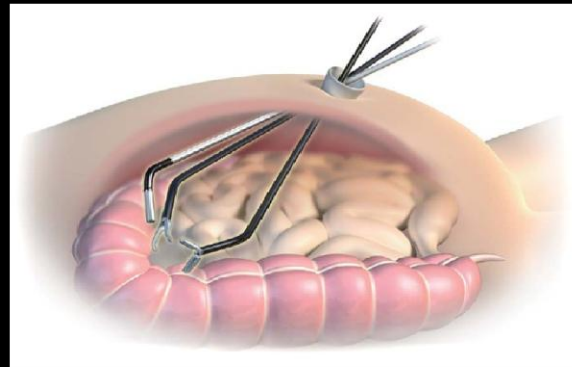


ROADMAP OF MINIMAL INVASIVENESS IN SURGERY

SCAR



SCARLESS



The Right Balance?

SINGLE PORT ACCESS SURGERY/LESS

FIRST EVER THERAPEUTIC PROCEDURES:

- KURT SEMM 1972-1982 – LAPAROSCOPIC ANNEXAL SURGERY THROUGH A SINGLE-PUNCTURE OPERATING LAPAROSCOPE
- GERHARD BUSS 1983-1985 – DEVELOPMENT OF ENDOSCOPIC PROCEDURE THROUGH A MULTICHANNEL PORT (TEM)
- NAVARRA G. 1997 – ONE-WOUND LAPAROSCOPIC CHOLECYSTECTOMY. BR J SURG 84:695

