Olavi Airaksinen, MD PhD Professor of PRM, Clinical Director. Department of Physical and Rehabilitation Medicine, Kuopio University Hospital Kuopio, Finland

Sidonnaisuudet

- KYS fysiatrian klinikan ylilääkäri (1986), kuntoutustoiminnan vastaava ylilääkäri. kuntoutustoiminnan tulosyksikön johtaja.
- Fysiatrian Dosentti KYO (1993)
- Yksityislääkäri Oma Lääkäri (1990) Oy/Terveystalo Oyj.
- Joukkueen vastuulääkäri Kalpa Hockey Oy.(1982-).
- Toimitusjohtaja Medsaco Oy ja Forto Oy.

Asiantuntija tehtäviä, luentoja, kongressimatkoja ja kliinistä lääketutkimusta mm seuraavien terveydenhuoltoalan yritysten kanssa (viimeisen kahden vuoden aikana): Suomen MSD, Leiras, Pfizer, GSK, Algol, Meda, Mundipharma, Boehringer, Lilly, Pierre Fabre Laboratories, Ferrosan, Orion, Parexell, Secret Files, Chiltern, TFS trials, St Jude Medical, Respecta, Foot Center, Mega Electronics, HDL, Fysioline, jne.. Is exercise of pelvic floor muscles effective for urinary incontinence ? critical point of view

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Olavi Airaksinen



Content:

Treatment methods for incontinence and pelvic floor muscles.
Cochrane- review of effectiveness 2006.
Biofeedback assisted exercise.
Principles of muscle exercise
Mobile biofeedback assisted exercise.
Conclusions Hunskaar 2008: A systematic review of overweight and obesity as risk factors

 CONCLUSIONS: Epidemiological studies document overweight and obesity as an important risk factor for urinary incontinence.

 There is now valid documentation for weight reduction as a treatment for urinary incontinence in women.

Urinary incontinence

@ Thurs 1996-92 FW

- stress incontinence
 urge incontinence
- mixed

The Treatment Spectrum

Behavior

n Diagnosis Is Critical

- Surgical vs. Non-surgical Candidate
- Complete Evaluation Necessary to Be Accurate

n Biofeedback Becomes a Vital Part of a Complete **Incontinence** Program

Surgery

TVT/Vesica

Bladder Suspensions

Collagen Injections

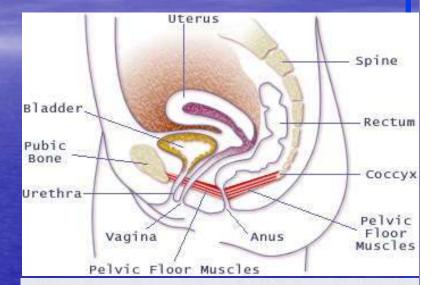
Modifications Prescription **Biofeedback** Drugs **Kegel Exercises Pelvic Floor** Retraining **Voiding Intervals Eating Habits Lifestyle Changes** Most Aggressive

