Sutureless Tension-free Sublay Ventral Hernia Repair

Prospective Multicenter Study. Prliminary report.





International Hernia Study Group

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Backround

1. In ventral hernioplasty sutures prevent
   - mesh migration
   - mesh wrinkling and curling
   - holds prosthesis in place allowing for connective tissue ingrowth

2. However suturing is:
   - time consuming
   - often challenging
   - could create tension in the mesh resulting in
     - postoperative pain
     - complications (1,2)

Hypothesis

1. There is no need for the mesh suturing in ventral hernia repair if the mesh is macroporous, made of monofilament polypropylene, and has flat-shape memory with proper rigidity.
2. This mesh will not migrate, wrinkle, or curl when placed in a closed anatomical space even without suturing to the surrounding tissue (3,4).
3. This prosthesis is held in place by intra-abdominal pressure and connective tissue ingrowth. Scar formation on flat mesh scaffold is essential for reinforcement of the abdominal wall, maintenance of its integrity and prevention of hernia recurrence

Aim

Clinical evaluation of the Sutureless Tension- Free Ventral Hernioplasty, technique, which involves the use of mesh without suture anchoring.

Prospective Multicenter Study

- Coordination Center- Columbia University, USA
- Participating Centers:
  - ✓ Catanzaro, Italy
  - ✓ Gdansk, Poland
  - ✓ Kazan, Russia
  - ✓ Niz, Serbia & Montenegro
- Medical treatment
  - ✓ Preferred- general anesthesia
  - ✓ Antibiotics prophylaxis
  - ✓ Thromboembolic disease prophylaxis
  - ✓ The same surgical technique
  - ✓ Early physical mobilization

Material

	Italy	Poland	Russia	Serbia	Total
Number of patients	52 39F, 13M	8 4F, 4M	27 23F, 4M	24 16K, 8 M	**111** **81F, 30M**
BMI	31± 4	33 ± 6	24 ± 2	27 ± 4	**28 ± 5**
Age (years)	63± 13	67.5 ± 11	60 ± 9	60 ± 7	**62 ± 10**
Incisional hernia	37 (71%)	7 (87%)	20 (74%)	21 (88%)	**85 (76%)**
Primary defect*	15 (29%)	1 (13%)	7 (26%)	3 (12%)	**26 (24%)**

***umbilical or epigastric hernia**

Material

Incisional hernia			85 (76%)
	midline incisional		52 (47%)
		supraumbilical M1	13 (11%)
		juxtaumbilical M2	17 (13%)
		subumbilical M3	15 (13%)
		xipho-pubic M4	7 (6%)
	paramedial		6 (5%)
	transverse		6 (5%)
	lumbar		8 (7%)
	paracolostomic hernia		4 (3%)
	after appendectomy		9 (8%)
	Recurrent hernia		8 (7%)
		mesh used before	4 (3%)

Material

	Italy	Poland	Russia	Serbia	Mean
Area of defect (cm^2)	120 ± 60	109 ± 56	80± 40	90 ± 60	**103 ± 49**
W1- D*<5cm	6 (11%)	1 (12%)	4 (15%)	3 (12%)	**13 (12%)**
W2- 5cm<D* <10cm	11 (21%)	1 (12%)	21 (78%)	9 (37%)	**42 (38%)**
W3- 10cm< D* <15cm	23 (44%)	4 (50%)	0	7 (29%)	**34 (30%)**
W4- D* >15cm	12 (23%)	2 (25%)	2 (7%)	5 (20%)	**21 (19%)**
TOTAL	52	8	27	24	**111**

