

Phase I design and evaluation of an isometric muscle reeducation device for knee osteoarthritis rehabilitation

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Abstract—Our long-term goal is to improve adherence to a home-based isometric program for rehabilitation of knee osteoarthritis (OA) using a force-biofeedback device (Isopad™). Our goal for Phase I was to design and evaluate an Isopad-based program in a *supervised* clinical setting. Our subjects were five patients with knee OA of Kellgren stage II or greater. A capacitive force sensor was tested for accuracy, repeatability, and durability. An Arthritis Foundation home-based isometric program inspired the Isopad design. The Isopad provided visual and auditory feedback instantaneously and continuously about force generated between the ankles. The five subjects completed a supervised 8-week progressive isometric program using the Isopad. Absolute isolated quadriceps and hamstring torques were quantified with a dynamometer, and patients completed a self-assessment of symptoms (Western Ontario and McMaster Universities Osteoarthritis Index). The capacitive sensor accuracy error averaged 10% and repeatability 4%. Cognitively intact subjects used the Isopad successfully for isometric progressive resistance training. Quadriceps and hamstrings absolute torques increased an average of 30%. Patients reported decreased functional complaints (Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index). All changes were trends. The Isopad helped subjects with knee OA adhere to a supervised isometric program and meet progressive strength targets. The next-generation Isopad will be employed in a home-based program.

Key words: biofeedback device, isometric exercise, muscle reeducation, osteoarthritis of the knee, patient compliance.

INTRODUCTION

Arthritis has a devastating impact on the U.S. population. It is one of the most prevalent diseases in the United States, affecting one in six people (43 million people) [1]. It is the leading cause of disability among persons aged 15 years and older, and it costs \$65 billion a year in medical care and lost wages [1]. Osteoarthritis (OA), the most prevalent form, affects an estimated 20.7 million Americans, most of whom are over age 45 and is responsible for more than 7 million physician visits per year [2]. Many studies have noted increased prevalence of OA with age [3,4], with 80 percent of the population having radiographic evidence of OA in at least one joint by age 60 and

Abbreviations: LED = light-emitting diode, NSAID = nonsteroidal antiinflammatory drug, OA = osteoarthritis, QPER = quantitative progressive exercise rehabilitation, WOMAC = Western Ontario and McMaster Universities.

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approximately 10 percent reporting limited activity because of arthritis [4]. OA, as a disease of aging, is also prevalent within the geriatric population treated by the Veterans Health Administration.

Knee OA is associated with more pain and physical disability than OA at other sites [4]. It causes difficulty in climbing stairs, rising from a seated position, and walking. Both radiographic and symptomatic knee OAs are more common among women than men older than age 50 years [4]. As the largest segment of the U.S. population ages over the next 50 years and more Americans live into their eighth and ninth decades, the prevalence of disability caused by OA is expected to increase [3].

Guidelines from the American College of Rheumatology recommend nonpharmacologic treatment, including patient education and support, exercise, weight loss, and joint protection as first-line therapy for knee OA, along with acetaminophen to control pain and other symptoms [5,6]. Analgesics and nonsteroidal antiinflammatory drugs (NSAIDs), including the new COX-2 (cyclo-oxygenase) inhibitors, are recommended as the next stage of treatment to reduce pain symptoms for individuals with mild-to-moderate knee OA. Adverse effects of these medications, such as renal and hepatic toxicity, are of concern among the elderly. Intraarticular injection of hyaluronic acid-like products may help to control pain and improve function, but improvements are temporary [7].

Although functional status improves for patients with more advanced knee OA who undergo arthroplasty, the risks associated with surgery, especially for the older individual, limit its use to those in whom more conservative approaches have failed. Physical therapy, generally applied in the clinical setting directed by a therapist, is effective in reducing pain, stiffness, and disability and in increasing functionality among patients with knee OA [8–14]. However, Fisher and colleagues found that only 2 percent of 500 patients who had knee OA had received any type of exercise therapy [13]. Such therapeutic underuse may be due to both medical professionals' limited understanding of the role of exercise in reducing symptoms and third-party payers' diminishing reimbursement for long-term treatment. Within the restraints of limited treatment time, the goal of physical therapy is often the demonstration of independent performance of a maintenance exercise protocol. Unfortunately, without professional supervision, patients frequently adhere poorly to a maintenance program [15,16].