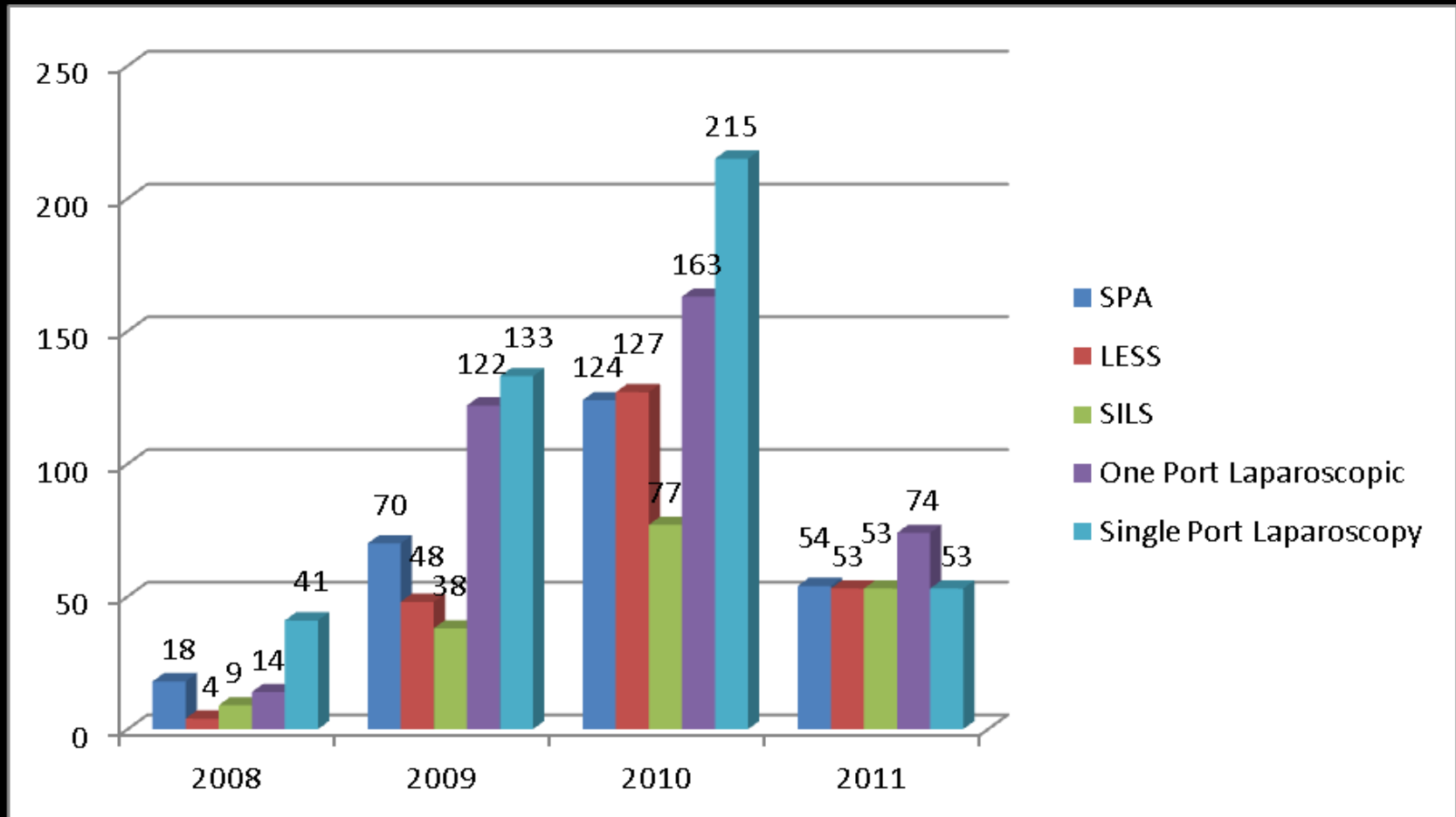


LESS White Paper

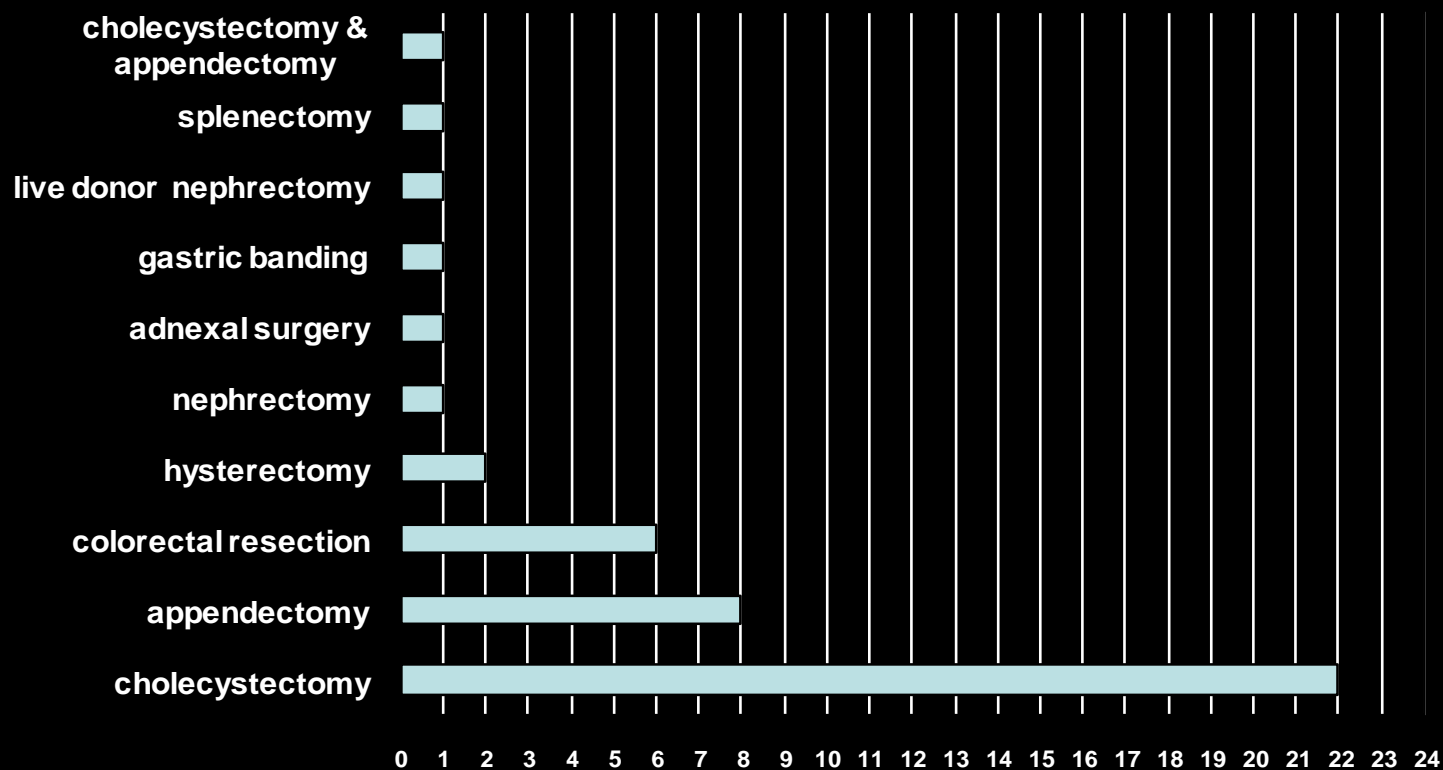
“Consensus Statement of the Consortium for Laparo-Endoscopic Single-Site (*LESS*) Surgery”. 28 urologists, gynaecologists and surgeons met at Cleveland Clinic and define the principles of Laparo-endoscopic Single-site Surgery and found the LESSCAR Consortium for assessment and research on LESS – July 2008 Consensus Conference – Gill et al. Surg Endosc 2010, ePub 2009

