

NEEDLELESS SLING ANTHROPOMETRIC STUDY

	EDITED	REVISED		APPROVED
Name:	José Luis Ceamanos	José Luis Ceamanos	María Sánchez	F. Farrer
Title:	Quality Manager	Quality Manager	Quality Department	General Manager
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1.- Study objective

The main aim of this study is verify the design dimensions of the product Needleless Sling using the information available about normal anatomical variations seen in different women.
The second aim of this study is compare the Needleless Sling Mesh with a standard Mini-sling Mesh.

2.- Standards and guidance documents

- Book "Occupational biomechanics" Second edition 1991
Don B. Chaffin
Gunnar B. J. Andersson
A Wiley Interscience publication
- Book "Ergonomic design for people at work" First edition 1986
Eastman Kodak Company
A Van Nostrand Reinhold publication
- Doctoral thesis "MODELIZACIÓN VIRTUAL DE LA PELVIS FEMENINA, A PARTIR DE IMÁGENES DE RESONANCIA MAGNÉTICA".
Salamanca University (Spain)
Julia Martínez de Ibarreta Zorita
2008

3.- Study dates

Starting date of test: 25-03-2013
Finishing date of test: 27-03-2013

4.- Persons who participate in the study**STUDY DIRECTOR:**

Francisco Farrer is a knowledgeable and experienced professional suitable to perform the study.

Francisco Farrer is physician, mechanical engineer and he has been designing and manufacturing permanent implants for more than 20 years.

Coauthor of the book "Manual de ergonomía" Fundación Mapfre publication.

MANAGEMENT:

José Luis Ceamanos is a knowledgeable and experienced professional suitable to perform the study.

José Luis Ceamanos is mechanical engineer and he has been designing and manufacturing permanent implants for more than 10 years.

MANAGEMENT:

María Sánchez is a knowledgeable and experienced professional suitable to perform the study.

María Sánchez is Chemical engineer and she has been designing and manufacturing permanent implants for more than 4 years.

MANAGEMENT:

Felipe López is a knowledgeable and experienced professional suitable to perform the study.

Felipe López is mechanical engineer and he has been designing and manufacturing permanent implants for more than 6 years.

5.- Materials used to perform the study

- Female Pelvic Radiographies

6.- Definitions

No definitions.

7.- Description study steps and study results

- 7.1.- Dimensions of female pelvis
- 7.2.- Anatomical situation of implanted Needleless Sling
- 7.3.- Anatomical situation of Internal Obturator Muscle
- 7.4.- Verification of design dimensions of Needleless Sling Mesh
- 7.5.- Verification of design dimensions of standard Mini-sling Mesh

7.1.- Dimensions of female pelvis

To analyze the dimensions of female pelvis it has been studied two books about ergonomic:

- "Occupational biomechanics"
- "Ergonomic design for people at work"

The book "Occupational biomechanics" establishes for female sitting breadth:

- Percentile 5th = 34.6 cm
- Percentile 95th = 43.7 cm
- Mean = 39.1 cm
- Standard deviation = 2.9 cm

The book "Ergonomic design for people at work" establishes for female hip breadth:

- Percentile 5th = 32.4 cm
- Percentile 50th = 38 cm
- Percentile 95th = 41.5 cm
- Standard deviation = 2.6 cm