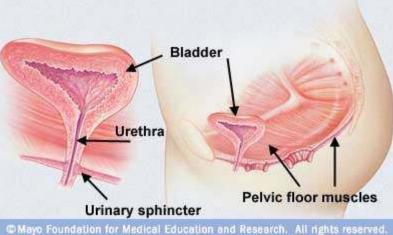
Least Aggressive

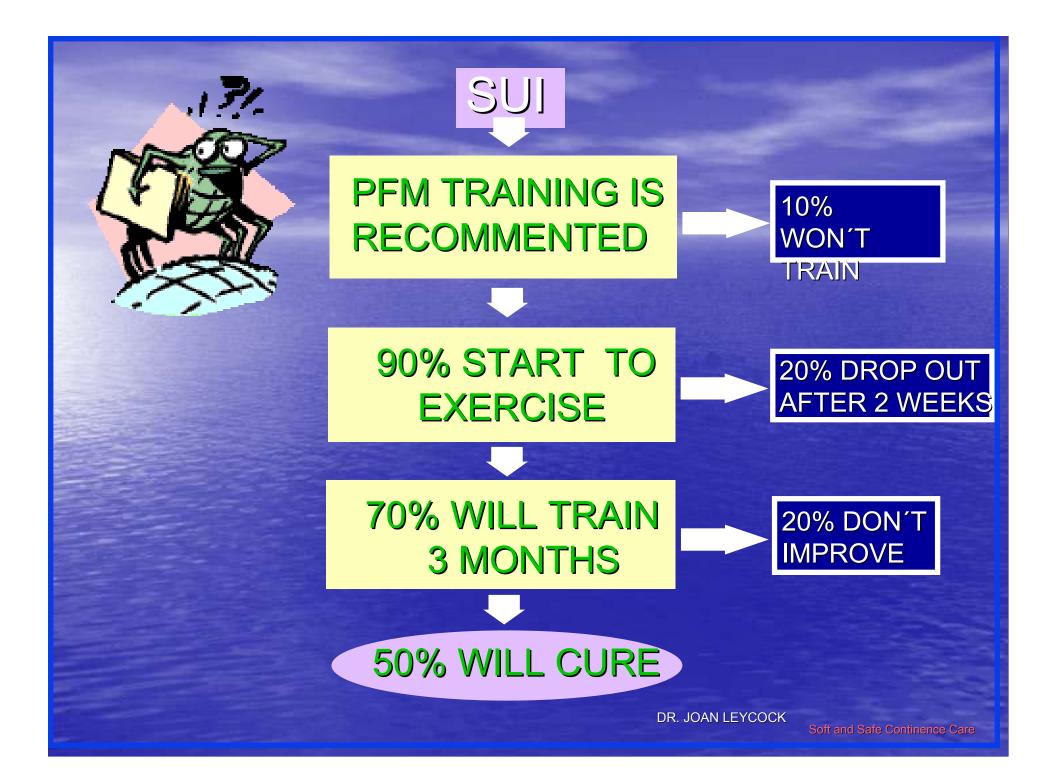
GOALS FOR PELVIC FLOOR MUSCLE EXERCISES

- IMPROVE URETHRAL RESISTANCE
- EXERTS A CLOSING FORCE ON THE URETHRA
- **INCREASES MUSCLE SUPPORT**
- BETTER AWARENESS OF PELVIC MUSCLE FUNCTION

 ALSO CALLED KEGEL EXERCISES







Muscle exercise and stress incontinence (=SUI).

 UP TO 80% OF WOMEN WITH SUI COULD BE CURED IF PFM EXERCISES ARE PROPERLY CARRIED OUT.

TOTAL CURING RATE IS ABOUT 50%.

VAGINAL CONES

 SET OF CONES THAT ARE IDENTICAL SHAPE AND VOLUME BUT OF INCREASING WEIGHT

WEIGHTED CONE IS PLACED INTRAVAGINALLY

• TWICE DAILY TRAINING (15 MIN)

BIOFEEDBACK

 A TYPE OF BEHAVIORAL TRAINING PROCEDURE

 VISUAL OR AUDITORY FEEDBACK OF A BODILY FUNCTION

LEARN TO IMPROVE CONTROL

Soft and Safe Continence Care

ELECTRICAL STIMULATION

STIMULATION OF THE PELVIC MUSCLES

STIMULATION OF THE NERVES SUPPLYING PELVIC STRUCTURES

 BENEFICAL BOTH URETHRAL AND BLADDER DYSFUNCTIONS

Pelvic Floor Muscle Training for Urinary Incontinence

 5 systematic reviews of effectiveness, (Fedorkow 1993 (meta-analysis), Bo 1996, de Kruif 1996, Berghmans 1998 ja Wilson 1999 (4 of these qualitative analyses).

 Conclusion: patients will have benefit from exercise.