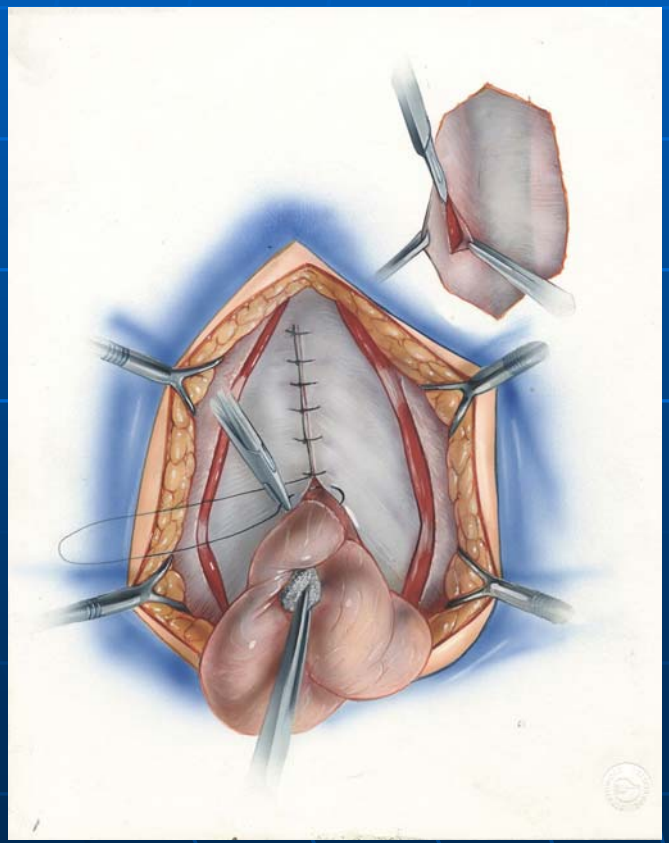
*** D- diameter of the defect**

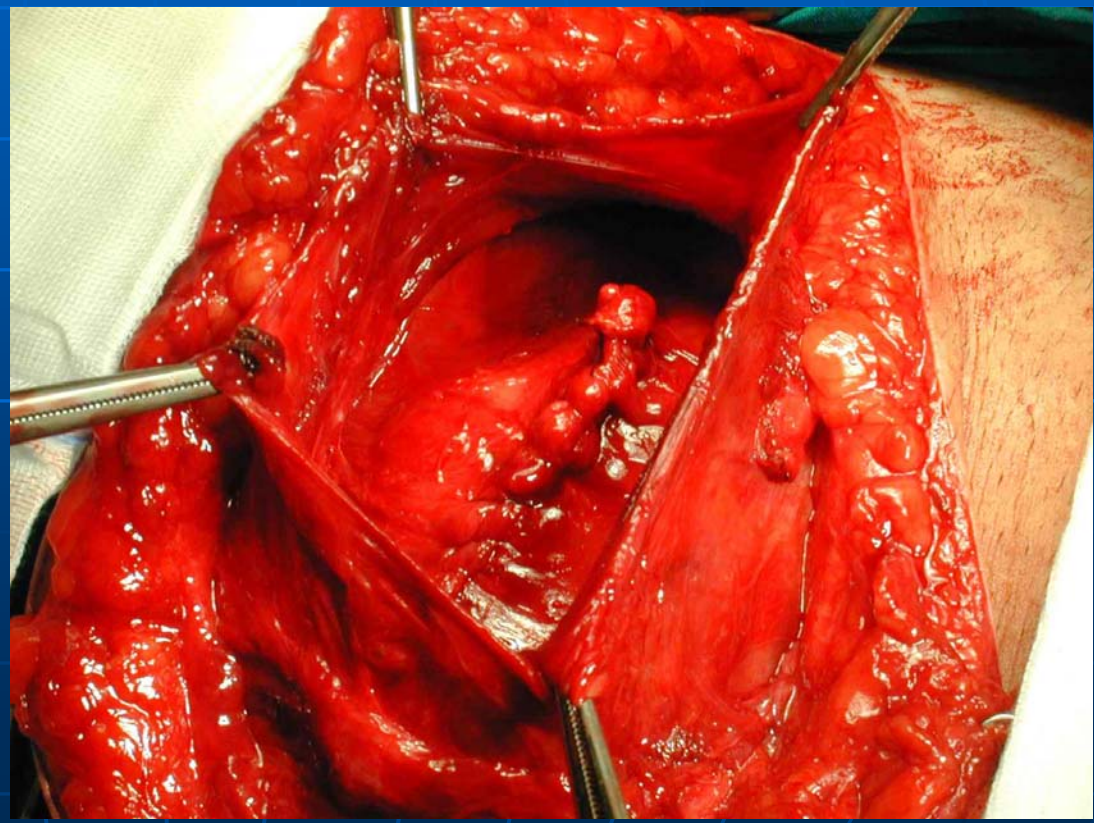
Metoda

	Italy	Poland	Russia	Serbia
Antibiotics prophylactics	**Ceftriaxone 2.0 g iv**	**Kefzol & Metronidazol**	**Cefazolin 1.0**	**Ceftriaxone 2.0 g iv**
Thromboembolic prophylactics	**Fraxiparine or Clexane**	**Fraxiparine or Clexane**	**Elastic compression**	**Fraxiparine (60%)**