According to these books it is selected the lower 5th percentile: 32.4 cm

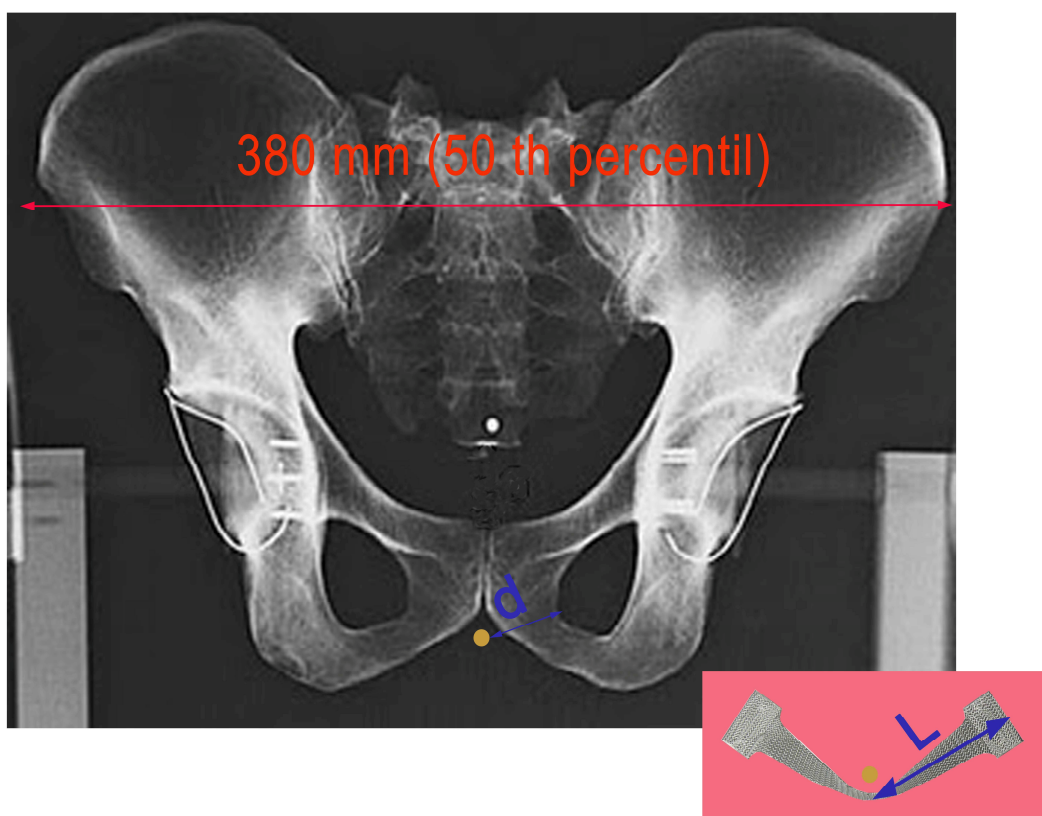
According to these books it is selected 50th percentile: 38 cm

According to these books it is selected the bigger 95th percentile: 43.7 cm

It has been selected 35 randomized female pelvic radiographies of 40-80 years old women from a hospital of Spanish Public Health. It has been checked that all these female hip width are included in the percentile described before.

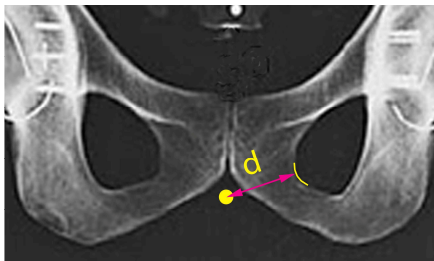
The distance between the urethra and the proximal point of the internal obturator muscle has been measured.

In the following picture it can be seen the distance measured in the radiographies and a Needleless Sling Mesh length:



Further, in this document, the distance "d" will be compared to the distance "L".

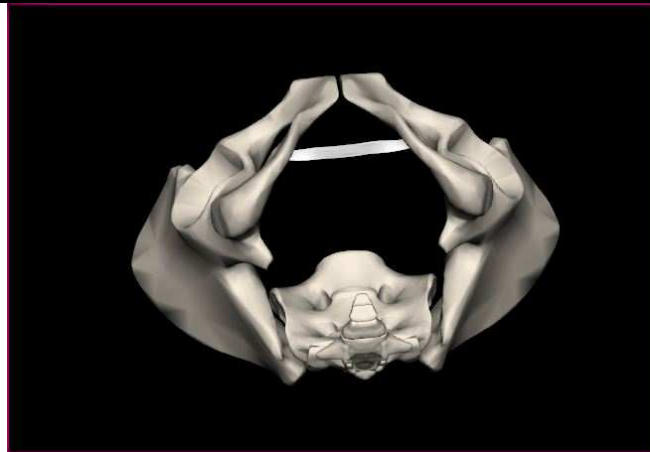
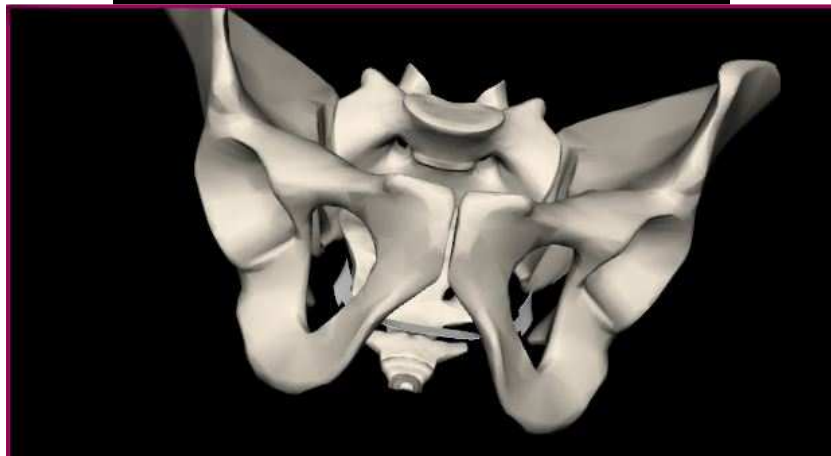
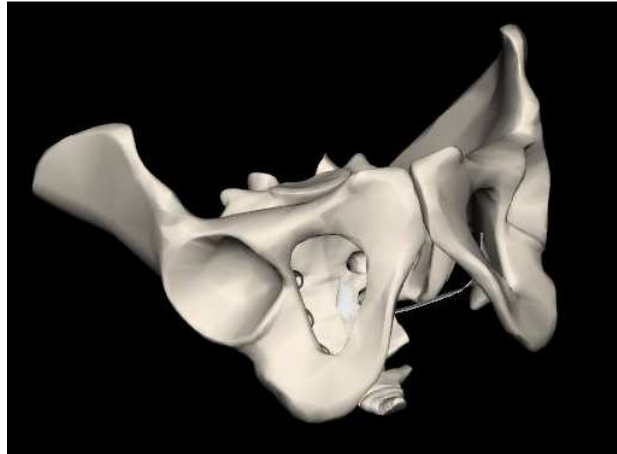
The result of this distance measurement process is:

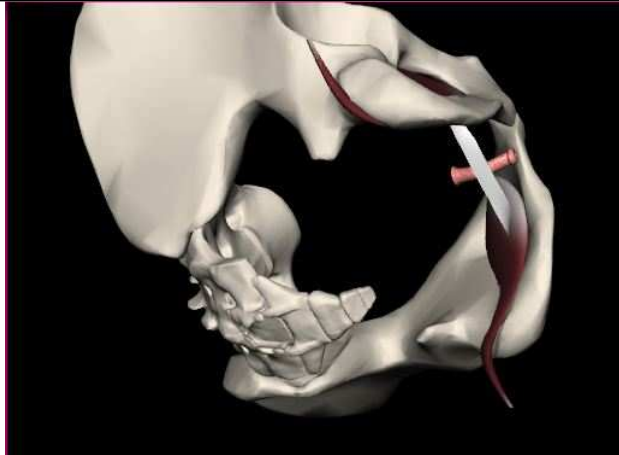
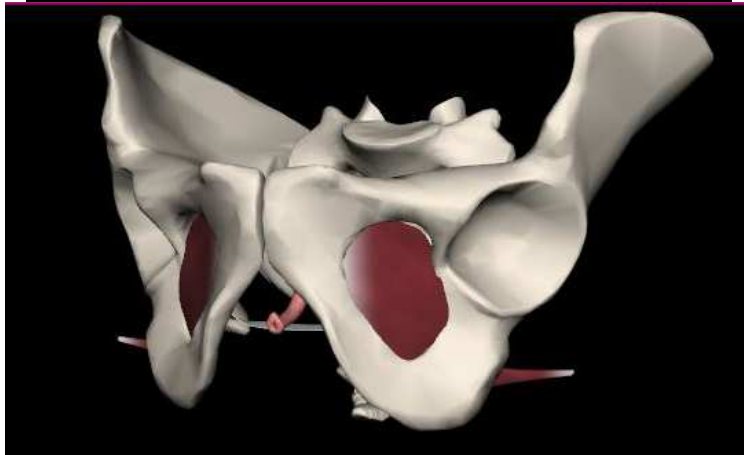
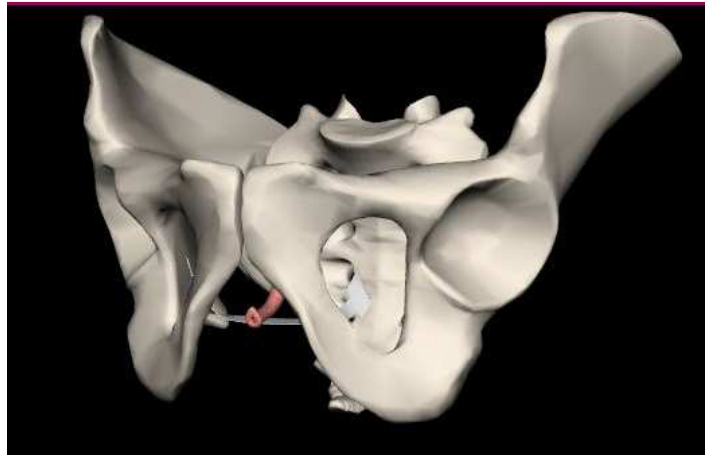
Nº	d (mm)	Reference patient
		
