Test report

ALVA

A NEW MEASUREMENT AND TRAINING VIBRATORY DEVICE FOR APPLICATION ON PELVIC FLOOR MUSCULAR TISSUES

INTRODUCTION

Institute of neuromedicine, represented by Prof. Gunnar Leivseth, was asked to test the reliability and clinical applicability of the newly developed ALVA device. The device is developed for use in evaluation and treatment of urinary and fecal incontinence.

BACKGROUND

The prevalence of stress urinary incontinence, especially among postmenopausal women, is estimated to be within 22-42% of the population. Female continence is maintained through the integrated normal function of pelvic floor muscles, fascial structures, nerves, supporting ligaments and the vagina. Different theories, e.g. Shafik's 'common sphincter' concept, Delancey's 'hammock' hypothesis [8] and Petros & Ulmsten's 'integral theory' [19, 21], are used to explain how this integrated system is mandatory for continence. Common to these theories is the important role of normal functioning of pelvic floor tissues.

Continence might be maintained despite defective function in one or more of the structures involved in the continence mechanism through increased efficacy in that unaffected tissue. In some cases therefore, stress incontinence might be the result of failed compensatory effects by the other tissue [8, 21].

During the last 50-60 years there has been an attempt to develop various measuring devices for evaluating the force developed in the pelvic floor in a reproducible and quantitative manner [1, 2, 3, 10]. However, despite these efforts, there is no consensus about how to measure force in pelvic floor muscles. In addition, although training of pelvic floor muscles reduces incontinence, the training is time consuming and the need for additional conservative treatment modalities seems to be needed.

Several clinical studies have shown that a reduction in the force developing capacity of pelvic floor muscles seems to play an important role in developing urinary stress incontinence. Therefore, different conservative treatment protocols have been developed [1, 2, 11]. Common to these methods is to increase force development in pelvic floor muscles. Training normally consists of one to two training sessions each day and the women normally have to perform this training for the rest of their lives. However, as continence improves, training is normally terminated and the women take up they're training as incontinence reoccur.

Recent studies have shown that vibratory stimulation to skeletal muscles might have an immediate and a long-term effect in increasing the force developing capacity, e.g. as the muscle contracts vibration with frequencies between 25-35 Hz is imposed [4, 5, 6, 7, 14, 15, 18]. Acute increase in the magnitude of 40 to 50% has been reported [4, 5]. The mechanism behind this increase in force is suggested to be related to tonic vibratory reflexes (acute effects), an increased efficacy of motor end-plates, better force transmission of the actin-myosin complex and the resulting increase in force transmission through the 'titin' muscle cell membrane system on connective tissues (long term). The duration of vibratory stimuli varies from 30 seconds to one minute and they are normally imposed three times a week.

The main aims of the present study were:

1. To examine the reliability of force measurements of pelvic floor muscles
2. To investigate the acute effect of vibration on pelvic floor muscles on force development
3. To test the Alva apparatus in a clinical setting with respect to handling of the equipment and whether training with vibration had a clinical effect with respect to reducing stress urinary incontinence

MATERIALS AND METHODS

The investigation was performed on two groups:
Group 1: comprised 12 female volunteers recruited from the hospital staff with no history of urine leakage (median age 40 years, median parity 2 and median BMI of 22). Group 2: comprised 7 female volunteers with stress urinary incontinence (SUI) recruited from department of gynecology (median age 40, median parity 2, and median urine leakage of 35 grams).

Both groups underwent a gynecological examination before force measurements and training.

The testing protocol for the two groups was as follows:
<u>Group 1</u> - force measurements and reliability study - i) the sensor was inserted to the vagina guided manually by the gynecologist; ii) all subjects were told to contract the pelvic floor maximally. Each subject performed three contractions and the highest force recorded during the trial was stored for further analysis. During all measurements the cranial movement of the pelvic floor was visually controlled. Active force was considered valid only for contractions with simultaneous observable cranial (inward) movement of the perineum; iii) the subjects were asked to contract the pelvic floor maximally and simultaneously vibration was induced with a frequency of 35Hz and duration of 30 seconds. The highest force recorded during the trial with simultaneous vibration was stored for later analysis.