Type of anesthesia	**general**	**general**	**general or spinal**	**general**
Type of suture for posterior fascia	**PDS 1**	**Prolen 0**	**Vicryl 3-0/ Prolen 2-0**	**Vicryl 2-0**
Type of suture for anterior fascia	**PDS 1**	**Prolen 0**	**Prolen 2-0**	**Prolen 2-0**

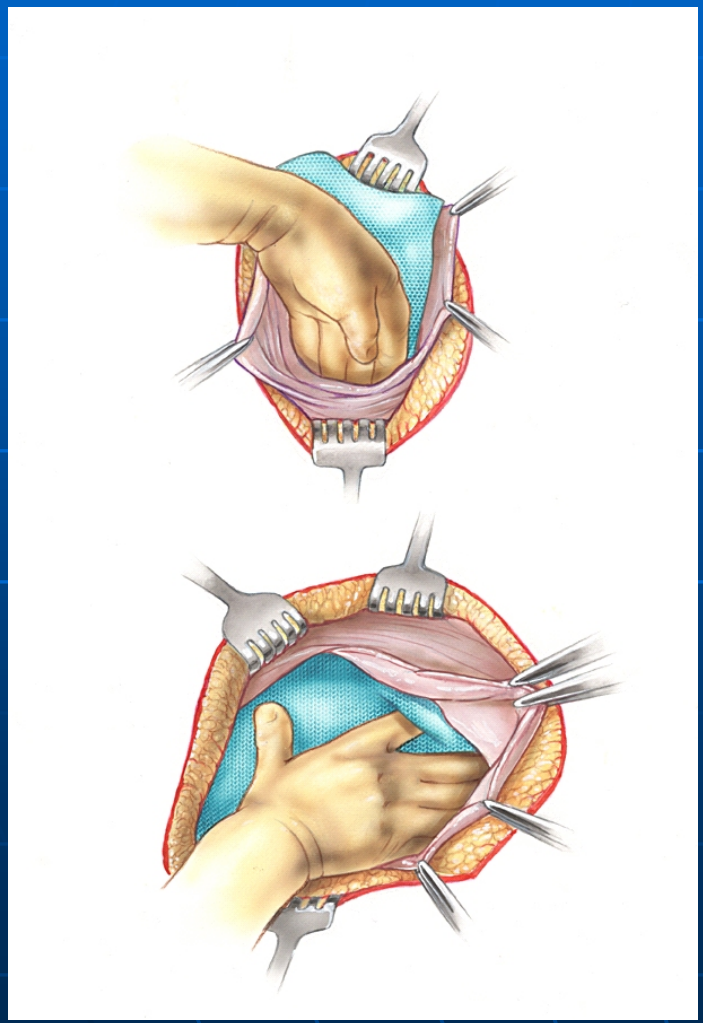
Surgical technique- based on Stoppa-Rives procedure, but in contrast, the mesh is placed without suture anchoring)