PFMT ja Biofeedback

 De Kruif et al: EMG biofeedback added the effectiveness of PFMT.

 Berghmans et al ja Wilson et al did not found additional benefit.

 Wheatherall et all 1999: a pooled data analysis: The use a EMG biofeedback in addition of PFMT give better results for urinary incontinece patients. Dannecker C, Wolf V, Raab R, Hepp H, Anthuber C : EMGbiofeedback assisted pelvic floor muscle training is an effective therapy of stress urinary or mixed incontinence: a 7-year experience with 390 patients. Arch Gynecol Obstet. 2005: 273:93-7.

 CONCLUSIONS: An intensive and EMG-biofeedback assisted PFMT is very effective. Often, avoidance of surgery is possible Pelvic floor muscle training for urinary incontinence in women Hay-Smith EJC, Bø K et al..., Cochrane review 2007

 43 original studies, from which 15 was congress presentations only.

Many of these studies have small patient groups.

 Pelvic floor muscle training (PFMT) was compared to placebo or other therapy, some has used electrical stimulation or/and biofeedback equipments.

PFMT versus no treatment

Study	Expt n/N	Ctrl n/N		RR(95%	CI Fixed)		Veight %	RR(95% CI Fixed)
Burns 1993a	7743	(1739			<u>.</u>	. 4	41.7	6.35[0.82,49.32]
Burns 1993b	9/40	(1/39				4	10.2	8,77[1,17,68.04]
Bø 1999	2725	0/30		1 <u>1</u> 1 1 1		\rightarrow	18:1	5.96[0.30,118.71]
Total	18 / 108	27108			-	1	00.0	7.25[1.99,26.49]
Test for heterogeneity	chi-square=0.07 dt	=2 p=0.97						
Test for overall effect 2	Z=3.00 p=0.00							
			0.01	0.1	1. 10	100		
			: Estrou	rs control	Favours PFN	ſſ		

Pelvic floor muscle training for urinary incontinence in women

Review

PFMT vs placebo

Pelvic floor muscle training for urinary incontinence in women

Review:

Comparison: PFMT versus placebo treatments self reported cure post beatment Outcome: Study Weight RR(95% CI Fixed) Expt n/N Ctrl n/N RR(95% CI Fixed) Ŵ Burgio 1998 (19/63 8/62 88.5 2.34[1.11,4.94] Hofbauer 1990a 8/11 0/10 57 11.92[0.76,187,85] 6.42[0.37,110.71] Hofbauer 1990b 3/41 0/40 57 100.0 3.12[1.56,6.23] Total 28/85 8/82 Test for heterogeneity chi-square=1.73 d≠2 p=0.42 Test for overall effect Z=3.22 p=0.00 0.01 11 100 Favours placebo Favours PFMT



Comparison of standard and intensive PFMT methods

Review: Pelvic floor muscle training for urinary incontinence in women

Comparison: Comparisons of PFMT

Outcome: self reported cure post treatment

Study	Expt n/N	Ctrl n/N	RR(95%	% Cl Fixed)	Weight %	RR(95% CI Fixed)
Bø 1990	2723	0/29	/	, - ,	→ −0,5	6.25[0.31,124.11]
Wilson 1997 a	65 / 156	37 / 124			50.5	1.40[1.01,1.94]
Wilson 1997b	: 45 / 120	317410			39.6	1.33[0.91,1.94]
Wilson 1998 I	10 / 19	22/91		+	. 9.3	2.18[1.24,3.81]
Total	122 / 318	90 / 354			100.0	1.47[1.17,1.84]
Test for heterogeneity	chi-square=3.15 df	=3 p=0.37				
Test for overall effect 2	Z=3.33 p=0.00					
			0.01 0.1	1 10	100	
			Favours standard	Favours inte	nsive	

PFMT vs electrical stimulation

Review: Pelvic floor muscle training for urinary incontinence in women Comparison: PFMT versus electrical stimulation



