Acta of Bioengineering and Biomechanics
Vol. 16, No. 1, 2014

Original paper
DOI: 10.5277/abb140115

A new medical device to measure a stiffness of soft materials

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An objective in vivo measurement technique for assessing the material properties of soft tissue would be a valuabe tool in diagnosing dermatological pathologies. In order to make advancements in this field, a new hand-held device was designed to measure the stiffness of soft materials. The device measures the reaction forces experienced by the soft tissue under constant indentation deformations at the time of stiffness measurement. Agarose gel samples were prepared in a range of molarities to mimic the stiffness variabilities found in vivo. The stiffness of each gel was evaluated using two different measurement techniques. The first method utilized an industry standard durometer, designed to measure the hardness of materials in shore type 00 scales of soft plastics. The second measurement was taken using an original custom-built soft tissue stiffness meter, designed specifically for the present study. These two devices were compared and a strong correlation was found between them (r^2 = 1.00, Spearman rank test). Additionally, it was observed that gels of different stiffness could be distinguished by both devices. In conclusion, the soft tissue stiffness can be accurately evaluated using the proposed device. The new device should be evaluated on human subjects in future studies, before it can be used to assess soft tissue disorders.

Key words: *soft tissue, dermatologic disorder, stiffness, biomechanics, durometer, biomedical engineering*

1. Introduction

Soft tissue stiffness is traditionally evaluated by the subjective method of manual palpation in clinical practices [1]. There are two different palpation techniques [2]. The first stiffness diagnostic method requires a physician to push a finger tip into the tissue until a certain amount of displacement is observed. The clinician then attempts to gauge the reaction force response of the tissue [2]. The second method of tissue stiffness evaluation also requires the physician to use a finger to push the tissue with a certain level of force. The physician then attempts to feel and measure the resulting displacement in the tissue surface [2]. While these two methods are the most commonly used, they are not completely reliable because they are subjective to human interpretation and are therefore not repeatable. In response to this problem, several devices have been developed to objectively quantify tissue tones, allowing researchers to study the effectiveness of clinical tissue therapies. Until then, many benifical soft tissue treatments are being witheld from routine clinical practice. It is believed that if a quantitative method of measuring tissue consistency were available, the clinical care of patients with spasticity, lymphedema and neck–shoulder problems would be more definitive [1].

Fischer [3] was the first researcher to devise a tissue compliance meter to quantify the palpation of tissue consistency and to document the results in an objective manner [3]. He suggested that the tissue compliance meter could be used to document the changes in soft tissue consistency which occur during muscle spasm, spasticity, swelling, tumors, hematomas, etc. Tanaka et al. [4] mentioned that prostatic carcinoma and hypertrophy are generally examined, by rectal palpation, using a doctor's index finger as

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Received: May 8th, 2013
Accepted for publication: August 5th, 2013

a probe and together, in most cases, with the use of the ultrasonic tomography. However, the palpation depends on the tactile perception of the forefinger, which is said to be ambiguous, subjective and much affected by the physician's experience [4]. Those situations have drawn interest in the development of objective instrumentation that measure and evaluate the stiffness and flexiblity of soft materials [5]. All of the techniques that have been developed thus far are complex and are generally used in surgical situations rather than the physicians in diagnosing the soft tissue disorders in dermatology clinics.

The objective of this study was to design a new soft tissue stiffness meter (STSM) and examine its feasibility on artificial agarose gels which are similar to human soft tissues. The quantitative analysis of soft tissue stiffness is important because it allows a physician to diagnose many dermatological disorders such as morfea, Hodgkin and non-Hodgkin lymphoma in dermatology clinics.

2. Materials and methods

2.1. Device design

The STSM was a compact device that could measure the resistance force (N) of soft materials subjected to deformations. Figure 1 shows the components of the STSM device. The STSM is composed of two main parts, one designed for application, and the other designed for measurement acquisition. The application component used an indentation rod (a) (diameter 1.50 mm) to reach the sample surface and served as a link between the sample and the measurement component of the STSM. The measurement piece is composed of a handle (b) (length 80 mm, diameter 40 mm) which contains the force transducer (h) (TML Loadcell, CLS-50NA, Japan) and electronic circuits within its cavity (i). The indentation rod length can be altered to better accomodate the specific measurement field. The shape of the indentation rod's tip was chosen to be a semisphere (diameter 3 mm) in order to minimize damaged inflicted on the test tissue. The indentation rod consisted of an external ring (c) (outer diameter 19 mm, inner diameter 17 mm), a spring (d), and a deformation control stopper (e). The position of the deformation control stopper can be fixed on the rod with two screws (f). This allows the user to customize the amount of deformation to the sample stiffness range by simply changing the stopper position on the rod. The position of the stopper, however, had to be determined to accomadate the sample stiffness range prior to performing the test. The stopper consisted of two switches (g) to ensure safety while taking the measurements, because the results were dependent on the deformation amount. Those two switches were positioned at different height levels in an attempt to maintain an intermediate deformation value, so the force value