Cleveland Clinic selects Laparoendoscopic Single-Site Surgery (*LESS*) as One of the Top Ten Innovations of 2009

PUBLISHED ARTICLES



NOVELTY, TREND OR REALITY?



INTERMEDIATE STEP OR GOLD STANDARD?

Nomenclature of Natural Orifice Transluminal Endoscopic Surgery (NOTES™) and Laparoendoscopic Single-Site Surgery (LESS) Procedures in Urology

Geoffrey Box, M.D.,¹ Timothy Averch, M.D.,² Jeffrey Cadeddu, M.D.,³ Edward Cherullo, M.D.,⁴ Ralph Clayman, M.D.,¹ Mihir Desai, M.D.,⁵ Igor Frank, M.D.,⁶ Matthew Gettman, M.D.,⁷ Inderbir Gill, M.D.,⁵ Mantu Gupta, M.D.,⁷ Georges-Pascal Haber, M.D.,⁵ Jihad Kaouk, M.D.,⁵ Jaime Landman, M.D.,⁷ Esteavao Lima, M.D.,⁸ Lee Ponsky, M.D.,⁴ Abhay Rane, M.D.,⁹ Mark Sawyer, M.D.,⁴ and Mitchell Humphreys, M.D.¹⁰ for the Urologic NOTES Working Group

Abstract

Introduction: The twenty first century has witnessed some amazing advancements in surgery. In urology minimally invasive surgery has become the standard treatment for many disease processes and procedures. One of the newest innovations into this field has been the development of Natural Orifice Transluminal Endoscopic Surgery (NOTES™) and Laparoendoscopic Single-site Surgery (LESS). While the practice and application of these new techniques are in their infancy, there has been a great deal of confusion regarding the nomenclature and terminology associated with these procedures. The aim of this publication is to attempt to define the many issues associated with the standardization of terminology for these procedures in order to promote effective scientific progress and communication.

Materials and Methods: A literature search using Medline and pubmed focusing on all terminology to describe NOTES™ and LESS from 1990 to 2008 was done. In addition, various acronyms were searched using four separate online acronym databases. The information was recorded by number of citations and by the number of citations specific to the urologic literature. Based on common usage, definitions and criteria were developed to describe these procedures for current scientific publication. These terms were then collectively reviewed and agreed upon by the Urologic NOTES™ Working Group as a platform for consensus to begin the arduous process of standardization.