1. Excision of the hernia sac.
2. Closure of the peritoneum and posterior fascia with running suture.

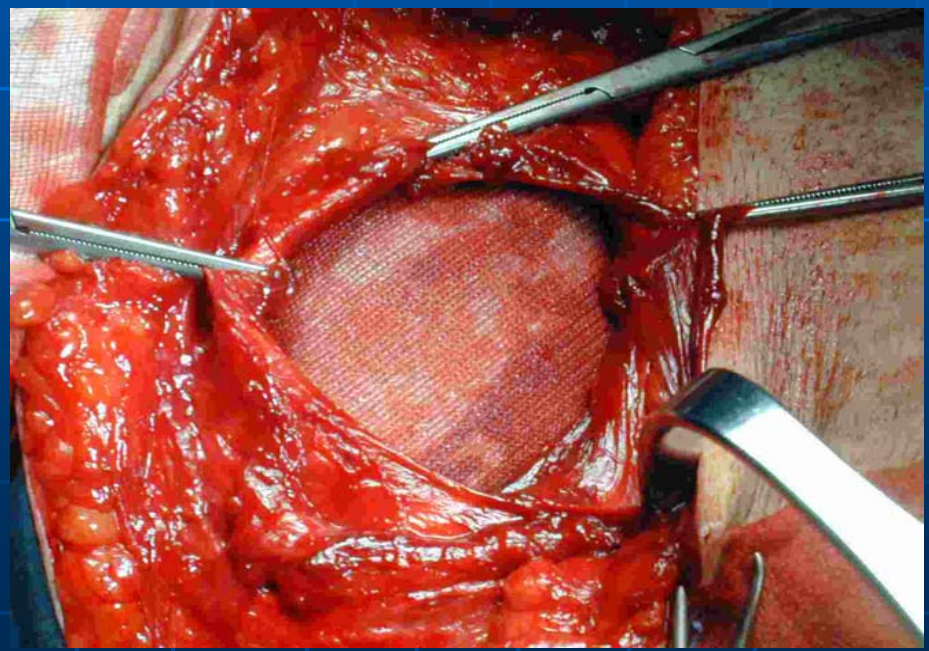




Surgical technique

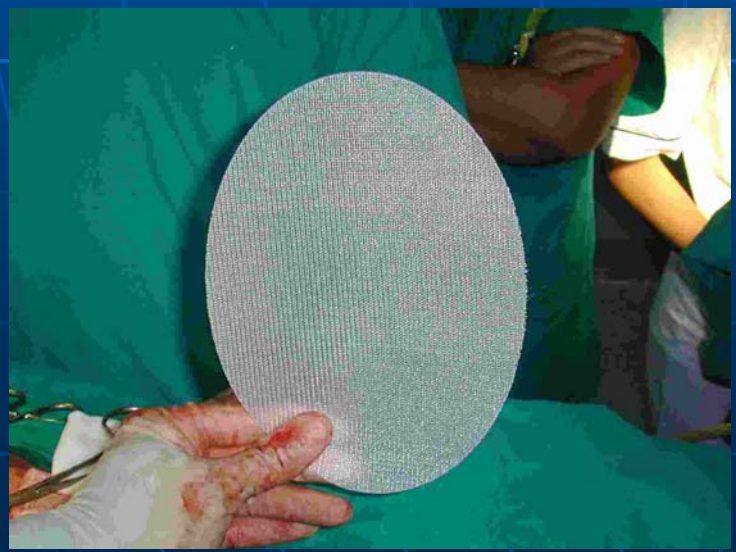


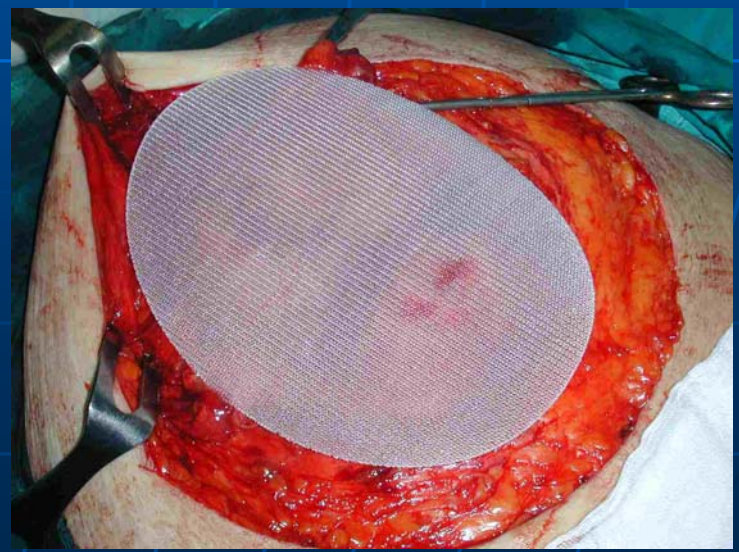
3. Placement of the mesh in preperitoneal space or retromuscular position without suturing