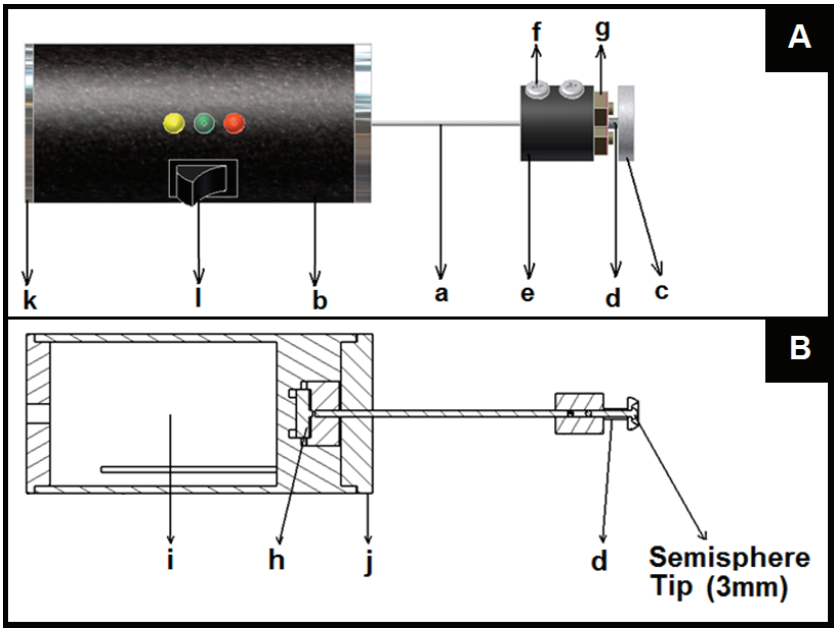

Fig. 1. Solid model of the soft tissue stiffness meter (STSM). The parts of the device are labelled as: solid model (A) and a crossectional view (B) of the STSM. An indentation rod (a), a handle (b), an external ring (c), a spring (d), a deformation control stopper (e), screws (f), switches (g), force transducer (h), cavity (i), a front lid (j), a back lid (k) and a power button (l)

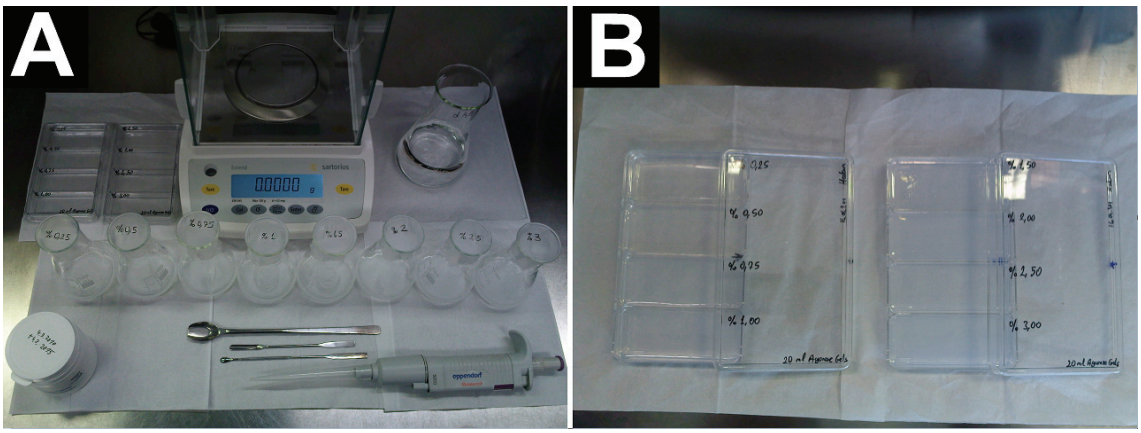

Fig. 2. Sample preparation. All samples were carefully prepared in the laboratory condition (A), and samples were poured in 4 wells rectangular Petri dishes (B)