Results: There is wide variation in the terminology and use of acronyms for natural orifice transluminal endoscopic surgery and laparo-endoscopic single-site surgery. The keyword literature search uncovered 8710 citations from MEDLINE and pubmed, with 363 citations specific to urology. There was significant overlap in the search of different terms. The search of established abbreviation and acronym databases revealed many citations, but relatively few specific to urology.

¹University of California Irvine, California.

²University of Pittsburgh Medical Center, Pennsylvania.

³University of Texas Southwestern Medical Center, Dallas, Texas.

⁴Case Western Reserve University, Cleveland, Ohio.

⁵Cleveland Clinic, Cleveland, Ohio.

⁶Mayo Clinic, Department of Urology, Rochester, Minnesota.

⁷Columbia University Medical Center, New York, New York.

⁸University of Minho, school of Health Science, Braga, Portugal.

⁹East Surrey Hospital, Redhill, United Kingdom.

¹⁰Mayo Clinic, Department of Urology, Phoenix, Arizona.

NOMENCLATURE

Single Port Access – SPA

Single Site Laparoscopy

One Port Laparoscopy

SILS – Single Incision Laparoscopic Surgery

LESS – Laparo-endoscopic Single-site Surgery

Single Access Laparoscopy

NOTUS – Natural Orifice Trans-Umbelical Surgery

e-NOTES – Embrionic NOTES

TECNOLOGIES

WORKING ENVIRONMENT
ERGONOMICS
ACCESS
INSTRUMENTS
VISION
PLATFORMS
ROBOTICS



WORKING ENVIRONMENT & ERGONOMICS

- **PHYSICAL CONSTRAINTS**
- **REDUCED DEGREES OF FREEDOM OF THE WORKING INSTRUMENTS**
- **LACK OF TRIANGULATION, POOR TRACTION**

**INSUFFICIENT EXPOSURE
MENTAL, VISUAL, PHYSICAL FATIGUE**

ACCESS

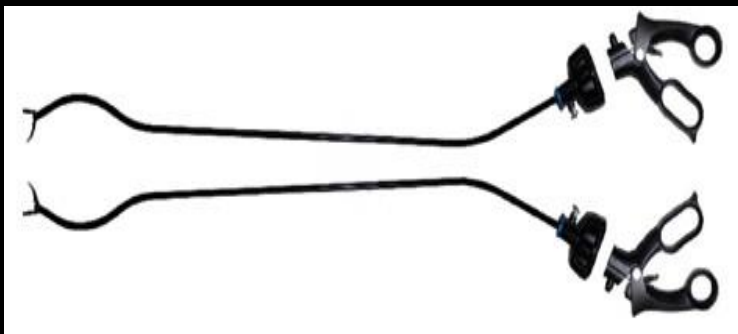
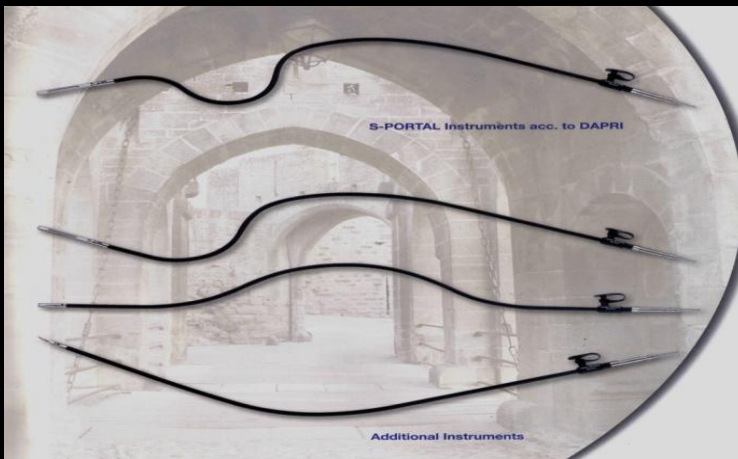


