Technology for determining constitutive biomechanical parameters of soft tissues - OMNITON

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Dear colleagues

- To begin with, the French adage – Savoir c'est prevoir – means to foresee.

Problem

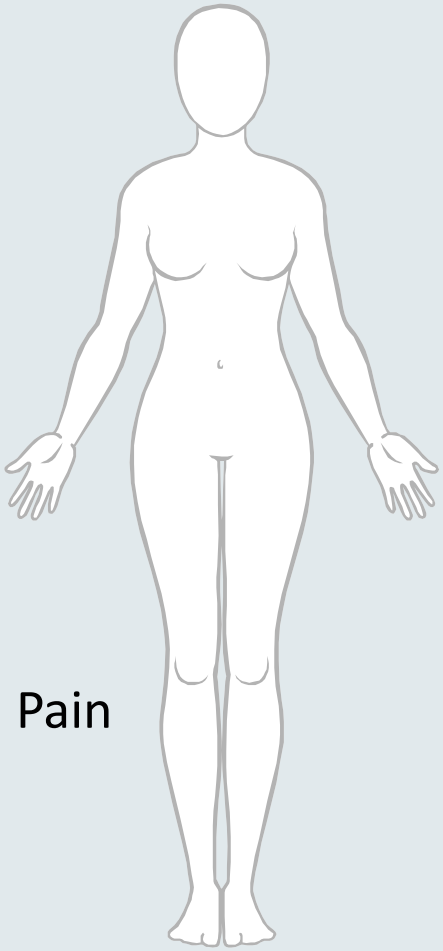
- For the treatment of diseases, new hospitals are built annually, and new doctors and medical personnel are recruited. This process is on a growing trend but does not reduce the burden on doctors. Disease prevention and evaluation of the effectiveness of treatment are second-rate.
- Modern clinical practice in assessing the condition of soft tissues is limited to subjective visual observation and manual palpation only (Hattam, P., Smeatham, A. (2020) Handbook of Special Tests in Musculoskeletal Examination E-Book: An evidence-based guide for clinicians. Elsevier Health Sciences). Such diagnostic information does not allow for evidence-based and early recognition of the disease or a reliable assessment of the effectiveness of treatment.

Palpation is the oldest, but not the best

Problem

- However, the introduction of novel practice in evidence-based medicine is difficult. It is not limited to the invention of new methods and equipment. The main difficulty lies in the interpretation of novel information by doctors (including the use of new parameters and terms) both in formulating the diagnosis and in monitoring the development of the patient's condition and rehabilitation.

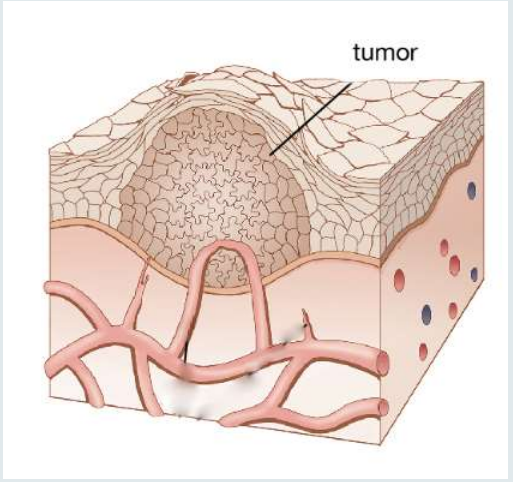
Where SOFT TISSUE monitoring is needed?



Pain

Rheumatology

Cancer



Dermatology

Why are these results important?

There is an unmet need to monitor the conditions in which physiological processes occur soft tissues under various physical loads and diseases.

The transition from treating diseases to preventing them becomes possible when there is a technology that assesses how healthy a person is who has no complaints about their health.

There is no certified, non-invasive and real-time technology for making assessments of the health status of both the organ and the organism. Biomechanical parameters of soft tissues can serve as additional criteria for an objective assessment of the conditions in which these processes occur in real time.

