NEW INFORMATION ABOUT INTRAUTERINE DEVICES

MINI SIZE IUD's EVALUATION

The importance of IUD's size and their relation to the menstrual loss of blood and other opposite effects for women

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Retrospective study of the results and their causes obtained after the insertion of 11,200 mini size Eurogine Intrauterine Devices in their 3 models, T de Plata 200, T de plata 375 Novaplus y T de Oro 375 – Gold T, by the last 10 years. 47 experienced Gynecologists in the use of IUD's have given this information and conclusions due to the high number of insertions made with these models.

Summary

The use of a major copper surface in the IUD's that Tatum and Van Os proposed, has been an important improvement in the contraceptive efficiency of them.
Besides, it has been demonstrated that this increment of the copper surface is harmless and has no significant disadvantages for women.
The high charge denomination that describes the new IUD's generation is not commercially well defined. But if we take the international bibliography, it is perfectly established that the amount of copper measured in mm2 of active surface is 380 and 375mm2, that are related to Copper T 380ª and Multiload 375 models respectively.
Some authors say that the concept "high charge" is valid from 300 mm2, and in some commercial ways it is intended to establish the maximum limit of 340mm2. In both cases the reality is obviated, because the international experience demonstrates properly that the best results have been achieved with 375-380mm2 copper surfaces (the spread of 1.3% between this two amounts is insignificant), without causing any adverse condition for the patient.
Because of the above mentioned after a rigorous analysis of these publications, the right definition for "high charge" has to be related to IUD's with a copper surface between 375 and 380mm2.

Nowadays, from the point of view of the contraceptive efficiency, the pregnancy rates with IUD's are equal to the contraceptive pill and are near by the surgical sterilization, but causing less side effects for women's well-being.

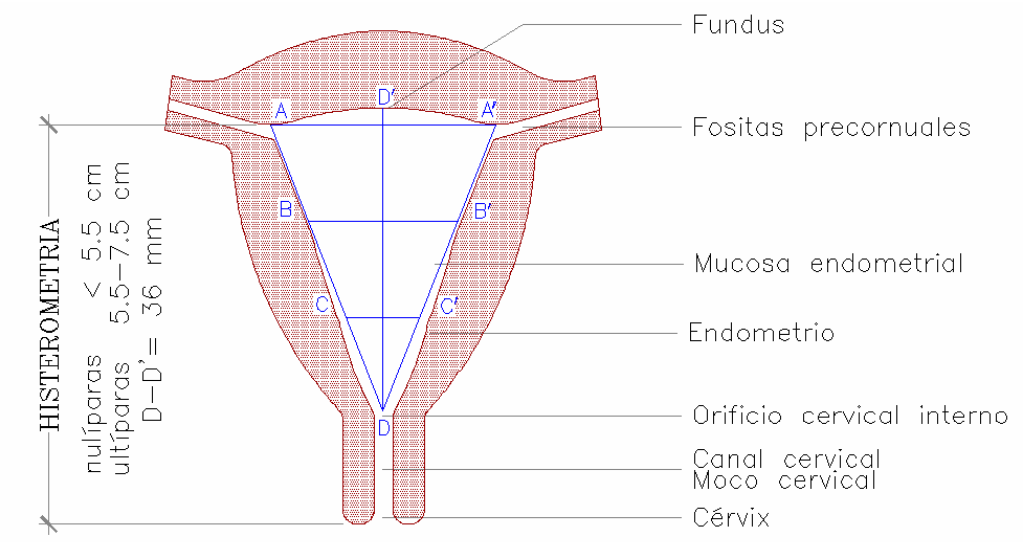
The improvements made in the IUD's for years that have contributed in their evolution and have set them in the optimal level of the contraceptive methods. These improvements have been made basically in three of their components:

1. The increase of the copper amount and the incorporation of other metals cores
2. The geometric shape of the IUD's and their insertion method
3. The sizes of the IUD's