Three basic types of therapeutic exercise exist: isotonic, isokinetic, and isometric. Of these three, isometric exercise might be most appropriate for home maintenance because it requires no or minimal apparatus and it is easy to learn. Further, isometrics causes the least intraarticular inflammation, pressure, and bone destruction of any type of exercise [17].

One investigation showed that isometric exercise designed to strengthen the knee with rheumatoid arthritis led to a 27 percent increase in quadriceps strength [18], with a crossover effect for the contralateral quadriceps, which gained 17 percent in strength. A 5 percent strength increase has been noted from a single 6 s daily isometric contraction at 67 percent maximal effort [19]. By the transfer of training principal (improvement from training in one position by improving the status of the nontraining area), isometrics increase strength only at the joint angle at which the exercises are performed [20]. However, Bandy and Hanten demonstrated that performing isometrics at 90° knee flexion improved strength in 127 subjects even in full extension [21].

Norden, Leventhal, and Schumacher acknowledge that “isometric exercises are simple and inexpensive to perform, and they rapidly improve strength [22]. Drawbacks are that it may be difficult to record objective improvement, and the patient may not comply well because these exercises are monotonous.”

The quantitative progressive exercise rehabilitation (QPER) model, proposed by Fisher et al. [13,23,24], is an outpatient program that has been shown to improve both strength and function in patients with symptomatic OA of the knee. The quadriceps and hamstrings initially are exercised isometrically, followed by low isotonic, endurance exercises (in a form of isometrics), and flexion/extension at maximal speed. Over 4 mo, muscle strength among those participating in the QPER improved 35 percent, approaching that of healthy age-matched controls. Walking speed increased 12 percent, and aerobic capacity (O_2 max) also improved. Gains persisted for more than 1 yr after the program ended, although a decline from peak improvement during that time was documented. Although effective, the QPER program is complex, expensive, and not easily translated to home use.

Not surprisingly, consumers who have arthritis do not adhere well to a long-term exercise program designed to prevent progression of a chronic condition when the end point is not clear [25,26]. Independent, home-based exercise that provides straightforward feedback of performance

could promote long-term maintenance without close professional supervision. After initial training, patients could exercise at home, with periodic evaluation and revision by the therapist as treatment progresses.

A moderately priced, simple-to-use isometric knee device could improve adherence to a *home* isometric program by providing immediate and tangible rewards (i.e., “hitting the strength target”). Our goals for Phase I are to—

1. Describe accuracy and reliability of the sensor.
2. Construct a prototype device incorporating the sensor.
3. Develop a program for isometric strengthening using the device that is *100 percent supervised* by a physical therapist.
4. Evaluate ergonomic design and clinical response.

The device has been named the IsopadTM.^{*} The Isopad senses force using a capacitive sensor (described in Methods section), which monitors force applied by a body part irrespective of its contour within a reasonable margin of error. The force information interfaces to microprocessor electronics, which immediately feeds force information back to the operator via light and sound. This electronic package meets criteria of transportability, reliability, cost-effectiveness, simplicity, and safety proposed by Rush and Grad for an effective generic measurement device [27]. In this paper, we present an engineering and clinical feasibility study of a prototype Isopad for knee OA rehabilitation.

METHODS

This project has two parts: (1) to demonstrate engineering feasibility of the capacitive sensor and define the physical, ergonomic, and functional characteristics of the prototype Isopad and (2) to do a pilot clinical evaluation of the prototype device and complementary knee isometric program. The goals of clinical testing are to evaluate the device and exercise and to determine if clinical outcomes are in the general direction one would expect (i.e., not to formally test hypotheses about symptom reduction or strength improvement).

^{*}The Isopad is trademark of SensorPad Systems, Inc. The first author (RG) and a coauthor (KR) have significant equity positions in the company. KR is a full-time employee of the company.

Engineering Feasibility

In 1995, Goldman patented a sensor for therapeutic rehabilitation that would be inexpensive, very durable, and straightforward to manufacture, since it was a laminate (**Figure 1**) [28]. The dielectric of this capacitive transducer laminate is called Poron[®] (Poron[®] is a registered trademark of Rogers Corporation, East Woodstock, Connecticut). Poron is extremely resilient microcellular polyurethane foam and is available in many thicknesses and densities, denoted by model number. The soft variety (type 4701-59) loses only 2 percent of its original thickness after 2,000,000 cycles of 60 percent compression (manufacturer’s data, Rogers Corporation). With this sensor (or several other “softer” types) placed between or against limbs, muscle-generated isometric force is easily measured.