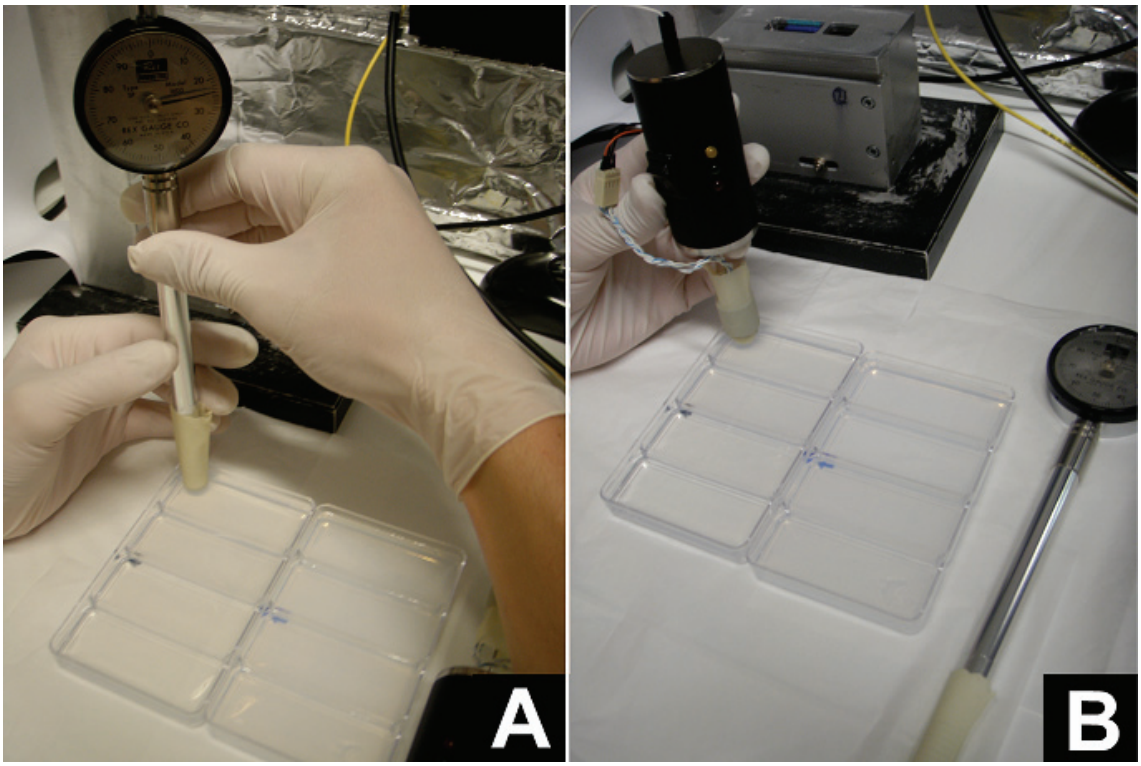

Fig. 3. Applications of both devices on agarose gels.
It is noticed that the durometer should be used vertically with 2 hands (A), and the STSM can be applied on a sample much easier with one hand (B)

was recorded under a constant deformation. There were 3 LEDs on the STSM to provide information feedback to the physician recording the measurement. The yellow LED indicated if the device had power, the green LED flashed when the device was at the correct deformation level, and the red LED indicated when the deformation recommendation was exceeded. To properly use the STSM device, a physician should only record data while the green LED is on.

2.2. Sample preparation

The primary objective of the device design was to measure the stiffness of soft materials with both accuracy and precision. Eight agarose gel samples with different concentrations (molarities) were prepared to mimic different soft tissue stiffness scales. The agarose gel samples were carefully prepared at 0.25%,

0.50%, 0.75%, 1.00%, 1.50%, 2.00%, 2.50%, 3.00% molarity concentrations (Fig. 2A). The liquid gel mixtures were poured into 20 ml Petri dishes to solidify (Fig. 2B). The stiffest sample was 3.00% and the thicknesses all exceeded 6.50 mm, which was enough for the stiffness measurement in shore type 00 [6].