<u>Group 2</u> – training group – after the gynecological examinations the subject were told how to use the training apparatus (Alva) and were at the same time informed about the training protocol. After inserting the probe into the vagina the subjects were told to contract the pelvic floor muscles maximally, this value is stored. The apparatus will apply vibration to the pelvic floor muscles when the test force is reached by the second contraction. Vibration last for 20 sec and the pause between two successive contractions was 10 sec. Training was performed until the subjects could not reach the test force. The subjects were told to train on a daily basis. If problems occurred, the subjects could contact the responsible gynecologist for support.

<u>Alva test and training device</u>
The force measurement and vibratory device consists of two round halves of ridged material. The two halves have a cavity in which a force sensor is mounted. Two metal sheet double-armed levers are pivotally supported in the cavity. This means that force developed anywhere along the longitudinal axis of the probe are summarized by the

levers and transferred to the force sensor. The force sensor measures the resultant force on a transverse axis and converts this force into an electrical output. The force signal will be independent upon the application of force at the distance of the levers.

In the cavity of the sensor there is also mounted an electrical motor developing vibratory stimuli in the range of 20 to 40 Hz. The device has a cylindrical shape with a diameter of 30 mm. The device is hermetically enclosed in a condom of latex.

STATISTICAL ANALYSIS

The coefficient of variation (CV) was used to calculate the reproducibility of the force measurement. To compare force developed without and with vibratory stimuli the student's t-test for paired observations were applied. Statistical significance was set at $p = 0.05$.

To test the applicability of Alva training device the subjects filled out a questionnaire after the training period of 6 weeks

RESULTS

The coefficient of variation (CV) of repeated measurement was 10%. Figure 1 shows voluntary contraction without and with vibration. As can be seen in the figure there is a major increase in force during vibratory stimulation. Table 1 and Fig. 2 shows the force developed in the pelvic floor, for each subject, without and with vibration. The mean force and (SD) developed in the pelvic floor without vibration was 8.14 (4.38) N. When vibratory stimuli were applied there was a significant ($p < 0.01$) increase in force development. During vibration the mean force and (SD) was 10.53 (5.32) N. These figures show that there is an increase in active force development during vibration in the magnitude of 29.4%.

4 of the seven training subjects reported that their stress urinary incontinence was reduced after the training period. The subjects who did not report any clinical benefit of vibratory training were subjected to failure of the training devices. These failures are possibly related to problems with the on/off button. Some reported that it was difficult to test whether the power supply (batteries) was sufficient. All subject reported that they did not have any problems with the manual following the device, the size of the probe or the design of the registration unit. One of the subjects wanted a longer connecting cable between the registration unit and the probe.

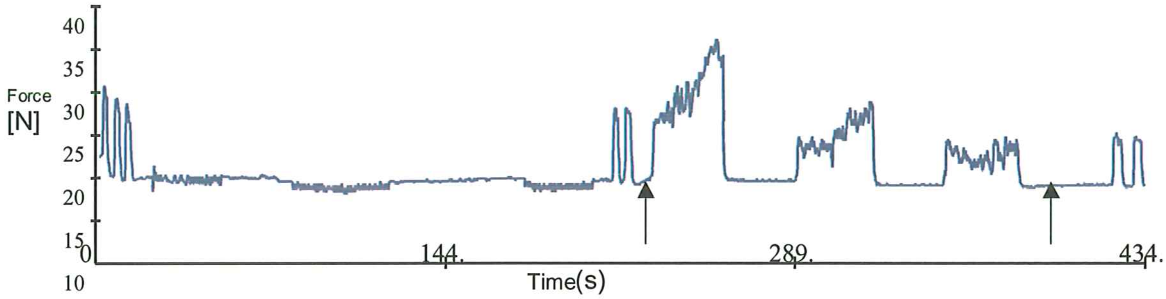

Figure 1: A typical graph showing force increase during vibration. The distance between the arrows shows three voluntary contractions with simultaneous vibration. The curves located to the left of the firs arrow show maximally voluntary contractions without vibration.