**DISPOSABLE OR REUSABLE
MULTIPOINT**



**ALTERNATIVE:
SWISS CHEESE TECHNIQUE**

INSTRUMENTS



**STRAIGHT, CURVED,
ARTICULATED**

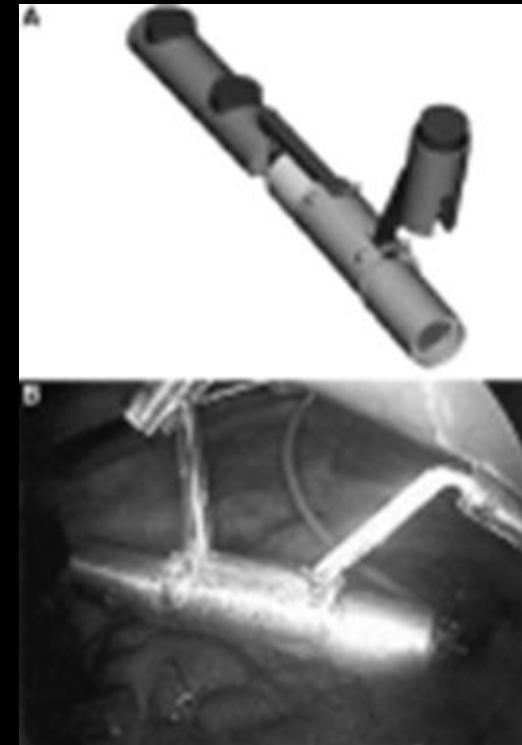


**SUPERELASTIC ALLOY
INTERNAL GRAB**

VISION



**ARTICULATED, CHIP-ON-TIP 5
mm SCOPES**



**EXTERNAL MAGNET
CONTROLLED MICROCAMERAS**
Courtesy of
JF Cadeddu - Ann Surg 2007

PLATFORMS & ROBOTICS

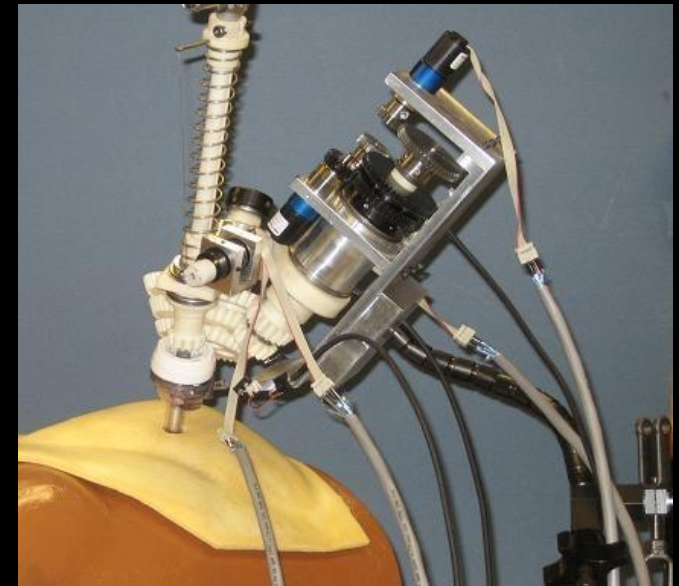
▶ Mouse over to view SPIDER details.