Sensor Testing

Our first goal was to determine accuracy, repeatability, and durability of the capacitive sensor. We determined durability by comparing accuracy and repeatability before and after accelerated life testing using an apparatus that we designed and constructed.

This testing apparatus had an elevating platform, upon which the sensor was centered. (This testing apparatus is shown in **Figure 2**.) A pneumatic piston beneath the platform was raised until the test sensor (sandwiched between the platform and boom) fully lifted the boom on which a series of known masses (11.1 kg, 22.4 kg, 33.8 kg, and 45.1 kg; 24.5 lb, 49.5 lb, 74.5 lb, and 99.5 lb) were suspended. These masses yielded forces of 109.0 N, 220.2 N, 331.4 N, and 442.6 N, respectively. This apparatus could repeatedly determine capacitance change produced by known forces applied for a programmable number of compression cycles.

Our first task was to calibrate a set of sensors by determining the best fit of the function $\text{Force} = f(\text{Capacitance})$. In the next step, we determined the accuracy of sensor measurements of known (actual) forces expressed as percent error: $\text{Accuracy} = ((\text{calculated force} - \text{actual force}) / \text{actual force}) \cdot 100\%$. Repeatability was defined as percent error of calculated forces from the calculated mean: $\text{Repeatability} = ((\text{max force} - \text{min force}) / 2) / \text{mean force} \cdot 100\%$.

To determine calibration curves, we tested three sensors at masses of 0 kg to 45.1 kg (99.5 lb) in 2.27 kg (5 lb) increments ($n = 3$ determinations per force per sensor). The baseline capacitance (with no force applied) was recorded on a BK precision multimeter before and after capacitance determination at a given force increment. Capacitance

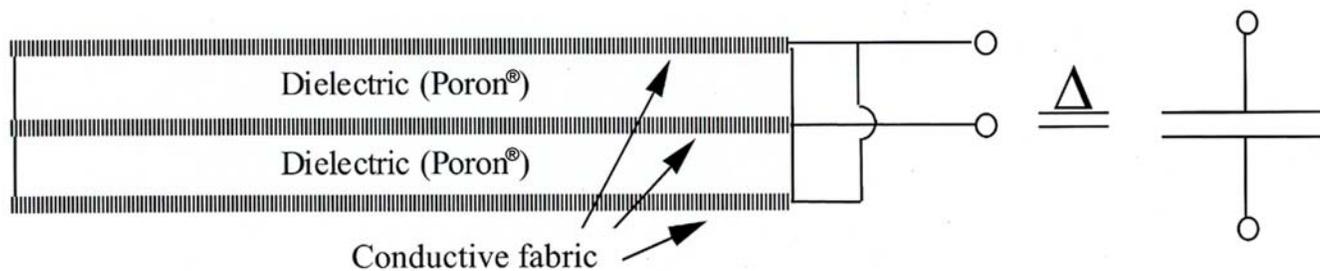


Figure 1.

Capacitive sensor used for Isopad. Sensor comprises materials of a durable polyurethane foam dielectric (Poron[®] 0.062 in., model 4701-30-20062) separated by a flexible conductive mesh (S158 metallized fabric from Swift Textile Metallizing). Conductive mesh was quite thin compared to Poron used. Therefore, it had a negligible effect on mechanical characteristics of transducer in compression. Transducer comprises three layers of metallized mesh and two layers of Poron laminated together. Lamination is achieved using No. 467 pressure-sensitive adhesive by 3M (Minneapolis, MN). Resulting transducer has a fabric-like quality that is flexible and can be cut into any required shape or size. Grounding two outer layers of metallized mesh adequately reduces noise and effects from stray capacitance.

recorded 5 s after the sensor was fully compressed was also logged and subtracted from baseline and expressed as ΔC . (Baseline capacitance was about 300 pF and maximum ΔC was about 100 pF.)

ΔC -versus-force curves (normalized to baseline) were generated for three sensors and a single curve rendered from these three. The grand average curve was fit to an equation of form: $Y = AX^2 + BX + C$. A second-order curve fit was optimal. (See **Figure 3**.)

To determine accuracy and repeatability, we applied forces of 109.0 N, 220.2 N, 331.4 N, and 442.6 N (24.5 lb, 49.5 lb, 74.5 lb, and 99.5 lb) to each of the three test sensors. This force series was applied to test sensors by one of two methods: (A) Single-set—five times at each force before increasing the force to the next highest force or (B) step-set—at each incremental force from lowest to highest, the cycle repeated five times. Baseline capacitance was recorded before and after each set. From each ΔC , a force was calculated from the second-order calibration curve.