Study	Expt n/N	Ctrl n/N		RR(95'	% CI Fix	(ed)	Weight %	t RR(95% CI Fixed)
Bs 1999	2/25	:1725		7		N.	28.0	2.00[0.19,20.67]
Hahn 1991	:17:10	<i>:11.1</i> 0		<u>.</u>	-		28.0	1.00[0.07,13.87]
Hotbauer 1990	8/11	(1741			-	I —	28.0	6.00[0.86,41.97]
Laycock 1993	2717	(1723					22.1	2.71[0.27,27.46]
Total	11/63	4/69				F	100.0	2.94[0.99,8.67]
Test for heterogeneity (:hi-square=1.27 df	⊧3 p=0.74						
Test for overall effect Z	=1.95 p=0.05							
			0.01	0.1	7	10	100	
			Favours s		, Fav	iours PFN		

PFMT + Electrical Stimulation vs stimulation only.

Review: Pelvic floor muscle training for urinary incontinence in women Comparison: PFMT with electrical stimulation versus electrical stimulation

Outcome: self reported cure post treatment

Study	Expt n/N	Ctrl n/N	RR(95% CI Fixed)	Weight RR(95% CI Fixed) %
Hofbauer 1990	3711	:1711		100.0 3.00[0.37,24.58]
Total	3/11	1/11		100.0 3.00[0.37,24.58]
Test for heterogeneity o Test for overall effect Z:	=1.02 p=0.30	=0 p=		
		0.1 Favo	D1 0.1 1 10 urs stimulation Favours co	, 100 ombination

PFMT + Electrical Stimulation vs PFMT only.

Review: Pelvic floor muscle training for urinary incontinence in women

Comparison: PFMT versus PFMT with electrical stimulation

Outcome: self reported cure post treatment

Study	Expt n/N	Ctrl n/N	RR(95%	Cl Fixed)	Weight RR(95% CI Fixed) %
Hofbauer 1990	8/11	3/11		.	100.0 2.00[0.86,6.04]
Total	6/11	3/11		•	100.0 2.00[0.66,6.04]
Test for heterogeneity Test for overall effect Z		=0 p=			
			1 0.1	1 10	100
		Favou	s combination	Favours PFM	T

PFMT vs anticolinergic medication

Pelvic floor muscle training for urinary incontinence in women

Comparison: PEMT variate modication (anticholingmic)

Review:

Study	Exptin	Expt mean(SD)	Ctrl n	Ctrl mean(SD)	ŴÌ	MD (95% C	I)	Weight WMD (95%Cl) %
Burgio 1998	63	0.40(0.67)	65	0.81(1.40)		+		100.0 -0.41[-0.79,-0.03
Total	63		65			•		100.0 -0.41[-0.79,-0.03
Test for heterogeneity	(chi-square=0.0	10 d≠0 p=						
Test for overall effect	Z=-2.12 p=0.03							
					a je			
				-1[] {	۵	5	10
					Faioux teath	ert F a o	in control	

PFMIT vs PFMIT+ biofeedback

Study	Exptn	Expt mean(SD)	Ctrl n	Ctrl mean(SD)		WMI	D (95%)	CI)	Weigh %	1 WMD (95%CI)
Berghmans 1998	20	0.20(0.51)	20	0.12(0.19)			- 2 - 2		81.5	0.08[-0.16,0.32]
Burns 1993	43	1.14(1.43)	40	0.71(0.86)					18.3	0.43[-0.07,0.93]
Sherman 1997	18	5.25(7.24)	22	2.90(6.53)		i,	-		0.2	2.35[-2.13,6.83]
Total	79		82						100.0	0.15[-0.07,0.36]
Test for heterogeneity c Test for overall effect Z=	영상 이상에 다	5 d⊭2 p=0.29								
					-10	-6	0	5	10	
					Faiot	ıs beatner	it fab	lotico a ic		