**SPIDER
TRANSENERIC**



da Vinci^{Si} HC1
SURGICAL SYSTEM
**MODULE FOR
SINGLE SITE SURGERY**



**COURTESY
D. OLEINIKOV
UNIVERSITY OF NEBRASKA**

INDICATIONS

High Volume Procedures

cholecystectomy
appendectomy
inguinal hernia repair
oophorectomy
salpingectomy
endometriosis surgery
tubal ligation
pyeloplasty
incisional hernia repair
renal cyst decortication
ablative renal surgery
pelvic lymphadenectomy
nephrectomy
gastric banding
colon resection

Intermediate Volume Procedures

adrenalectomy
splenectomy
hysterectomy
pelvic organ prolapse
donor nephrectomy
ureteral re-implant
ileal interposition
radical nephrectomy
small bowel resection
fundoplication
wedge liver resection

Low Volume Procedures

Major bariatric procedures
myomectomy
prostate resection
cystectomy
partial nephrectomy
retroperitoneal lymph node dissection
esophageal myotomy
distal pancreatectomy
formal liver resections
gastric resections

INTERMEDIATE STEP OR GOLD STANDARD?

PERSONAL RECORD 2008-2010

Cholecystectomy	50
Appendectomy	15
Sleeve gastrectomy	9/1
Annexectomy	4
Colonic procedures	4
Diagnostic laparoscopy	5
Wedge resection liver	1
Inguinal hernia repair	1





Laparo-endoscopic Single Site (LESS) Cholecystectomy Versus Standard LAP-CHOLE (LESSCHO)

Sponsor: San Giovanni Addolorata
Hospital

Information provided by: San Giovanni Addolorata
Hospital

ClinicalTrials.gov Identifier: NCT01339325

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Cholelithiasis	Procedure: Cholecystectomy	Phase IV

LESS-CHOLE VS STANDARD LAP-CHOLE



LIRICI – CORCIONE

RCT 2009

Epub ahead of print 2010

RCT

PILOT TRIAL (2 CENTRES THAT WILL BE JOINED BY FURTHER 3 IN THE PHASE 3 RCT)

40 PATIENTS WITH BMI \leq 30, ASA I-III :

20 STANDARD LAPAROSCOPIC CHOLECYSTECTOMY

20 LESS CHOLECYSTECTOMY

PRIMARY ENDPOINTS:

QoL → POSTOP PAIN, LoS, COSMETICS, SF36

SECONDARY ENDPOINTS:

OP TIME, CONVERSION RATE, DIFFICULTY OF DISSECTION AND EXPOSURE

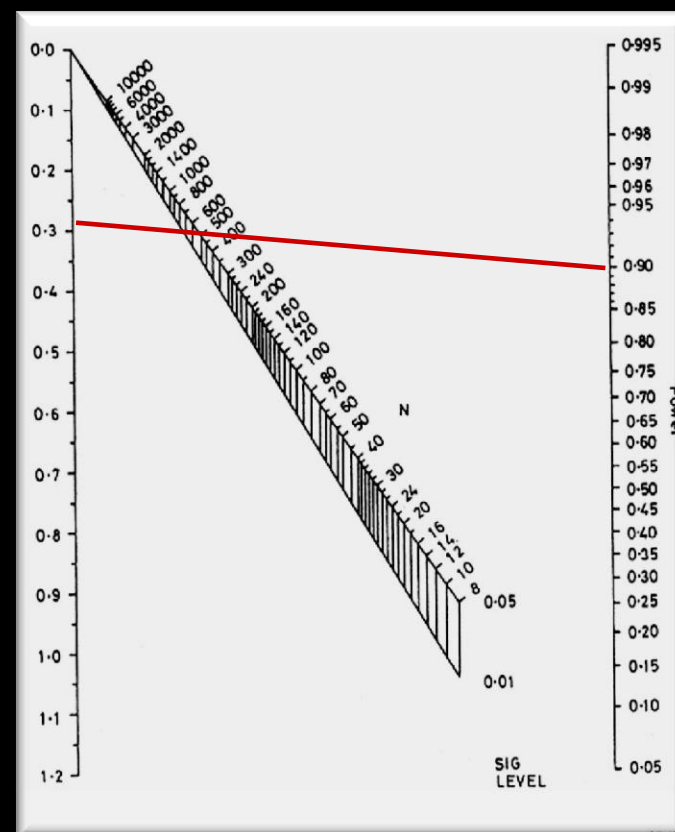
DIFFICULTY GRADE EVALUATED ACCORDING TO THE NASSAR SCALE

STATISTICAL ANALYSIS: MANN-WHITNEY U TEST, CHI SQUARE TEST, SIGNIFICANT $p \leq 0.05$,
SOFTWARE ADDINSOFT XL STAT

WHY A PILOT TRIAL?