Table 1. Mean force (N) and (SD) developed in 12 subjects without and with vibration. Frequency of vibration = 35 Hz.

Subjects	Force (N)	Force (N)+ Vibration 35 Hz
1	7,74	12,39
2	5,41	8,77
3	2,32	4,13
4	17,38	17,94
5	14,27	17,84
6	6,71	6,97
7	2,58	4,65
8	11,10	14,97
9	9,04	17,3
10	7,74	9,29
11	6,45	5,16
12	6,97	6,97
Mean (SD)	**8,14 (4.38)**	**10,53 (5.32)**

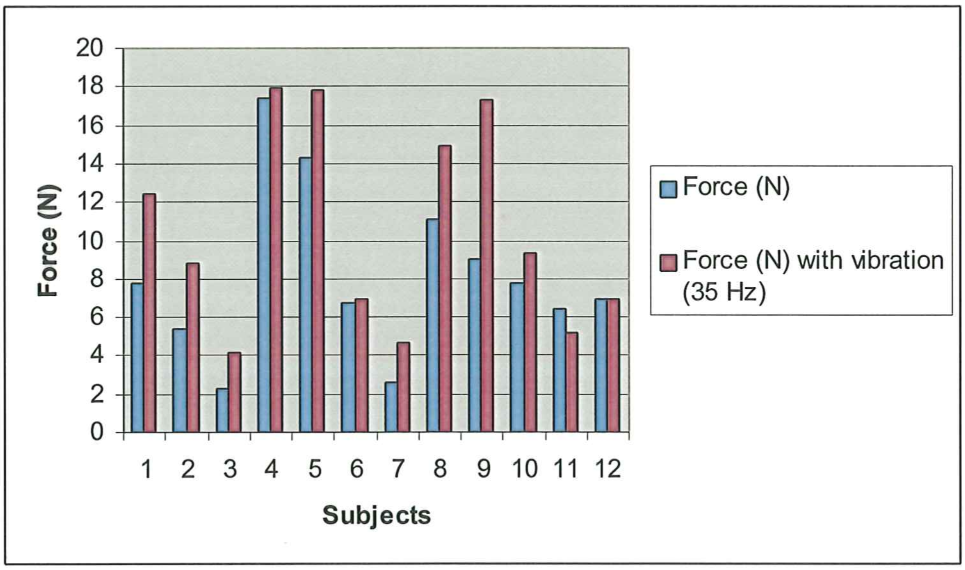

Figure 2: Maximal voluntary forces in each subject without and with vibration. Frequency of vibration = 35 Hz.

DISCUSSION

This study presents a new device that measures the force developed in the pelvic floor muscles. The device measures the sum of radial forces perpendicular to the length axis of the measuring rod. Contractions of the puborectal sling/- pubocoggygeus muscle result in an upward movement of the perineum, together with a squeeze effect inwards to the lumen of the vagina. These forces are detected by the device and expressed in Newton and the force signal is independent upon the application of force at the distance of the levers.

The new force measuring and vibratory device (Alva) gives reliable and valid force measurements (CV 10%). Comparing the new with an established method usually assesses evaluation of a new device. However, to our knowledge there are no other devices available that measure pelvic floor muscle force in Newton, except from one method mentioned in two studies [13, 20]. They use an instrumented speculum with a non-standardized opening to measure pelvic floor muscle strength. They report a 13% minute to minute repeatability and a 27% week to week repeatability.

The increased repeatability using this new method, might result from several factors: i) although the pelvic floor muscles move in relation to the probe, no differences in moment arms occur. This is due to the fact that the force sensor senses the sum of forces delivered from both levers, ii) the subjects were tested with a device diameter of 35 mm. This reduces the variability in force readings due to an optimum force-length relationship of the pelvic floor muscles [22].

Most of the variation is related to the biological variance within the cohort and it is less influenced by measurement errors related to earlier devices. Therefore, it is reasonable to suggest that our new device give more reliable force measurements of pelvic floor muscles.