MyotonPRO
Digital Palpation

USER MANUAL

in compliance with Device Firmware v.10C
and Desktop Software v 5.0.0.177

For research Use Only

Not for Use in Clinical, Diagnostic or Therapeutic Procedures

Revision no. 16
19th May 2016

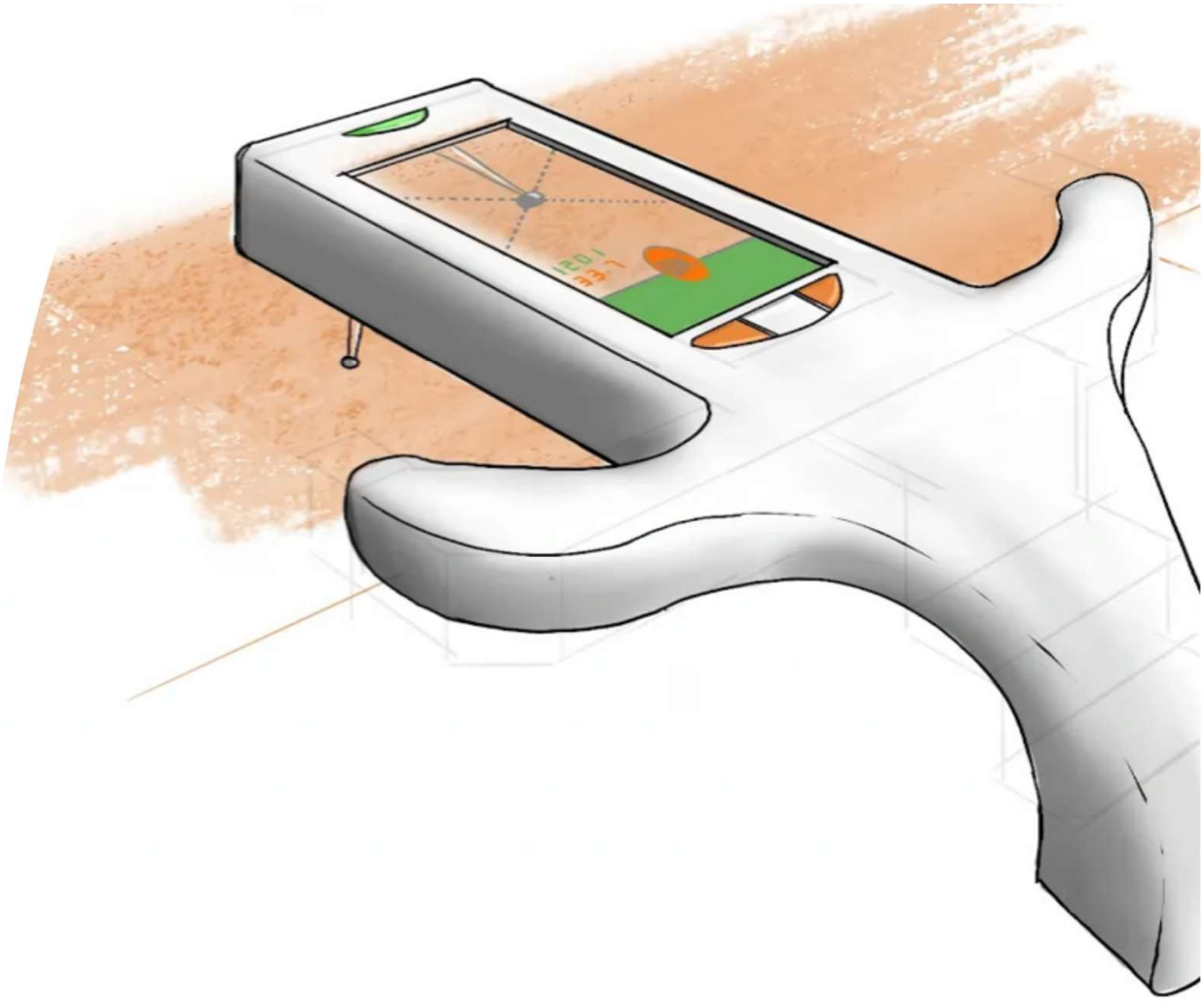
MYOTON AS, Lootsa 8A, Tallinn 11415, ESTONIA
www.myoton.com; contact@myoton.com

Why are these results important?