Results of VAS pain, VAS cosmetics, incision length, LoS, SF36 are compared: therefore the standardized difference could vary. **Altman nomograms** were used to calculate the presumed sample size of an actual RCT, arbitrarily assuming a most likely small standardized difference (0.3). **With a significant criterion set at 0.05, using a two-tailed test, the number of patients per group, required to have a 90% power is ~500.**

RCT



LESS-CHOLE VS STANDARD LAP-CHOLE

RESULTS PRIMARY ENDPOINTS

		LC	LESS	p
RCT	PO PAIN VAS I	3.15	3.80	0.041
	PO PAIN VAS II	2.25	2.65	NS
	PO PAIN VAS III	1.15	1.45	NS
	PO PAIN VAS IV	0.3	0.6	NS
	PAIN MEDICATION I	80%	85%	NS
	PAIN MEDICATION II	20%	25%	NS

LESS-CHOLE VS STANDARD LAP-CHOLE

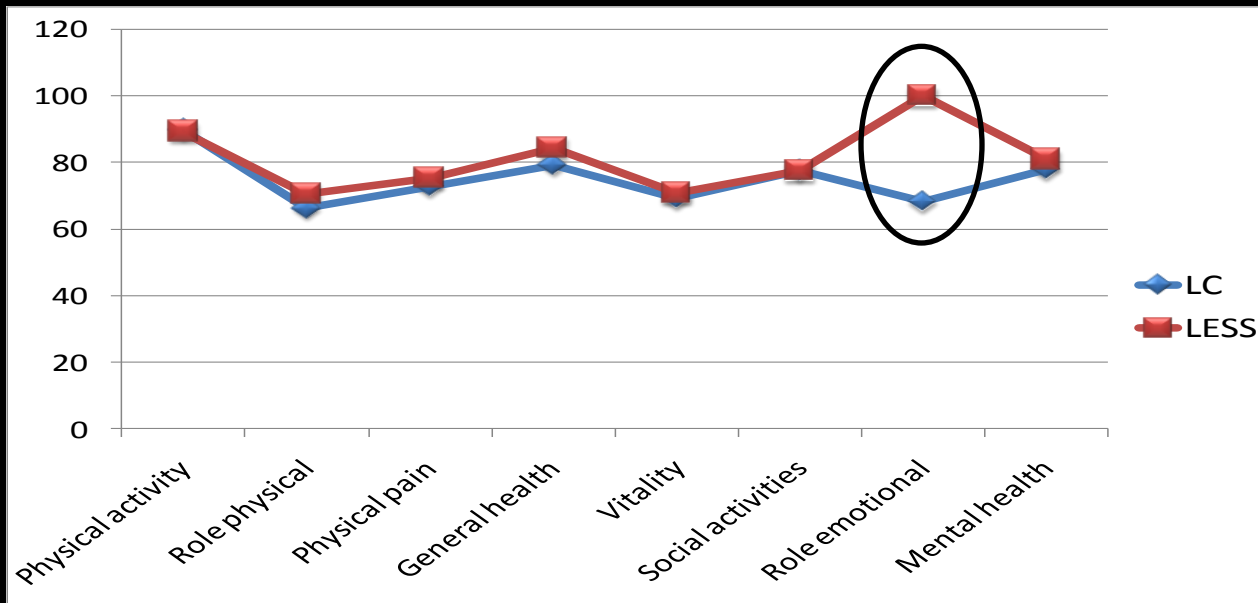
RESULTS PRIMARY ENDPOINTS

RCT		LC	LESS	p
	LoS	2	2	NS
	INCISION	14.31	18.8	0.002
	COSMETICS VAS I	7.5	8.35	NS
	COSMETICS VAS II	8.6	9.45	0.025
	QoL SF36	75.14	78.59	NS