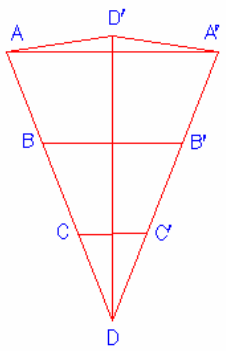
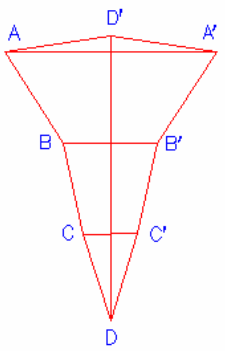
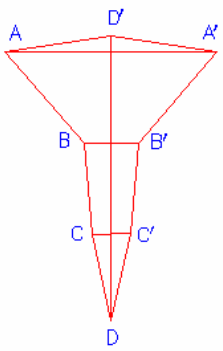
The first improvement has permitted to increase the contraceptive safety of the IUD's, almost at the 100% against an undesired pregnancy. The incorporation of a non-corrosive noble metal core inside the copper wire has notably improved its life and guarantees its non-fragmentation, even in long lasting insertions.

Secondly, the evolution of geometric shapes for IUD's has permitted the removal of two negative features of some models: the difficult insertion or the readiness for that, and the high level of aggressiveness at the insertion and removal.
Moreover, these improvements make easier the insertion, if the manufacture's instructions are followed correctly, guarantee a harmless insertion, the right placement of the IUD in the fundus and the almost impossibility of cause an accidental perforation even if the physician is not an expert in this matter. All of these improvements will determine the tolerance, durability and safety of the IUD placed.

Finally and depending on the shape of the uterine cavity, its measure and the variations detected along the time in it, different sizes of IUD's have been proposed and experimented. In this study, we will try to demonstrate the relevant importance of this argument, mainly related to the tolerance levels, the pain, the blood flow and the life of the IUD, without forgetting the maximum level of contraceptive safety.



FISIOLOGIA DEL UTERO
TAMAÑO MINI

EN REPOSO		CONTRACCIÓN MEDIANA		CONTRACCIÓN MÁXIMA	
					
A–A'	27 mm	A–A'	27 mm	A–A'	27 mm
B–B'	18 mm	B–B'	12 mm	B–B'	7 mm
C–C'	9 mm	C–C'	7 mm	C–C'	5 mm

Introduction

It is known that the effectiveness of an IUD is directly related to its right placement in the uterus. Moreover, a proper size and shape improve this effectiveness and minimize the side effects, the intolerance and discomfort.

The lack of fitting between the IUD's shape and the endometrial cavity where the IUD is being placed will affect negatively the behavior of the IUD. This can cause an unnecessary increase of the side effects (increase of spotting, painful, etc.), which will have been told the patient as normal effects and she will not inform about them to her doctor. As told before, these side effects can be avoided with the proper shape and size.

The purpose of this survey is to explain to all the Gynecologists the experience collected after some years of placing "Mini" size IUD's. We know that this definition is not the best for this IUD, because "Mini" can suggest very or extremely little, but the reality shows (fig. 1) that this size fits to most of the actual women's uterus, and the difference with the medium, normal or standard size is minimal.

