

Erasmus MC *Erasmus* Spaarne ZIEKENHUIS

3D-Gel Instillation Sonohysterography (GIS)

Niek Exalto en Mark Hans Emanuel

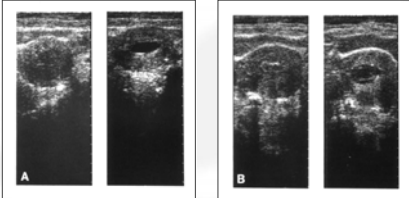


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Uterine cavity distention

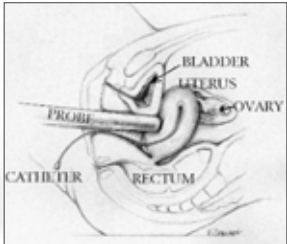
Van Roessel J, Wamsteker K en Exalto N
 Sonographic investigation of the uterus during artificial uterine cavity distention. J Clin Ultrasound 1987; 15: 439-450



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Saline Infusion Sonohysterography



De Kroon, 2003
Thesis AZL

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SIS

QuickTime™ and a YUV420 codec decompressor are needed to see this picture.

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SIS / Gel Instillation Sonohystography



- Simple technique
 - single handed
- Less leakage / pain
 - minimal inconvenience
- Stable filling
 - nice view
 - longer investigation time

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Teamwork

- development
 - Mark Hans Emanuel & Niek Exalto
 - ID-NL and Dutch Patent Office
 - Corry Stappers en Ineke Tromp
- Gel
 - Mies van Raamsdonk Pharmacist
- Application device

– Kitty ter Borg	Fac Industr Design TU Delft
– Jan Dirk Burggraaf	Afd Klin Pathologie
- Echoscopie
 - Jort Nijenhuis e.a. Biomedic, Aloka

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Gel: glycerol + hydroxyethylcellulose

Without other substances like
Chloorhexidine and /or lidocaine

- = Medical device # Pharmaceutical
- = ExEm®-gel proper viscosity

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Safety

- Urology urethra
- Surgery intra-abdominal
- Ophthalmol eyedrops (artificial tears)
- Gynaecol intrauteriene lokaal anaesth
- Safe in case of intravasation

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Gel



avoid air bubbles

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Application device

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Prototype

IUI canule - plastic tube - syringe

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Filling slowly

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Indications and findings GIS

Indication	N	abn	%
Abnormaal uterine bleeding	63	31	49
Postmenopausal bleeding	37	22	59
Tamoxifen use	5	5	100
Residual trophoblastic tissue	10	7	70
Recurrent miscarriage / infertility	5	4	80
Evaluation myomas/polyps	17	7	41
Failed procedure ostium closed 4 / leakage 3	7		(4,8)
Totaal	144	76	52

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FERTILITY AND STERILITY

The Official Journal of the American Society for Reproductive Medicine

Virtual Hysteroscopy

Powered by GIS*

Gynaecologie

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Position upright (n=7)

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Position anteflexion

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Position Retroflexion

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Artefacts: air bubbles

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Residual placental tissue

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Polyp

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Polyp ?

proliferation blood clot polyp

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Secretion phase

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Subseptate uterus

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Medisign Delft

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The GIS®-kit

GynaecologIQ

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Mouse Embryo Test	Requirements for Passing	Result
Control Assay Results:	<ul style="list-style-type: none"> ≥ 80% 1 cell to blastocyst within 120 hrs ≥ 50% blastocysts hatching within 120 hrs 	<ul style="list-style-type: none"> 100% 95%
Test Assay Restuls: (see graph below)	<ul style="list-style-type: none"> ≥ 80% 1 cell to blastocyst within 120 hrs ≥ 50% blastocysts hatching within 120 hrs 	<ul style="list-style-type: none"> 87% 77%

Blastocyst Development

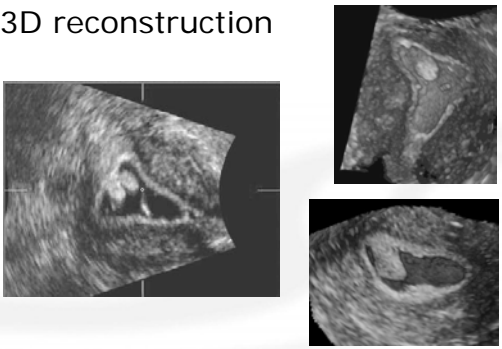
Hours in Culture	2 cell	4 cell	8 cell	morula	Blastocyst	Hatching
24	22	0	0	0	0	0
48	0	12	0	0	0	0
72	0	0	12	0	0	0
96	0	0	0	12	0	0
120	0	0	0	0	12	12

MEA RESULTS: PASS

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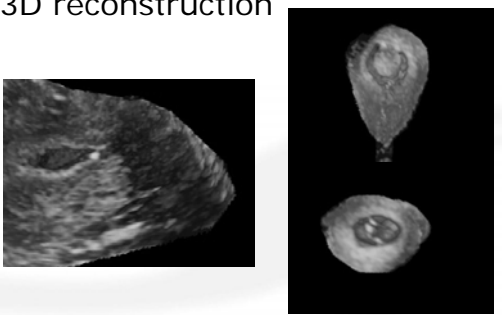
3D reconstruction



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3D reconstruction

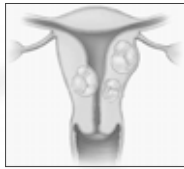


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Innovations

- Application device
 - Better cervical closure
- improvement gel
 - viscosity / air bubbles
- color Doppler
 - polyp / myoma
- visualisation
 - Intramural?



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Discussion

Gel instillation is an effective and safe alternative for Saline infusion.

GIS is an ideal contrast technique for 3D reconstruction, CT-scan en MRI

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ExEm® Gel

No additional pharmaceuticals
METC / Medirisk proved
CE-marked medical device
FDA 510k pending

>2000 procedures
allergic reactions
no infections
only vasovagal reactions

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Product



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www.gynaecologIQ.nl



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Product



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