LESS-CHOLE VS STANDARD LAP-CHOLE

RESULTS

SF-36 Median



	LC	LESS	p
QoL SF36	75.14	78.59	NS
ROLE EMOTIONAL	68.33	100.00	<0.0001

Extent to which emotional problems interfere with work or other daily activities, including decreased time spent on activities, accomplishing less, and not working as carefully as usual.

LESS-CHOLE VS STANDARD LAP-CHOLE**SIDE STUDY ON POSTOPERATIVE INCISIONAL
HERNIAS
AT 1-YEAR FOLLOW-UP****INCISIONAL
HERNIA**

	F.U.	LOST	# HERNIA
LESS	18/20	2	0
LC	19/20	1	0

QoL E COSMESIS



LESS CHOLECYSTECTOMY



LESS APPENDECTOMY



LESS SLEEVE GASTRECTOMY



LESS SIGMOIDECTOMY



COSTS INDICATORS

Voce di costo o aggregati di costo

- 1 Personale medico
- 2 Altro personale laureato
- 3 Pers. tecnico sanit. (tecnici di laboratorio, radiologia, fisiokinesiterapisti, ecc.)
- 4 Personale infermieristico
- 5 Personale ausiliare ed OTA
- 6 Personale amministrativo
- 7 Altre figure professionali
- 8 Farmaci
- 9 Presidi sanitari e chirurgici
- 10 Servizi sanitari (consulenze e altre prestazioni sanitarie richieste a strutture diverse da quelle dell'azienda oggetto dell'analisi)
- 11 Servizi non sanitari (ad esempio: pulizie di ditte esterne)
- 12 Cucina e Guardaroba/Lavanderia (se tali attività sono svolte da servizi interni all'azienda)
- 13 Altri costi imputati al centro di responsabilità (beni di consumo tecnico economale, ecc., ivi compresi gli ammortamenti di pertinenza del centro di responsabilità medesimo)
- 14 Costi comuni

ANALYSIS OF 4th LEVEL COSTS

Centri di attività Voce di costo	Degenza	Sala operatoria	A.U.O.	Ambulat.	TOTALI
1-Personale medico	450.000	350.000	50.000	150.000	1.000.000
2-Altro pers. laureato					
3-Personale tecnico					
4-Pers. infermieristico	1.500.000	400.000		100.000	2.000.000
5-Pers. Ausiliario/OTA	640.000	160.000			800.000
6-Pers. amministrativo	45.000			5.000	50.000
7-Altre figure profess.					
8-Farmaci	280.000	100.000	20.000		400.000
9-Presidi sanitari/chirur.	240.000	140.000	20.000		400.000
10-Servizi sanitari					
11-Servizi non sanitari					
12-Cucina Lav./guard.	140.000	50.000	6.000	4.000	200.000
13-Altri costi	70.000	5.000	3.000	2.000.000	100.000
TOT. COSTI SPECIFICI	3.365.000	1.225.000	99.000	261.000	4.950.000
14-Costi comuni	841.250	306.250	24.750	65.250	1.237.500
TOTALE COSTI PIENI	4.206.250	1.531.250	123.750	326.250	6.187.000

≤ 13%

CONCLUSIONS

BENEFITS

Cosmetics
Postoperative pain
Quality of Life
Natural approach
Prompter recover?
Easy conversion

DRAWBACKS

Safety
OP time
OP costs
Postoperative pain?

EVIDENCE

No evidence
Need for
larger RCTs
and
methanalyses