2.3. Study design

The stiffness measurements obtained using the STSM were compared with data collected using the durometer (REX Gauge Company, Inc., Shore Type 00, USA) to validate the accuracy and precision of the STSM. Agarose gel samples were prepared to mimic human soft tissue, and tissue measurements for each gel sample were repeated in sixteen different locations. The STSM measurements were acquired using a force transducer, and the measured values were carried by a data acquisition pad (National Instruments, NI-USB 6008 DAQPad, USA). A Labview Software program (National Instruments, Labview^{TM} 2009, USA) was used for creating an interface for the STSM. The durometer served as an alternative method for soft tissue stiffness measurement acquisitions. The device had to be oriented vertically while operating because it cuses gravity to obtain the measurements. This detail is important when considering the device's versatility, and suggests that the durometer may not be a convenient device for soft tissue assessments. Altering the device orientation to accomadate the patient is undoubtedly preferred to repositiong the patient to accomadate the device. Figure 3 depicts the STSM and durometer devices during experimental data acquisition.

2.4. Statistical analysis

The statistical analysis was carried out using Sigma Plot, Version 11.0 for Windows (Systat Software Inc., San Jose, CA, USA). The acquired data included mean ± standard deviation (SD). A Spearman rank test was used to evaluate a correlation between the two different measurement techniques and a Mann–Whitney rank sum test was employed to compare differences between the agarose gels. A value of $p < 0.01$ was considered statistically significant.

3. Results

Two experimental measurement sets were acquired, for which 8 pairs of agarose gel samples with varying stiffnesses were prepared. Each gel was measured 16 times using the durometer technique, while the STSM was able to perform dynamic measurements in a specified frequency, so the measurements of the STSM were acquired at 0.10 kHz. A graph in Fig. 4 shows the data distribution acquired using the STSM measurement method. As can be seen on the graph, a zero level represents the noise of the technique and 8 agarose gels in different scales can be distinguished easily.

The average values for each of the gel measurements were used for the statistical calculations and to plot graphs. Table 1 shows the data distribution of all the stiffness measurements. As you can see in Table 1, the agarose gels in 0.25% and 0.50% could not be measured with durometer, because the stiffness of these gels was too soft and would not allow for any permanent surface deformation, which is essential to

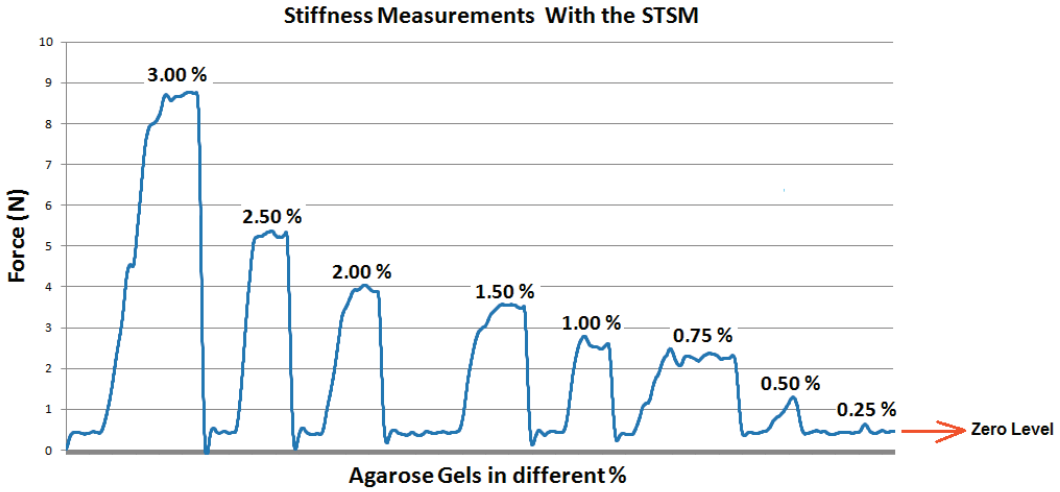

Fig. 4. Data distribution of the STSM

Table 1. Data distribution of all measurements

Samples		Experimental methods			
		Durometer (shore type 00)		STSM (N)	
		n	Mean ± SD	*n*	Mean ± SD
Agarose gels in different stiffness scale	0.25	16	–	100	0.11 ± 0.065**
	0.50	16	–	100	0.74 ± 0.105**
	0.75	16	23.25 ± 2.14	100	1.92 ± 0.019**
	1.00	16	27.25 ± 2.72*	100	2.10 ± 0.027**
	1.50	16	44.69 ± 5.31*	100	3.11 ± 0.022**
	2.00	16	55.31 ± 4.92*	100	3.56 ± 0.043**
	2.50	16	62.44 ± 2.94*	100	4.80 ± 0.036**
	3.00	16	64.19 ± 2.94^{N}	100	8.27 ± 0.038**

n: number of measurement; SD: standard deviation, STSM: soft tissue stiffness meter; N: Newton.