Pelvic floor muscle training for urinary incontinence in women

Review:

PFMT vs PFMT with cones

Review:	Pelvic floor muscle training for urinary incontinence in women
Comparison:	PFMT versus PFMT with vaginal cones
Outcome:	self reported cure post treatment

Study	Expt n/N	Ctrl n/N		RR(95'	% CI Fi:	ked)	Weight %	t RR(95% CI Fixed)
Wilson 1998a	22/91	6/14		9			60.1	0.56[0.28,1.14]
Wilson 1998b	107/19	6/14					39.9	1.23[0.59,2.57]
Total	32/110	12/28			•		100.0	0.83[0.50,1.37]
Test for heterogeneity Test for overall effect Z	n an tha tha tha an an ta	=1 p=0.14						
		Fa	0.01 Ivours c	0.1 ombination	t T Fav	10 rours PFN	^{'100} П	



PFMT vs surgery

Pelvic floor muscle training for urinary incontinence in women

Review

Study	Expt n/N	Ctrl n/N		PR/OA(% CI Fix	'nď	Wainh	RR(95% CI Fixed)
Juuy	Evhr inn.	ournm		πησο		.cu) :	weigin %	ninioo w orrived)
Klarskov 1986	3/24	16 / 26					100.0	0.20[0.07,0.61]
Total	3/24	16 / 28		•	,		100.0	0.20[0.07,0.61]
Test for heterogeneity	chi-square=0.00 di	=0 p=						
Test for overall effect Z	≓-2.84 p=0.00							
	na a ay ar		1	1	1	. [- I	
			0.01	0.1		10	100	
			Favour	's surgery:	Fav	ours PFN	Π	

Conclusions of litterature:

- Quided/controlled pelvic floor exercise therapy is effective for urinary incontinence (for all types) and prevention.
- Continued self-exercise is very importat to maintain the good outcome.
- Biofeedback (emg) will help the patient to perform the exercise, it will also inrease the patient compilance and motivation for exercise.

Transversus abdominis exercise

 Evidence for benefit of transversus abdominis training alone or in combination with pelvic floor muscle training to treat female urinary incontinence: A systematic review. K. Bo et al (2009)

 There is insufficient evidence for the use of TrA training instead of or in addition to PFMT for women with UI.

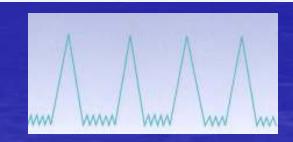
What kind of exercise and How to carry out that??

 To maintain the performance of muscle condition it needs exercise 2 – 3 times a week for each type of muscle exercise.