Recent studies, using a similar device, have shown that the force generating capacity (expressed as $N \times kg\ BW^{-1}$) of the pelvic floor muscles between continent and in-continent women, are significantly different. In the incontinent group there was a mean reduction in force ($N \times kgBW^{-1}$) of 37,5 % compared to the continent group ($p< 0.02$) [22]. This indicates that a reduction in force development of pelvic floor muscles might be one of several factors responsible for stress urinary incontinence.

When two times the coefficient of variation (CV) is used, i.e. 20% (a rather conservative approach), as the minimum detectable level, the observed acute increase in force during vibration is 10% above this limit. Therefore, the observed increase in force during vibration is not due to measurement errors.

Recent studies [4, 5, 6, 7, 14, 15, 18] have shown that vibratory stimulation of striated muscles leads to an increase in force development. Different mechanism might explain the increase in force development induced by vibration. The tonic vibration reflex activates both mono- and polysynaptic muscular afferents which in turn leads to an increased force output of the stimulated muscles via increased activities of the muscle spindles.

Johnston et al [16] showed that it is possible to induce the tonic vibration reflex in all striated muscles. Hagbarth [12] confirmed these findings. Bosco et al [4] investigated the effects of whole body vibration in six female volleyball players at national level. They found a statistically significant ($p < 0.05$) increase in average velocity, average force and average power. They concluded that these increases might be due to enhancements of neural muscular factors. As the athletes were well accustomed to the exercises performed, learning effects were minimized.

Other studies [5], which used international level boxers, showed statistically enhancement of the average power in the arm treated with vibration. The root mean square electromyogram (EMGrms) had not changed following treatment but, when divided by mechanical power, as an index of neural efficiency, a statistically significant increase was shown. They concluded that mechanical vibrations enhanced muscular power and decreased the related EMG/Power relationship in elite athletes. Moreover, the analysis of EMGrms recorded before the treatment and during the treatment itself showed an enormous increase in neural activity during vibration up to more than twice the baseline values. This would indicate that this type of treatment is able to stimulate the neuromuscular system more than other treatments used to improve neuromuscular properties.

Insurin et al [14, 15] showed that long term training with simultaneous vibration stimuli's increased the maximum developed force by 49.8% compared to an increase of 16% by conventional training. In addition, other studies have shown that training with vibration leads to increase in: i) testosterone and somatotropin (growth hormone) [7], ii) increase in muscle blood flow [17].

None of the women reported any discomfort during vibration. The majority reported that it was easier to contract the pelvic floor muscles. Three women reported that contractions were more difficult to perform. All of the women said that they would have no problem in using such a device for the treatment of pelvic floor muscles. However, they suggested it would be more convenient to use such a device in a private atmosphere.

Our training period lasted 6 weeks. Normally subject train for 3 months. 4 out of 7 subjects reported less urinary incontinence after training with the Alva device, e.g. an effect of approximately 60 %. This implies that the reported effect of training are reached after 50% less training time compared to other studies. It is possible that the training effect might have been better if device failures have not occurred. In addition, the study is a "worse case scenario", i.e. the subjects were told how to train only once. This is not comparable to other training studies in which subjects are attaining training groups and becomes information and training advices two to three times a week. We therefore suggest that the effects reported here could have been better if we have followed similar training protocols; however, this was not the intention. We suggest that it is more applicable for subjects to train when hey have time without interfering with other activities of daily living. As suggested by the participants, the subjective effects, i.e. less urinary leakage, occurred relatively quickly (within 2 to 3 weeks).

Conclusions

The new measurement and vibratory device give reliable and valid force measurement. The acute increase in force, observed under simultaneous vibration, is not a result of measurement errors. The observed increase in force seems to depend on increased neuronal drive to the stimulated muscles. Subjects report a qualitative reduction in stress urinary incontinence. The device is evaluated as a promising tool in evaluating and treating persons with stress urinary incontinence.