*: There is a statistical significant difference between each agarose gel with a one step softer one in measurements with the durometer (P = <0.001).

^{N}: There is not any statistical significant difference between the one step softer one in the measurement with the durometer (P = 0.122).

**: There is a statistical significant difference between each agarose gel with a one step softer one in measurements with the STSM (P = <0.001).

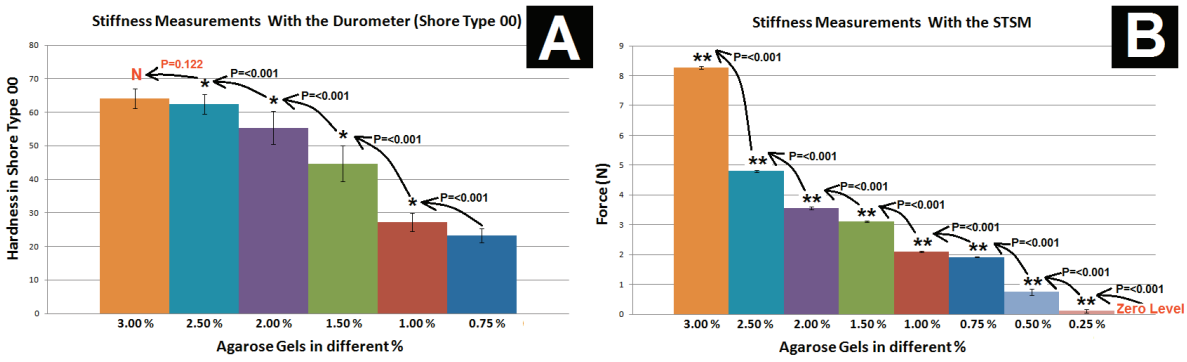

Fig. 5. Comparative results of the study. Each agarose gel in different stiffness scale could be distinguished in measurements of both techniques, durometer (shore type 00) (A) and STSM (B).
N: There was not any statistical significant difference between the 3.00 % and the 2.50 % stiffness scales in measurements of durometer method (P = 0.122).
*: There was a statistical significant difference between each agarose gel with a one step softer one in measurements of durometer method (P = <0.001).
**: There was a statistical significant difference between each agarose gel with a one step softer one in measurements of STSM method (P = <0.001).
Comparisons were performed with respect to one scale softer one for each stiffness scale (according to the Mann–Whitney rank sum test)
The Mann–Whitney rank sum test was performed in statistical calculations

the measurement technique. On the other hand, all the agarose gels in 8 different stiffness scales could be measured with the STSM, because its measurement technique depends on force tranducer, and that force transducer could enable the measurement of very low stiffness sensitively.

The results for each gel were compared with the next softer gel measurements in the same main group (Fig. 5). The difference was statistically significant (P = <0.001, Mann–Whitney rank sum test) for 2.50%, 2.00%, 1.50% and 1.00% gels in the group of the durometer and the difference between 3.00% and 2.50% was not statistically significant (P = 0.122, Mann–Whitney rank sum test). Conversely, all results were statistically significant in the measurements of STSM group (Fig. 5B).

Additionally, the correlation was investigated between the two devices. According to the Spearman correlation analysis, there was a positive strong correlation between the durometer and the STSM (correlation coefficient = 1.00, "*p*" value = 0.00278, Spearman rank test).

4. Discussion

Measuring the mechanical properties of biological tissues is a complex problem. Because the nature of the tissues and limits imposed by minimizing or preventing damage to tissues are obstructing measurements. Despite the apparent problems, objective tissue stiffness studies have been going on for many years now. According to Ping-Lang Yen [2], there are two methods to take stiffness measurements from soft tissues; a constant contact depth method and a constant contact force method. The constant depth method is able to distinguish tissue stiffness more effectively because soft tissues behave as vicsoelastic materials and have a concave force–displacement relationship [2]. Based on these findings, the STSM was designed to measure stiffness using the constant depth method.