In medicine, every additional reliable and evidence-based information is important for more effective diagnosis. Biomechanical parameters of soft tissues can provide additional valuable diagnostic information. More than 400 scientific articles can be found in the literature about the studies conducted with devices that preceded Omniton, where a positive assessment of the technology is given, as well as recommendations for its further development.

The most important results of the project

- Omniton – a portable, handheld medical device for noninvasive determine of biomechanical parameters of soft biological tissues. Knowing your health is half the treatment.



Publications

Market area	Number of publications
Basic science/R&D	98
Product assessment	74
Rehabilitation	79
Sport medicine	55
Neurology	31
Dermatology	14
Dentistry clinics	12
Occupational health	12
Orthopaedics	10
Rheumatology	2
Oncology	5
Space medicine	2
Veterinary	2
Total	**396**

Chen, F., Dellalana, L. E.; Gandelman, J. S., Vain, A., Jagasia, M. H., Tkaczyk, E. R. (2019). Non-invasive measurement of sclerosis in cutaneous cGVHD patients with the handheld device Myoton: a cross-sectional study. Bone Marrow Transplantation, 54 (4), 616−619.10.1038/s41409-018- 0346-7.

We demonstrated MyotonPRO's ability to differentiate sclerotic chronic graft-versus-host disease patients from post-stem cell transplant controls. We used stepwise variable selection on multivariable logistic regression models, as well as 2 machine learning algorithms, LASSO regression and random forest, to select the optimal biomechanical parameters for assessing sclerotic chronic graft-versus-host disease. Our models identified frequency and relaxation time to have higher discriminative ability than the previously published stiffness parameter. Additionally, measuring a clinically convenient subset of anatomic sites accessible in the supine position maintained diagnostic accuracy. The expedient supine-only measurement protocol eliminates the potentially uncomfortable process of turning from supine to prone described in our previously published full-body protocol.

For clinical implementation, MyotonPRO measurements in sclerotic chronic graft-versus-host disease still require further validation with prospective longitudinal study and associated clinical disease course.

Yapeng, L., Jiafeng Y., Zhang, J., Zhang, Z., Wang X. (2022) Quantifying the stiffness of lumbar erector spinae during different positions among participants with chronic low back pain. Journal:PLOS ONE - June 2022, 17(6):e0270286 (DOI: 10.1371/journal.pone.0270286).

In the current study, we indicated that the MyotonPRO device has excellent intra- and inter-rater reliabilities in quantifying the stiffness of the lumbar erector spinae muscles in patients with chronic low back pain. Meanwhile, the erector spinae stiffness on the painful sides was higher with a marked increase in sitting when compared with the non-painful side.

Hence, the MyotonPRO can be used in clinical assessment and research in patients with chronic low back pain, although there was no significant correlation between the lumbar erector spinae muscle stiffness and pain intensity.

Yeo, SM, Kang H, An S, Cheong I, Kim Y, Hwang JH. (2020) Mechanical properties of muscles around the shoulder in breast cancer patients: Intra-rater and inter-rater reliability of the MyotonPRO. PM R.;12(4):374–381. doi:10.1002/pmrj.12227.

The results of our study showed significant correlations between the biomechanical properties of biceps brachii tissues measured in the impaired limb and the lymphedema occurred in women with brest-cancer-related lymphedema. These correlations may suggest that myotonometry can be used in brest-cancer-related lymphedema detection. Measurements of the viscoelastic properties of the central part of the biceps brachii of impaired and unimpaired limbs can provide useful information concerning lymphedema.

Moreover, it is possible that myotonometry can be useful for the evaluation of lymphedema development and treatment efficacy of brest-cancer-related lymphedema; however, future studies are needed.

Chuang, L-L, Wu C-Y, Lin K-C. (2012) Reliability, validity, and responsiveness of myotonometric measurement of muscle tone, elasticity, and stiffness in patients with stroke. Arch Phys Med Rehabil; 93:532-40.