Strength

Endurance

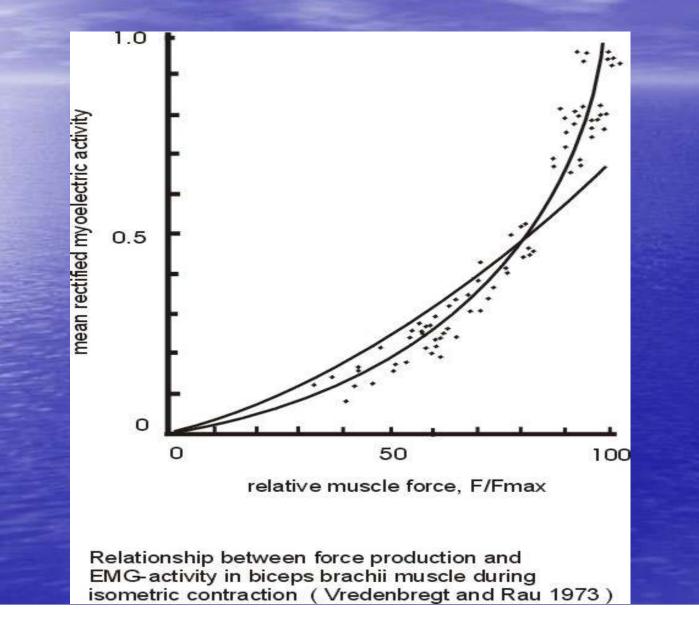
Rapid Stength



EMG-biofeedback -Pelvic Floor Muscle Rehabilitation



EMG - Force relationship



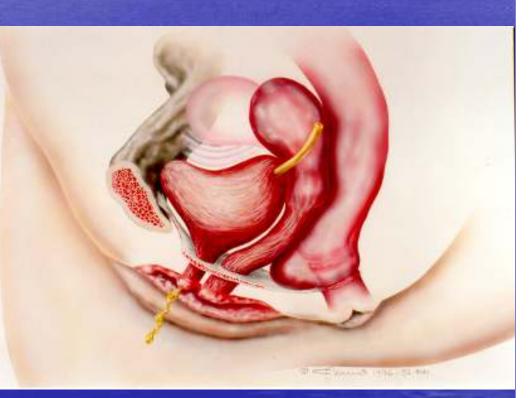
EMG QUIDED BIOFEEDBACK:INDICATIONS

Stress incontinence

Pelvic floor
 rehabilitation

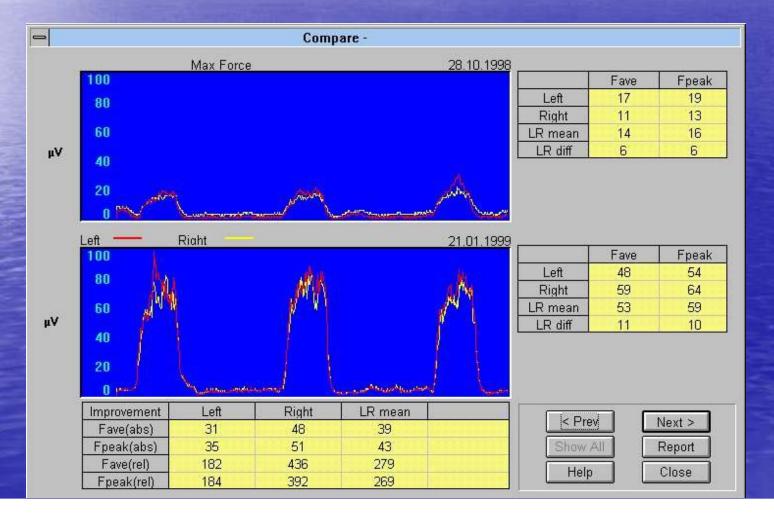
Pelvic pain

Sexual disability



Biofeedback training - Documentation

Complete reports



FemiScan Therapy Outcome - ANATOMICAL RECOVERING

Uterus No more leakage! Bladder Neck is Bladder collapsed Neck is Rectum recovered Leakage Pelvic Flo Muscles are **Pelvic Floor** weakened Muscles are Vagina strengthened Urethra **Before treatment** After 8 to 12 weeks of training

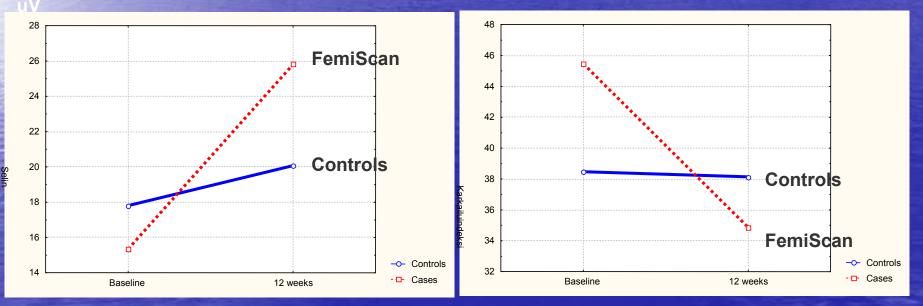
www.femiscan.com

Clinical data

Aukee p, Immonen P, Penttinen J, Laippala P, Airaksinen O, "Increase in Pelvic Floor Muscle Activity After 12 Weeks Training; A randomised prospective pilot study", <u>Urology, 2002, Dec; 60(6)</u>