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References

1. Bø K. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. Neurol Urodyn 9: 479-487, 1990.

2. Bø K. Vaginal weight cones. Theoretical framework, effect on pelvic floor muscle strength and female stress urinary incontinence. Acta Obstet Gynecol Scand 74: 87-92, 1995.

3. Bø K. Vaginal palpation of pelvic floor muscle strength: inter-test reproducibility and comparison between palpation and vaginal squeeze pressure. Acta Obstet Gynecol Scand 80: 883-887, 2001.

4. Bosco C, Cardinale M, Tsarpela O, Colli R, Tihany J et al. The influence of whole body vibration on jumping performance. Biology of Sport 15 (3): 157-64, 1999.

5. Bosco C, Cardinale M, Tsarpela O, Colli R, Tihany J et al. Influence of vibration on mechanical power and electromyographic activity in human arm flexors. Eur J Appl Physiol 79: 306-11, 1999.

6. Bosco C, Colli R, Introini E ,Tsarpela O, Madella A , Tihany J, Viru A., et al. Adaptive responses of human skeletal muscle to vibration exposure. Clin Physiol 19 (2): 183-87, 1999.

7. Bosco C, Iacovelli M, , Tsarpela O, Cardinale M , Bonifazi M, Tihany J, Viru A, De Lorenzo, Viru A. Hormonal responses to whole body vibration in men. Eur J Appl Physiol 81: 449-54, 2000.

8. DeLancey JOL. The structural support of the urethra as it relates to stress urinary incontinence: the Hammock hyputhesis. Am J Obstet Gynecol 170: 1713-23, 1994.

9. Enoka RM. Neuromechanical basis of kinesiology. Tonic vibration reflex. Human Kinetics, USA, 1994.

10. Glazer HI, Romanzi L, Polanczky M. Pelvic floor muscle surface electromyography. Reliability and clinical predictive validity. J Reprod Med 44 (9): 779-82, 1999.

11. Hay-Smith EJ, Herbison P, Morkved S. Physical therapies for prevention of incontinence in adults. Cochrane protocol, Update Software, Oxfors, 2001.

12. Hagbarth K. Evaluation Methods to Change in Muscle Tone. Scand J Rehab Med, Suppl 30: 19-32, 1994.

13. Howard D, DeLancey JOL, Tynn R, Ashton-Miller JA. Racial differences in structure and function of the stress urinary continence mechanism. Obstet Gynecol 95(5): 713-7, 2000.

14. Issurin VB, Liebermann DG, Tenenbaum G. Effect of vibratory stimulation training on maximal force and flexibility. J Sport Sci 12: 561-66, 1994.

15. Issurin VB, Tenenbaum G. Acute and residual effects of vibratory stimulation on explosive strength in elite and amateur athletes. J Sport Sci 17: 177-82, 1999.

16. Johnston RM, Bishop B, Coffey H. Mechanical Vibration of Skeletal Muscles. Phys Ther 50 (4): 499-505, 1970.

17. Kerschan-Schindl K, Grampp S, Henk C, Resch H et al. Whole-body vibration leads to alterations in muscle blood volume. Clin Physiol 21 (3): 377-82, 2001.

18. Liebermann DG, Issurin V. Effort perception during isotonic muscle contractions with superimposed mechanical vibratory stimulation. J Human Movement Studies 32: 171-86, 1997.

19. Petros PP, Ulmsten U. An integral theory of female incontinence. Acta Obstet Gynecol Scand (Suppl 153), 1990.

20. Sampselle CM, Miller JM, Mims BL, DeLancey JO, Ashton-Miller JA, Antonakos CL. Effect of pelvic muscle exercise on transient incontinence during pregnancy and after birth. Obstet Gynecol 91(3): 406-12, 1998.

21. Ulmsten U. Some reflections and hypotheses on the pathophysiology of female urinary incontinence. Acta Obstet Gynecol Scand (Suppl 166) 76: 3-8, 1997.

22. Verelst M, Leivseth G. A new method for diagnosing and testing of the pelvic floor musculature. 2002, in preparation.