Geometry of the uterus

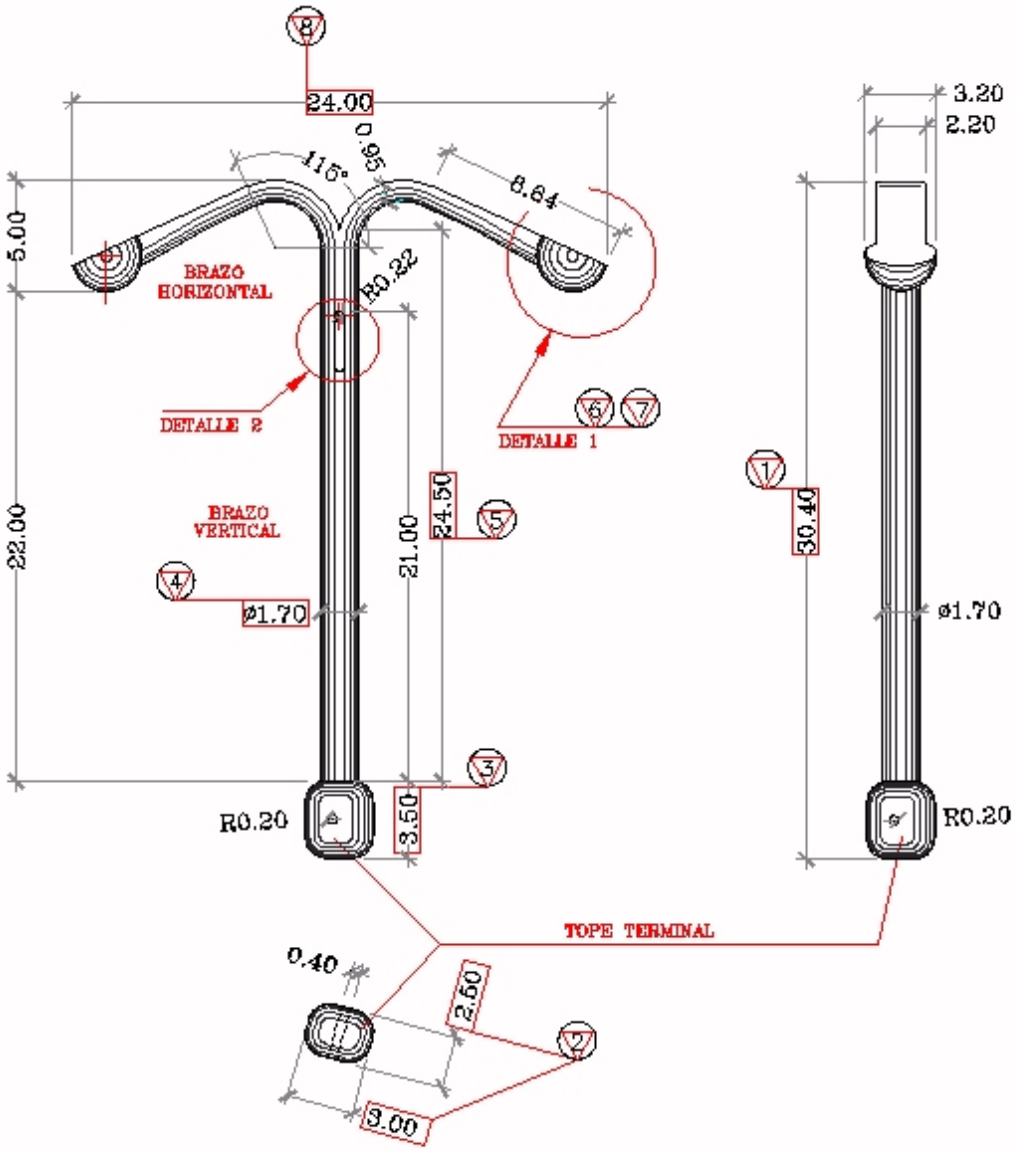
Despite being the IUD's a contraceptive method used worldwide for the last years, there are very little publications that describe with detail the geometry of the uterus.

In general, the relation existent between the length of the endometrial cavity, form the fundus until the internal cervical orifice, and the histerometry from the cervix till the fundus is rather unknown.

It is also very important to know the distance between the unions of the uterus and the Fallopians. The histerometries that show 7 and 8 cm give a medium valor of 26 mm between them.

The contractions of the uterus that happen after an IUD insertion can produce a decrease of the axial and transversal length of the uterine cavity

If the IUD has been selected properly, these variations of the cavity give no problems, in other cases an incompatibility between the uterus and the IUD may occur, causing more painful and spotting, even make the extraction necessary or causing an spontaneous expulsion.



Descripción	Dimensión	Material	Pos.	Observaciones
Brazos horizontales. Envergadura.	24.00 mm	Polietileno	8	
Brazos horizontales. Ancho	2.20–3.18mm	Polietileno	7	
Brazos horizontales. Grueso.	0.95–1.80mm	Polietileno	6	
Brazo Vertical. Longitud.	24.50 mm	Polietileno	5	
Brazo Vertical. Diámetro.	1.70 mm	Polietileno	4	
Tope Terminal. Longitud.	3.50 mm	Polietileno	3	
Tope Terminal. Diámetro.	2.50/3.00mm	Polietileno	2	
Longitud Total.	30.40 mm		1	

ARMADURA-BASE "T" peculiar MINI

DIU	P.O.C.	Código
T de pro 375 mini	CVD_17	01040200
T de plata 375 Novaplus mini	CVD_12	01010300
T de plata 200 mini	CVD_11	01010100

Dibujado Drawn: 11.10.97

Código Comp.: 01040201

Escala: 3:1

Archivo: IUD–01–41

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Evolution in IUD's sizes

In 1962, Lippes made public his model of IUD called Lippes Loop or Lippes' Handle, which would be the most used from 1962 till 1968, being these dates the beginning of the use of this contraceptive method worldwide.