We performed accelerated life testing using the apparatus just described. With a suspended mass of 45.12 kg (100.5 lb), three calibrated sensors underwent cyclical-compression testing. Sensor 1 was compressed 6,667 times, sensor 2 was compressed 13,334 times, and sensor 3 was compressed 20,000 times. Upon completion, each sensor again underwent accuracy and repeatability testing.

Strengthening Program

Our starting point was an isometric exercise program suggested for home use by the Arthritis Foundation in its booklet on home-based exercise for arthritis [29]. The suggested isometric exercise for knee arthritis is illus-

trated in **Figure 4**. In this figure, the subject is sitting comfortably in a chair with the hips and knees in 90° of flexion, with ankles crossed. The ankles are pressed against each other to contract the quadriceps and contralateral hamstrings for a series of contractions. Then, the ankles are crossed in reverse fashion, and the opposing quadriceps and hamstrings are cocontracted.

Since this exercise had been widely disseminated in an educational brochure for the lay public, it was considered to be a useful starting point for the Isopad program. However, the intensity, and number of repetitions were not specified in the booklet (nor is a reference cited). Therefore, the design team (i.e., all authors) agreed on several additional therapeutic exercise parameters to “fill in the gaps” to include:

1. Isometric contractions would follow the BRIME (BRief Isometric Exercise) protocol suggested by Liberson that consisted of 6 s of isometric contraction [30], followed by 20 s of rest (purported to maintain normal pulse and blood pressure) [30,31].
2. Multiple angle isometrics [32]—besides exercises at 90° knee flexion, cocontractions at 20° of flexion would be included to strengthen terminal knee extension.
3. Six contractions in each of four positions to comprise a cycle (left ankle on right, right ankle on left, knees in 90° of flexion then repeat with knees in 20° of flexion).
4. Three total cycles per session and two 5 min rest periods, comprising 72 total contractions.

By consensus, several features of the program were added: (1) The Isopad program would be based on an

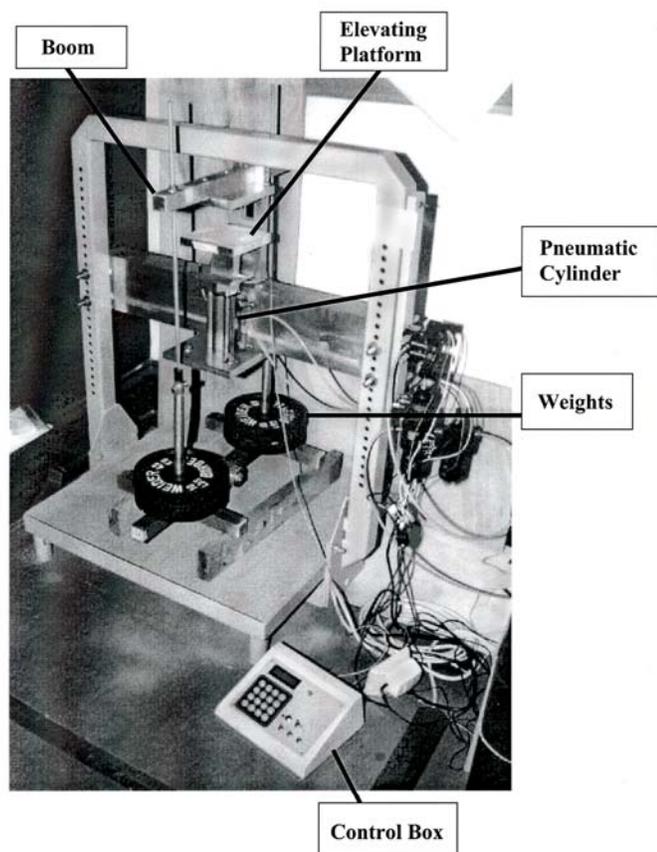


Figure 2.