Findings from this study indicate that the Myoton-3 myometer can be applied as a reliable, valid, and responsive device for objectively quantifying muscle tone, elasticity, and stiffness of resting forearm muscles in patients with stroke. Mechanical characterization of the skeletal muscle measured by the Myoton-3 myometer may provide new insights into muscle functions to diagnose and treat muscle pathophysiology.

Thus, performance documented by the Myoton-3 might be a useful indicator of biomechanical tissue changes in clinical practice and research. Further research is needed to study the clinical utility of the instrument based on a larger sample.

Toomla, T., Vain, A. (2018) Diagnostical informativity of the myometrical method in the medical research of occupational health care. *J.Clin.Exp Med.Res., DOI 10.21272/jcemr:6(2):268–277.*

The sample was sufficient to determine the reference values of the muscles examined for the population. Statistical relationships between persons' age, arterial blood pressure, body mass index and muscle parameters were determined.

The research provided at the level of health risk, diagnosis of an occupational physical overload diseases and arterial blood pressure are related to myometrical parameters.

Baker L. X., Chen F., Cronin A., Chen H., Vain A., Jagasia M. and Tkaczyk E., R. (2021) Optimal Biomechanical Parameters for Measuring Sclerotic Chronic Graft-Versus-Host Disease: JID Innovations;1:100037 doi:10.1016/j.xjidi.

To determine which biomechanical parameter(s) can accurately differentiate patients with sclerotic chronic graft-versus-host disease from post hematopoietic cell transplant controls, 15 patients with sclerotic chronic graft-versus-host disease and 11 post hematopoietic cell transplant controls were measured with the myotonometer on 18 anatomic sites. Logistic regression and two machine learning algorithms (least absolute shrinkage and selection operator regression and random forest) were developed to classify subjects. In univariable analysis, frequency had the highest overfit-corrected area under the curve (0.91). Backward stepwise selection and random forest machine learning identified frequency and relaxation time as the optimal parameters for differentiating patients with sclerotic chronic graft-versus-host disease from post hematopoietic cell transplant controls. Least absolute shrinkage and selection operator regression selected the combination of frequency and relaxation time (over fit corrected area under the curve ¼ 0.87). Discriminatory ability was maintained when only the sites accessible while the patient is supine (12 sites) were used.

We report the distribution of values for these highly discriminative biomechanical parameters, which could inform the assessment of disease severity in future quantitative biomechanical studies of sclerotic chronic graft-versus-host disease.