The Lippes' Handle and the Saf-T Coil, another model historically very used, were manufactured in different sizes, what let the Gynecologists select the proper IUD depending on the histerometry of the patient. However, those IUD's were big even though the patients had histerometries bigger than 11 o 12 cm.

In the middle of the 70's, the IUD's of new generation or medicated IUD's appeared, which established the basis of the actual IUD's (Nova T, Multiload, etc.) You have to notice the considerable decrease of their size related to their predecessors, and the fact that the histerometries in the 70's did not exceed of 10 cm.

In the information collected for the confection of this survey, as you can see in the summary of results, the percentages of histerometries over 8 cm is very low. This data plus the specialists' experience have leaded us to inform all the Gynecologists about the convenience of using the "Mini" size IUD. This is the reason why we manufacture this size in its different models.

Improvements in the reasons of displacement or expulsion

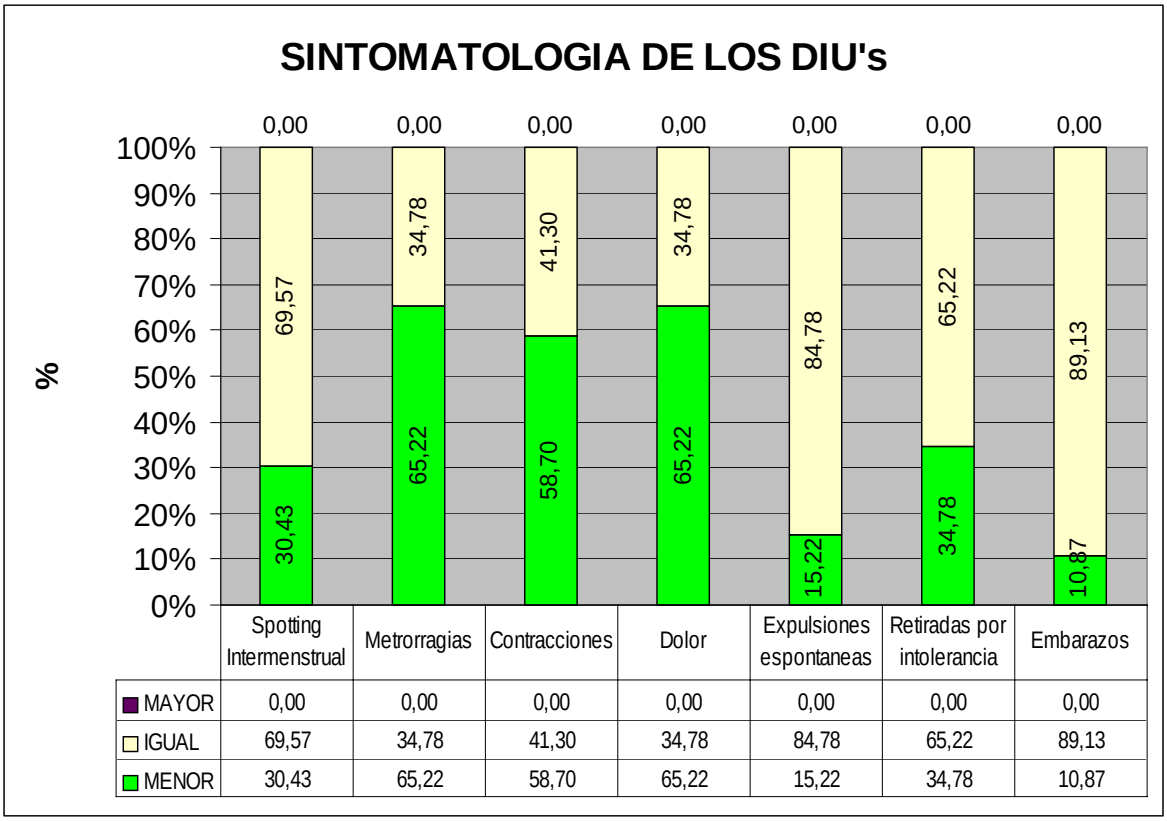
The addition of the following mechanisms:

- The increase of the uterine contractions after the insertion of an IUD,
- The morphology of the virtual cavity inside the uterus,
- The shape of the placed IUD,
- The placement of it after the insertion,

will determine, specially in the early weeks, the intention of displacement of the IUD through the cervical canal, causing a loss of effectiveness or even its expulsion.
We cannot do anything about the two first mechanisms, but we can in the others if the "Mini" size IUD is used in any of its models.

You can see in Fig. 1 (Plane of the same structure for all the models of the Eurogine's "Mini" size IUD), the transversal arms have originally a pronounced downwards trend. This shape has been studied carefully to compensate the own deformation of those IUD's which are pulled by the threads inside the cannula for its insertion. These types of IUD's, which the transversal arms are opened from top to bottom, can usually adopt a "Y" shape that, in addition to an ineffective viscoelastic memory, may favor the displacement or the expulsion.

Inside the uterus, when the IUD is pushed outside the cannula, its arms trend to recover its original position, what will be achieved in a major or minor grade depending on the viscoelastic memory of the plastic and its original shape. Both features are improved in the "Mini" size IUD with the intention of giving to it the best conditions of resistance against the possible expulsion.



	Spotting Intermenstrual	Metrorragias	Contracciones	Dolor	Expulsiones espontaneas	Retiradas por intolerancia	Embarazos
MAYOR	0,00	0,00	0,00	0,00	0,00	0,00	0,00
IGUAL	69,57	34,78	41,30	34,78	84,78	65,22	89,13
MENOR	30,43	65,22	58,70	65,22	15,22	34,78	10,87

Material and Method

47 experienced Gynecologists in the field of the Eurogine's "Mini" size IUD's have been asked about their experiences with them in order to elaborate this study.

To make this compilation more homogeneous, we have defined, in a questionnaire divided in 5 parts, the values of those parameters that are important for the right evaluation of the mechanisms that are intended to be studied in this survey:

1. Which is the most usual histerometry measured by the Gynecologists? It is studied the percentage of each measurement?

2. For what histeromtries are you using the Eurogine's "Mini" size IUD's?

3. Which is the "Mini" size model that you are using? The valuation is made depending on the Copper charge

4. What other models or brands did you used before? In the survey are going to be considered the possible differences found between them

5. Which is, related to your opinion and your experience, the valuation of the effectiveness and tolerance parameters compared to the other models, sizes or brands used before?

Conclusions

The 28% of the referred cases indicates a significant decrease of the spotting when the "Mini" size is used. It is important to notice that most of the comparisons has been made with other models of IUD's such as the "Normal" size of the T de Plata or Nova T.

When it is asked about the metrorrhagia, the 76% of cases shows an important decrease if the IUD used is a "Mini" one.

About the contractions, there is the same decrease of the 76%.

The painful is the most significant parameter because its percentage of decrease: the 86% of the cases studied.

The 80% of the expulsions is equal to the other models used and a 20% shows even a decrease of them. This make us suppose that it can be improved the relation uterus-IUD with the election of the “Mini” size IUD.

The extractions caused by intolerance are similar in their percentages, what tell us the right election of the IUD made by the participants in this study.

About the pregnancy rate, is next to 100% as the other models are. It cannot be expected another conclusion.

The significant improvements, the important decrease in the undesirable effects of the IUD’s, and the non-existence of a unique case of increase in any of the parameters, let us inform you about the notable advantages of “Mini” size IUD’s in all the uterus between 6 and 8.5 cm. This is not related to patients who are or not nullipara.
The association between “Mini” size IUD’s with high charge copper wires, is nowadays the best option in mechanical contraception, the most effective, comfortable and which has the minor risk for women among the options existing in the market.