Surgical technique

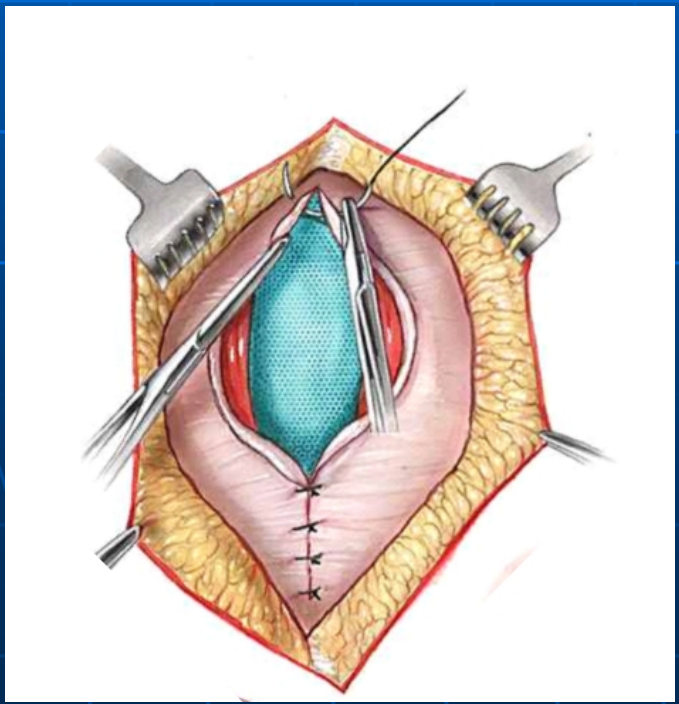
- Mesh must have proper rigidity and flat shape memory
- Mesh should be macroporous, made of polypropylene and significantly larger than the defect
- Test for rigidity- mesh hold in upright position should not band
- Mesh used in the study- Oval Patch (14x 18cm) or Hertra O (20x20cm or 30x30cm) (Herniamesh, Italy)

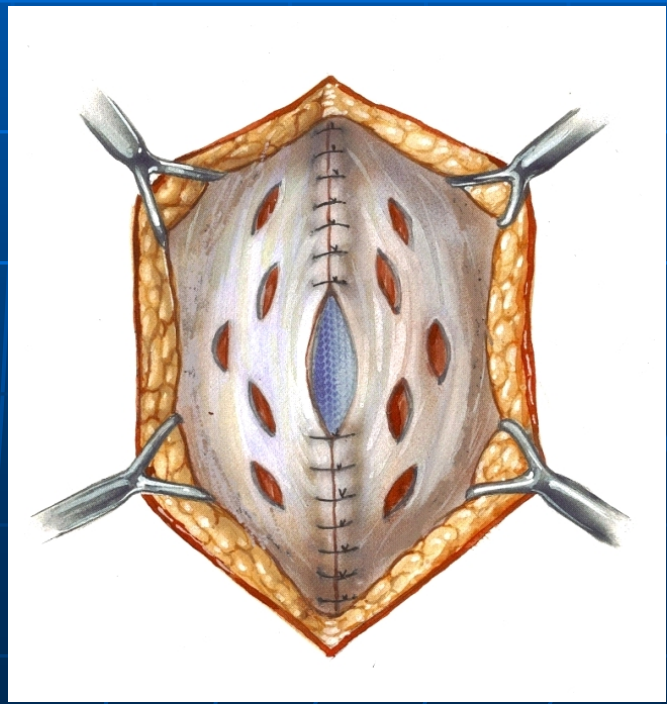




Surgical technique

4. Closure of the anterior fascia with running suture.
5. Relaxing incisions, if necessary to reduce the anterior fascia tension.
6. Suction drainage of the space over the mesh.





Results

	Italy	Poland	Russia	Serbia	Total
Area of defect (cm^2)	120 ± 60	109 ± 56	80± 40	90 ± 60	**103 ± 49**
Time of operation (min)	115 ± 26 (30-185)	116 ± 54 (40-180)	70±32 (35-160)	80±33 (35-120)	**96 ± 32**
Time of mesh implantation*	23 ± 8	33 ± 17	23 ± 16	18 ± 5	**23 ± 12**
Retromuscular mesh (n)	39 (75%)	6 (75%)	19 (70%)	14 (58%)	**78** (70%)
Preperitoneal mesh (n)	13 (25%)	2 (25%)	8 (30%)	10 (42%)	**33** (30%)
Redon applied (n)	52 (100%)	8 (100%)	17 (63%)	24 (100%)	**101**(91%)