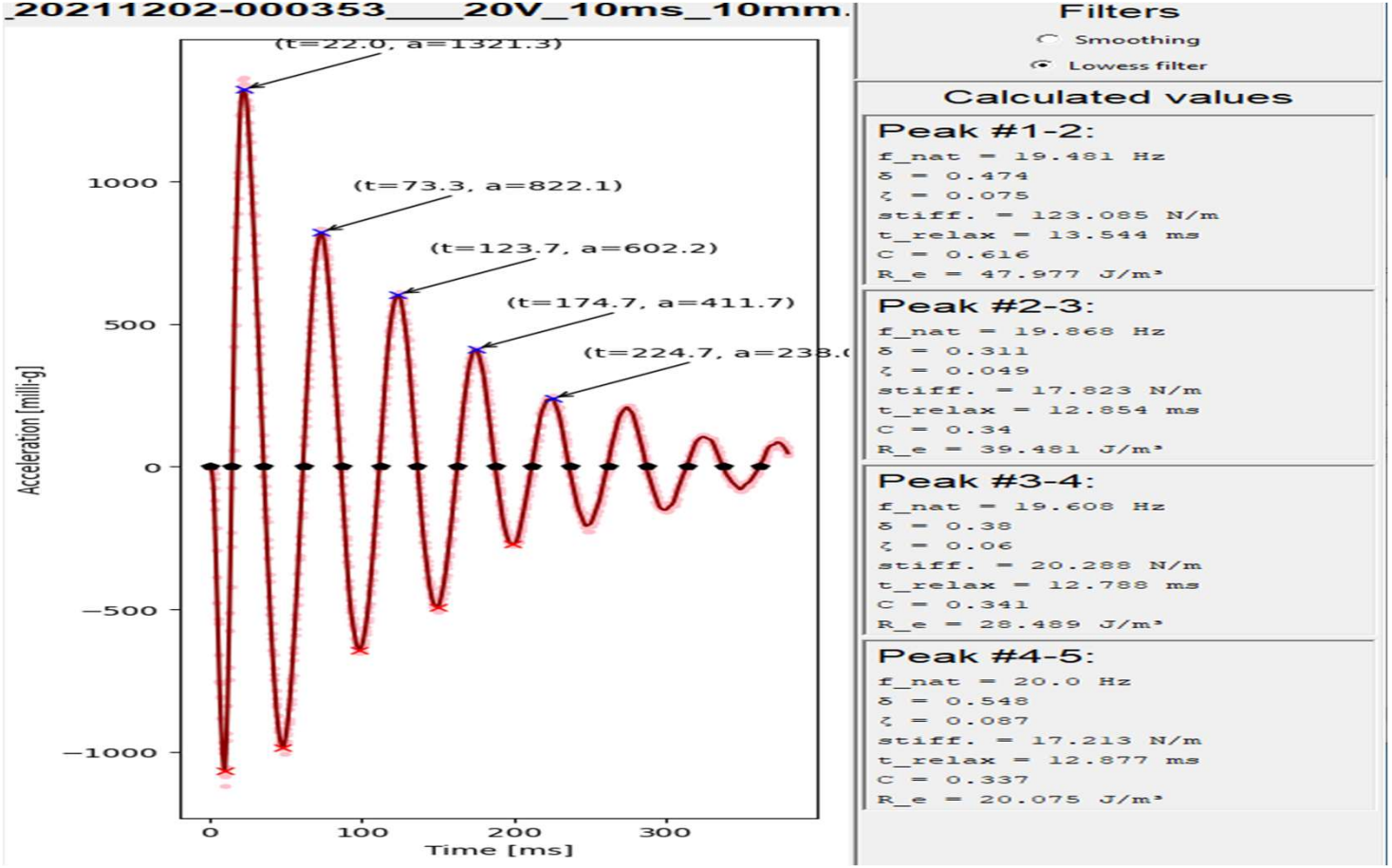
New method for clinics

- Soft tissue as a material with elastic-viscous properties is subjected to a single mechanical impact by the testing ends of the device with a dosed pulse lasting a few milliseconds and is followed by rapid release.
- Soft tissue responds to this with an extinguishing free oscillation, capturing all layers of soft tissue during the first period of oscillation. The shock wave travels at a soft tissue velocity of 20 m/s on average, depending on the elasticity of the tissue. The signal from the acceleration sensor attached to the testing end shall be recorded.
- In the second period of oscillation, the lower layers no longer oscillate due to the dispersion of mechanical elasticity energy. In subsequent periods of oscillation, only the skin and subcutaneous layers are involved in the oscillation. If the oscillation lasts, then only the skin, which is characterized by a constant oscillation frequency.