Patients suffering from painful muscle contractions, such as tension-type headaches, have muscle problems that become physically hard [7]. Physical therapists assess these changes subjectively through careful palpation in order to arrive at a clinical diagnosis. Quantitative measurement of muscle stiffness could be useful for assessing several conditions, and muscle stiffness also depends on viscoelastic properties. Clinical improvement is associated with reduced muscle stiffness [8], [9]. According to Morisada et al. [7], they produced a new device that consisted of a main spindle (5 mm in diameter) and an external cylinder (6.5 mm in diameter) with spring constants of 0.18 and 0.16 (N/mm), respectively. They gently applied these terminals vertically to the body surface, and the stiffness was estimated based on the relation between the monitored pressure and amount of skin deformation [7]. The stiffness was then calculated from the main spindle displacement (mm). The design of Morisada's device was an improvement on previous designs because measuring a deformation was more difficult than measuring a force magnitude. A similar technique employed by Morisada's device was also used in the design of the STSM, so the force values were measured under predefined deformations of samples. The control measurements were recorded using the durometer (shore type 00), because a device like durometer was preferred to be used in one of the study in measurements of tissue siffness [10].

The measurement principle of the durometer was different than that of the STSM. Using a weight, the durometer applied a constant compression force on a surface of the sample. A deformation in the tissue is formed as a result of the applied compression, and the needle of the durometer begins to penetrate the sample at a depth proportional to the stiffness of the sample. If the sample is very soft, then the entire durometer needle would penetrate the tissue, and an indicator would show a "0" value. If the sample is too hard, the needle of the durometer is unable to penetrate the tissue, so the indicator would show a "100" value. When the stiffness of the sample lies between these two extremes, then the indicator shows a value between "0" and "100". In the current study, sample measurements could not be taken under the 0.75% agarose gel concentration using the durometer because the gels were too soft for the shore type 00 scale. The measurement principle of the STSM, however, was much more sensitive to soft sample material properties.

5. Conclusion

The novel STSM device components and its quantitative measurement principle have been thoroughly explained in the study. The STSM is a hand held tool designed to assess the stiffness of biological soft tissues in situ, which distinguishes it from other in vitro evaluation devices. Since in-vitro measurements are performed on excised tissue, the sample must be removed from its natural position and prepared before measurements are taken [11]. The preparation of ex vivo samples always has the potential to introduce stiffness measurement inaccuracies when compared to an in situ tissue measurement, which always shows natural results.

In the current study, validation tests were performed using agarose gel samples, and the results indicated a strong correlation between the durometer and STSM measurements. Additionally, a relationship between the deformation reaction force and the resistance of the material was observed. The diameter of the indentation tip was chosen to be as small as possible in order to minimize the effect of the material thickness on resistance forces [12], [13]. Based on the STSM's performance on the agarose gel samples, it was determined that the STSM may be used to obtain accurate and precise stiffness measurements of soft tissue.

The STSM was designed to create an objective measurement device to replace the flawed traditional palpation method currently used to investigate the stiffness of biological soft tissue. Since the testing of human tissue is a long term goal, a minimally invasive form was chosen so that it might be used during open surgical settings. Moreover, the STSM might be used in future cancer tissue assesments because it is known that cancerous tissue is stiffer than healthy tissue [14].

As to the future human tissue testing, the STSM may eventually be used for both diagnostic and prognostic purposes in breast cancer or skin cancer cases [15], [16]. The STSM may also be able to detect tissue hypertrophyin lymphatic tissue as an additional cancer detection technique.

STSM proved to be a reliable stiffness assessment device as shown by the measurement results on the agarose gels. These findings are encouraging, and the study represents the first step before the device can be reliably implemented in a clinical or surgical setting to assess tissue pathologies. This study is just one step of the studies to follow, which should be carried out with animals and afterwards with patients in dermatology clinics.

Acknowledgements

The contribution of the prematurely departed Dr. Onder BARAN, who was instrumental in initiating this research, is respectfully acknowledged.

I would like to thank the University of Izmir Katip Celebi for their financial support in the form of a grant to Dr. Hakan Oflaz (BAP, 2013N041). The grammatical review was performed by Mark Davision at Michigan State University, College of Engineering, Orthopaedic Biomechanics Laboratory.

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