*** * Time of posterior fascia suturing, mesh placement and anterior fascia closure.**

Results

	Italy	Poland	Russia	Serbia	Median
***VA S_1** median (min- max)	3 (1-8)	5 (3-6)	5 (2-6)	4 (3-5)	**4 (1-8)**
Treatment	Tramal & NSAID Iv	Tramal 3 (37%)	Petidine 5 (19%)	Tramal 19 (79%)	**27 (46%)**
		NSAID 5 (63%)	Banalgin 22 (81%)	NSAID 5 (21%)	**32 (54%)**
Duration of treatment (days)	2 (1- 2)	4 (2-6)	3 (2-9)	3 (1-4)	**3 (1-9)**
Hospitalization (days)	5 (3-9)	7 (3-12)	11 (7-14)	5 (4-10)	**6 (3- 14)**

*** Pain assessed in Visual Analogue Scale (0-10) on the first day after surgery**

Results

	Italy	Poland	Russia	Serbia	
	Early complications				**Total**
Wound hematoma	1 (2%)	1 (12%)	0	1 (15%)	**3 (3%)**
Seroma & aspiration	2 (4%)	1 (12%)	1 (4%)	0	**4 (3,6%)**
Wound infection	0	1 (12%)	3 (11%)	3 (12,5%)	**7 (6%)**
	Follow up- 2 weeks after surgery				**median**
***VAS**	1 (0-3)	2 (0-3)	4 (0-7)	3 (0-4)	**2 (0-7)**
Return to normal home activity (weeks)	2 (1-3)	1 (1-2)	3 (2-4)	1 (1-2)	**2 (1-4)**

*** Pain assessed in Visual Analogue Scale (0-10)**

Results

Follow up	Italy	Poland	Russia	Serbia	Total
3 months	46 (88%)	8 (100%)	24 (100%)	20 (83%)	**98 (88%)**
6 months	40 (77%)	7 (87%)	18 (66%)	13 (54%)	**78 (70%)**
1 year	35 (67%)	7 (87%)	10 (37%)	0	**52 (47%)**
1,5 year	20 (38%)	5 (62%)	3 (11%)	0	**28 (25%)**

Results

	Italy	Poland	Russia	Serbia	Total
Recurrence	0	0	**0**	**0**	**0**
Physical activity limitation of abdominal wall	0	0	**0**	**0**	**0**
	Pain 6 months after surgery				
Mild *	7 (14%)	1 (12%)	4 (22%)	2 (16%)	**14 (18%)**
Moderate*	0	0	**0**	**0**	**0**
	Pain 12 months after surgery				
Mild *	2 (6%)	0	1 (10%)	-	**3 (6%)**
Moderate*	0	0	**0**	**-**	**0**
Satisfaction score (5-0)	5 (4-5)	5 (4-5)	**5 (4-5)**	**5 (4-5)**	**5**

***Mild pain- discomfort does not limit life activity**
***Moderate pain- limits life activity**

Summary

- 111 patients were submitted to the Sutureless Tension-free Ventral Hernioplasty repair.
- 76% incisional hernia,
- 24% primary hernia
- 86% hernia with defect 5-15cm
- Mean duration of operation was 96min, however mesh implantation took only 23 minutes.
- Patients required mild pain relief treatment for 3 (1-9) days
- There were no wound infections in Italian center; the wound infection rate was 7 (12%) in the rest hospitals.
- Hematoma or hyrocele which required intervention, was recorded in 7 (7%) patients.

Summary

- Patients resumed their normal home activity within 2 (1-4) weeks after surgery.
- Follow up longer then 1 year was recorded in 52 (47%) patients.
- Neither recurrence nor physical activity limitation due to scar formation was noted after rigid mesh implantation.
- Low level discomfort with no influence of the life activity was recorded in 14 (18%) patients 6 months after procedure, it persisted only in 3 (6%) patients up to first year after operation.
- Majority of patients assessed the results of the procedure as excellent.

Conclusions

1. Preliminary results of the study showed that the Sutureless Sublay Technique is safe and effective procedure for ventral abdominal hernia repair.

2. This technique allows surgeons to save work and time of the operation and patients recover fast with low level of postoperative pain after procedure.

References

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Thank you