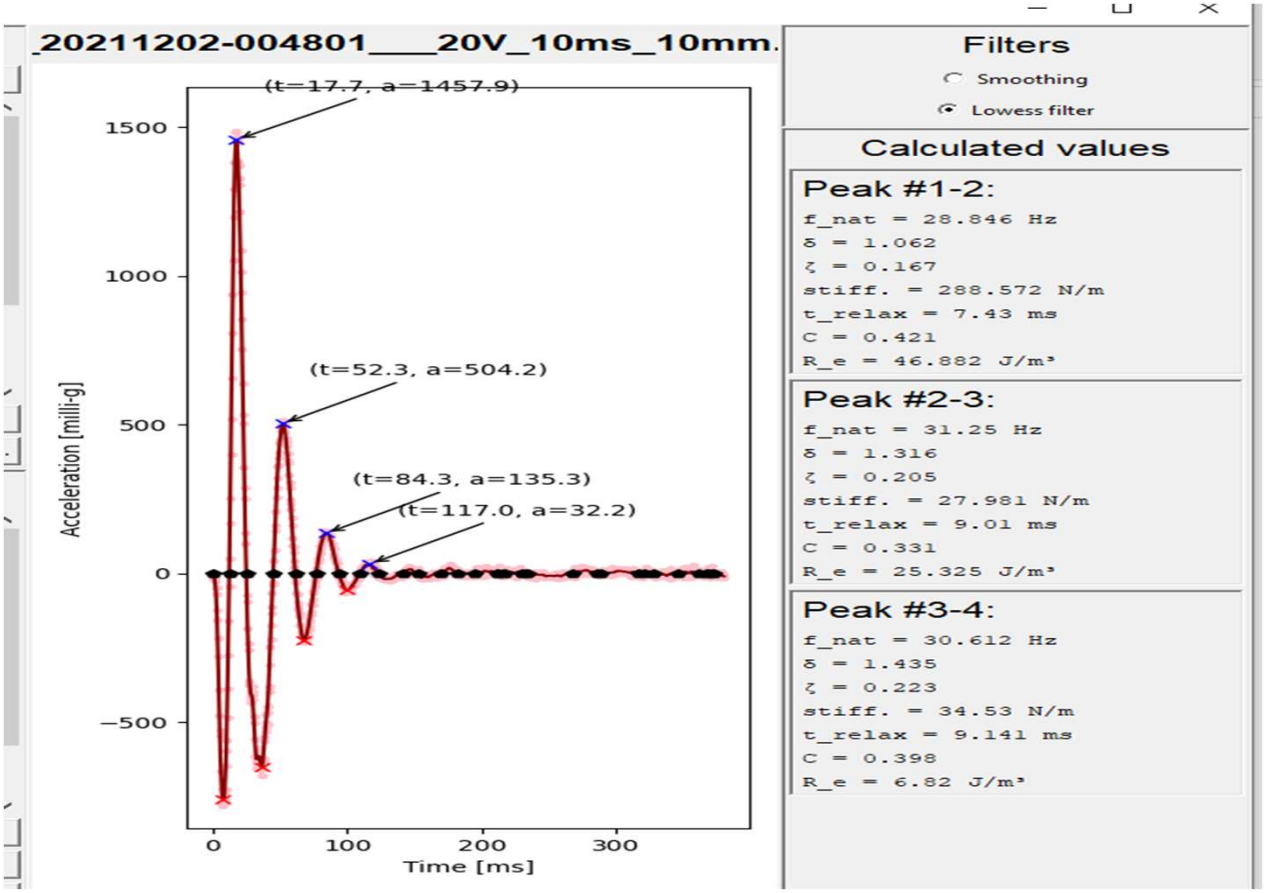
New method for clinics

- From the resulting acceleration characteristic, biomechanical parameters are determined in different layers of soft tissue: free-oscillation frequency Hz (a state of mechanical stress that cannot be reduced by will - tone), logarithmic decrement of free oscillation - the ability to dissipate mechanical energy, creepiness–Deborah number - characterizes the slowdown of deformation of the energized biomaterial, the relaxation time of mechanical stress, stiffness - resistance to shape-changing force N/m and coefficient of resilience characterizes the maximum energy that can be absorbed per unit volume without creating a permanent deformation J/m^3.

Omniton analyses a test-body



Omniton analyses skeletal muscle



The most important results of the project

- For the prevention of disease, it is important to know soft tissues the conditions in which the processes of vital activity take place, which make it possible to predict in time even minor changes caused by pathological processes. Early detection of symptoms of illness is key for timely diagnosis and successful treatment. The human body is a whole, and the symptoms of the onset of the disease can be expressed in the form of, for example, changes in the state (tone) of skeletal muscles or skin, as well as in biomechanical and viscoelastic properties.

The most important results of the project

- Non INVASIVE!
- Less expensive than MRI*, ultrasound, MyotonPro etc.)
- Objective results!
- Digital camera,
- Easy to use
- Real time digital measurements

THANKS