1	35	PCF-2001
2	39	APC-1995
3	35	MGA-1982
4	35	RGM-2001
5	35	GCN-2003
6	35	AGC-1997
7	34	MCG-2000
8	35	BMS-2000
9	33	ICA-1999
10	35	VEA-2000
11	40	NGC-1980
12	34	JSS-1979
13	34	CG-1980
14	38	MOS-1997
15	40	EGM-1994
16	32	JDR-1990
17	34	MVB-1996
18	35	ACC-1994
19	35	PNG-1986
20	35	HZ-1996
21	40	GMR-1995
22	32	PDS-1987
23	33	IRL-1989
24	36	SCL-1989
25	33	MBR-1980
26	38	MBP-1989
27	30	TMA-1982
28	35	CGC-1982
29	40	AAM-1982
30	34	MPC-1982
31	40	MSO-1981
32	38	EC-1997
33	35	OG-1997
34	36	MGB-1996
35	35	IG-1979
Maximum	40 mm	
Minimum	30 mm	
Mean	35.5 mm	
Standard deviation	2.55 mm	

7.2.- Anatomical situation of implanted Needleless Sling

The center of Needleless Sling Mesh is situated under the urethra and the extremes of Needleless Sling Mesh are situated in the internal obturator muscles.



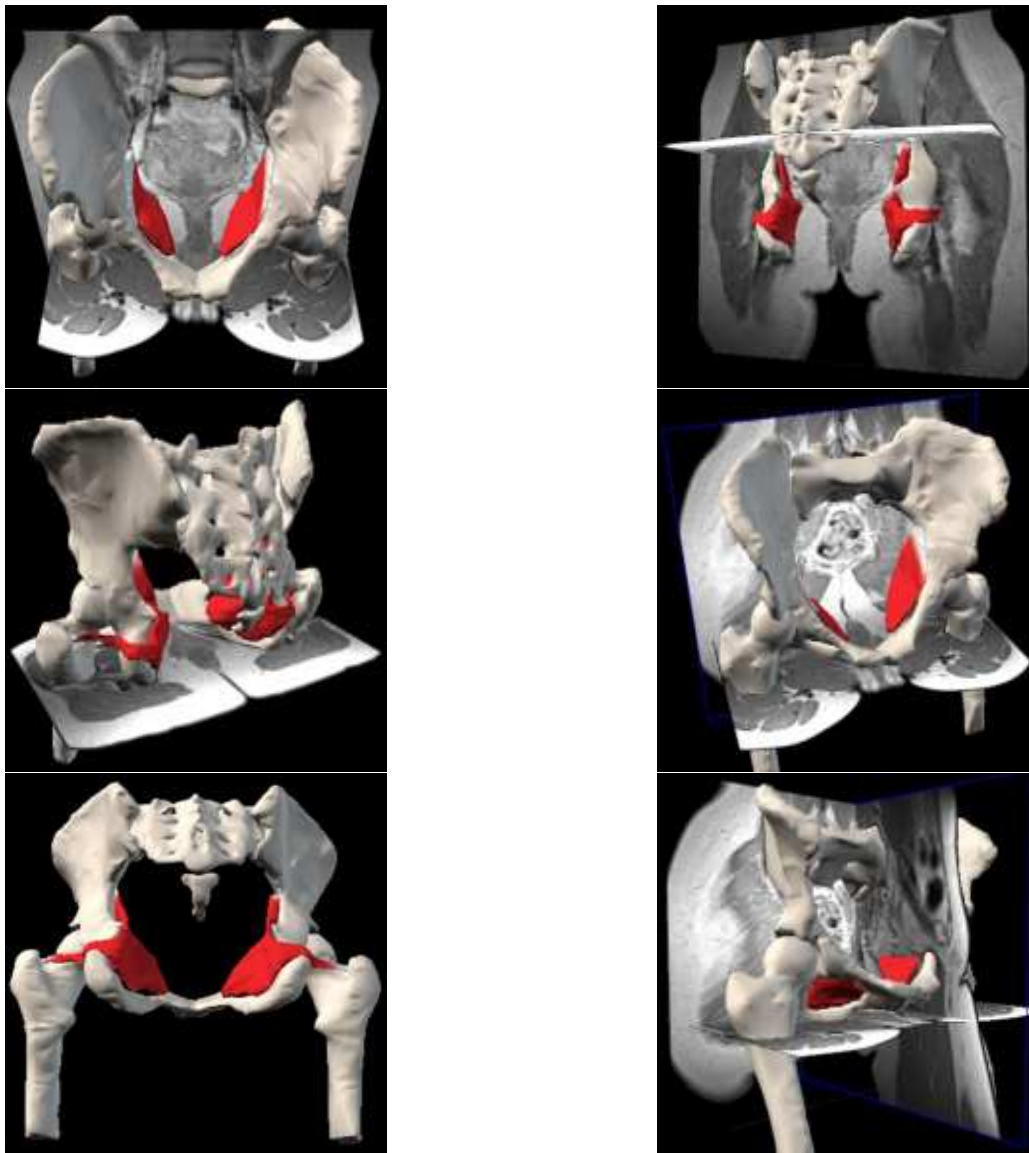




7.3.- Anatomical situation of Internal Obturator Muscle

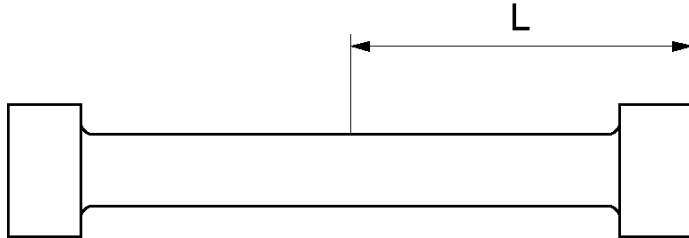
It has been studied the Doctoral thesis “MODELIZACIÓN VIRTUAL DE LA PELVIS FEMENINA, A PARTIR DE IMÁGENES DE RESONANCIA MAGNÉTICA” to situate the Internal Obturator Muscle.

This doctoral thesis shows different resonance magnetic images of the Internal Obturator Muscle:



7.4.- Verification of design dimensions of Needleless Sling Mesh

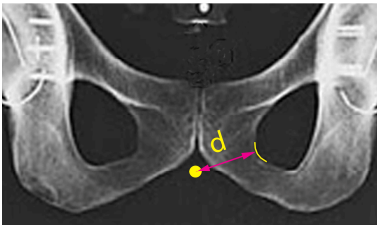
The Needleless Sling Mesh size is:



$L = 57 \pm 2 \text{ mm}$

Maximum Needleless length = 59 mm
 Minimum Needleless length = 55 mm

The distance between the urethra and the proximal point of the internal obturator muscle is:



$d = 35 \pm 5 \text{ mm}$

d = Distance between the urethra and the proximal point of the internal obturator muscle

The acceptance criteria is that the minimum Needleless length is bigger than the maximum distance between the urethra and the proximal point of the internal obturator muscle:

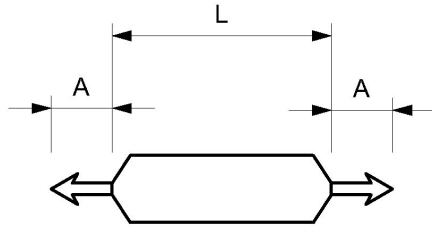
Minimum Needleless Sling length = 55 mm

Maximum distance between the urethra and the proximal point of the internal obturator muscle = 40 mm

All “d” measurements performed in the radiographies are $\leq 40\text{mm}$. Therefore, Needleless Sling comply with the acceptance criteria.

7.5.- Verification of design dimensions of standard Mini-Sling mesh

The standard Mini-sling mesh size is:

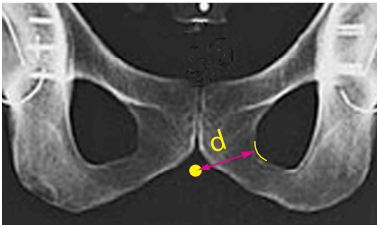


$L = 33 \pm 1 \text{ mm}$

Maximum Mini-Sling Mesh length = 34 mm

Minimum Mini-Sling Mesh length = 32 mm

The distance between the urethra and the proximal point of the internal obturator muscle is:



$d = 35 \pm 5 \text{ mm}$

d = Distance between the urethra and the proximal point of the internal obturator muscle

The acceptance criteria is that the minimum Mini-sling Mesh length is bigger than the maximum distance between the urethra and the proximal point of the internal obturator muscle:

Minimum Mini-Sling Mesh length = 34 mm

Maximum distance between the urethra and the proximal point of the internal obturator muscle = 40 mm.

All “d” measurements performed in the radiographies are $\leq 40\text{mm}$. Therefore, Mini-Sling Mesh does not comply with the acceptance criteria.

8.- Conclusions

The anatomical variations seen in different women have been studied and it has been verified that the dimensions of Needleless Sling Mesh assures that it may be supported in all cases by the internal obturator muscles.

The Needleless Sling Mesh design dimensions satisfy the anatomical female conditions for the intended use of the product.

According to this study, it cannot be assured that the Mini-Sling Mesh design dimensions satisfy the anatomical female conditions for the intended use of the product.