Mean pelvic floor muscle activity

Leakage index



Changes of pelvic floor muscle activity (uV) measured in supine position

Changes in leakage index among cases and controls

www.femiscan.com

Biofeedback: ANATOMICAL RECOVERING



Treatment begins

After 8 to 12 weeks training

The Treatment Spectrum

Prescription Drugs

Voiding Intervals Eating Habits Lifestyle Changes

Least Aggressive

www.femiscan.com

FemiScan

Surgery

Collagen Injections

Bladder

- Natural method
- No risks, no side effects
- 80% will be cured
- high compliance
- well proven concept

Behavior Modifications Biofeedback Kegel Exercises Pelvic Floor Retraining **Suspensions** TVT/Vesica

Most Aggressive

Mobile Health Gateway - *FemiScan management*



Bluetooth

Mobile measuring

and monitoring

platform

Mobile device collects data directly from training device

Training program can be updated to FemiScan[™] device using mobile device for the best possible incontinence treatment

www.femiscan.com

Measured results are transferred securely from mobile device to clinic using wireless communication

GSM/GPRS

Secure communication

Feedback directly to patient mobile device or by letter

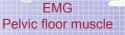


Regular following and changes to patients' treatment to fulfill patients' needs

Analysis

Health Gateway -Kuopio University Hospital incontinence treatment and diabetes treatment





The patient regularly performs her training exercises at home

The mobile phone of the patient collect the data and sent it to the health centre At the clinic, information are made available for the physician/nurse

The patient regularly measures the glucose values at home



The mobile phone of the patient collect the data and sent it to the health centre



Feedback including changes to the treatment or diet or modification of the training program can be immediately sent to the patient Femiscan clinic (=outpatient visits) vs mobile (=controlled by mobile phone) – clinical study.

51 urinary stress incontinent women.
Mean age 49 years
Mean of deliveries 2,1.
Mean length 164 cm, mean weigth 67 kg.
mean of Menopause 49 years.

Health Gateway CASE: Kuopio University Hospital



Mega Electronics Ltd FemiScanTM Incontinence treatment

Communication / Communication



Roche Accu-Chek AVIVA Blood glucose Nokia Series60 smart phone

Mega Electronics Ltd eFemiScan – Incontinence monitoring



EHIT Ltd eGluco – Blood glucose monitoring Measured data is transferred from mobile device to clinic using GPRS connection

patients treatment and changes to patient treatment to fulfil patients needs

Regular following



Data is analysed with Health Gateway clinic platform



Mega Electronics Ltd FemiScan[™] clinic software

> EHIT Ltd eGluco clinic software



Feedback to patient mobile device or by letter

Femiscan clinic vs mobile – clinical study.

Marked improvement in both groups
Disability points
Incontinece Impact Questionaire – II Q72.
Urogenital Distress Inventory – UDI63.
Patients and Doctors Global assessment.

Femiscan clinic vs mobile – clinical study.

78 per cent had benefit of programme.
 no significant differences between the mobile and clinic groups.

the similar results can be reach by mobile phone quided PFMT programmes.

Finnish Clinical Practice Quidelines 2007.

 Quided Pelvic Floor Muscle Exercise is <u>the</u> <u>First line therapy</u> for Urinary Incontinence.

 Every patient suffering from Urinary Incontinence should be treated by PFME/PFMT 3 months before evaluation for Surgery (if needed).



Conclusions

PFMT is effective for stress and mixed urinary incontinence.

 The effectiveness is better to placebo or no treatment.

 PFMT requires continous exercise of strength, endurance and rapid strength

 EMG biofeedback is good way for quidance the PFMT – to increase patient compliance.