Sensor testing apparatus. Testing equipment was specially fabricated to apply cyclical force to a test sensor for accelerated life or static load testing. Test capacitive sensors (3 1/2 in. \times 3 1/2 in.) were placed on an elevating platform that consisted of a 3 in. \times 3 in. aluminum block. Elevating this platform was a 2-way pneumatic cylinder (PHD model CTS1U50X3/58-BB-M, Rankin Corp., Broomall, PA). This cylinder was controlled by a 2-position, 4-way valve (ARO model A212SD-000-N, Rankin). Cylinder pressure was controlled by a Speedaire (model 5Z420A, Dayton Electric Mfg. Co., Dayton, OH) filter/regulator controlled, which also filtered compressed air and added lubrication oil to line. A 4.5 Hp, 20 gal Speedaire (model 48227C) air compressor supplied compressed air. Investigator KR fabricated a control box that used a Basic Stamp II microcontroller and a 2-line alphanumeric LCD display. With this control unit, operator could either raise or lower cylinder a single time or a set number of times (up to 99,999) as required by cyclical compression tests. Testing jig was welded out of 1/4 in. steel L beams, steel square stock, and aluminum stock by Liberty Arms Works Inc., West Chester, PA.

progressive resistive exercise program, with increasing strength goals set week to week [33]; (2) strength goals would be 80 percent of weekly determined maximum quadriceps or hamstrings strength [8]; and (3) the program would be 8 wk long, somewhat shorter than the program devised by Fisher et al. but consistent with a

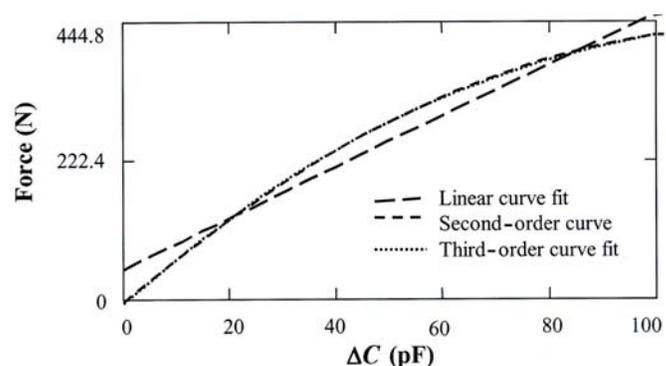


Figure 3.

Representative calibration curve of capacitance change (ΔC) of resilient polyurethane sensor because of compression by various forces on testing apparatus. A second-order curve fit is more accurate than a first-order (linear) curve fit, with no appreciable difference in accuracy between second- and third-order curve fit. Each curve fit is derived from about 15 data points.



Figure 4.

Isometric exercise for knee illustrated in "Arthritis for Exercise" booklet by Arthritis Foundation [29].

typical outpatient physical therapy experience [23,24,34]. Also similar to typical outpatient physical therapy, sessions would be held 3 days a week [35]. At the end of each week, the physical therapist would set the patient's target levels for the following week. Sessions would be

100 percent supervised by the physical therapist, both to assure correct use of the Isopad and to monitor the isometric program for safety.

Prototype Device Design Features

The Isopad had several initial design concepts. These included (1) a completely self-contained unit (sensor and electronics) held between the ankles, (2) sensors affixed to concave plastic shells with a hand-held control unit, and (3) sensors within a vinyl pouch with a hand-held control unit. Of these concepts, the last proved to be the most ergonomic and comfortable and took maximum advantage of the material properties of the sensor to measure nonparallel forces between irregular body parts.

Based on the “winning” concept, two custom-built Isopad prototypes were designed and fabricated (**Figure 5**), consisting of a hand-held control unit and an ankle cuff component. An engineer (KR) configured a 3 1/2 in. × 2 1/2 in. sensor within a 4 in. × 3 in. vinyl pouch, with two attached Velcro® straps. After the straps were secured and the contralateral ankle was pressed against the sensor pouch, the control unit registered the degree of force on the visual display during informal preliminary testing. One of the purposes of the clinical evaluation was to observe the sensor performance during therapeutic conditions to suggest any additional modifications for subsequent trials.

The Isopad hand-held unit provided feedback of performance. Numerous control and feedback features specified how force information would be presented to the person doing the contraction. The control unit would cue the subject doing isometrics as to when to contract the quadriceps and hamstrings and when to rest based on sound and light cues from the device. Additionally, the target force in each of four positions was programmed into the device. Around the target, the device would inform the subject when he or she was in an acceptable force range (labeled “window”).

The force window is nominally set to within 20 percent of the target force. This bracketed force or “window span” represents the accountability range for the user. As the applied force increases from -20 to -8 percent of the target force, the amber light-emitting diode (LED) lights and the 1,250 Hz tone sounds. As the applied force continues to increase to -7 to +7 percent of the optimal force, the green LED lights and the 2,500 Hz tone sounds. If the patient exerts too much force, beyond 7 percent above the target, the red LED lights and the 3,750 Hz tone sounds. If a user has difficulty maintaining a force within the

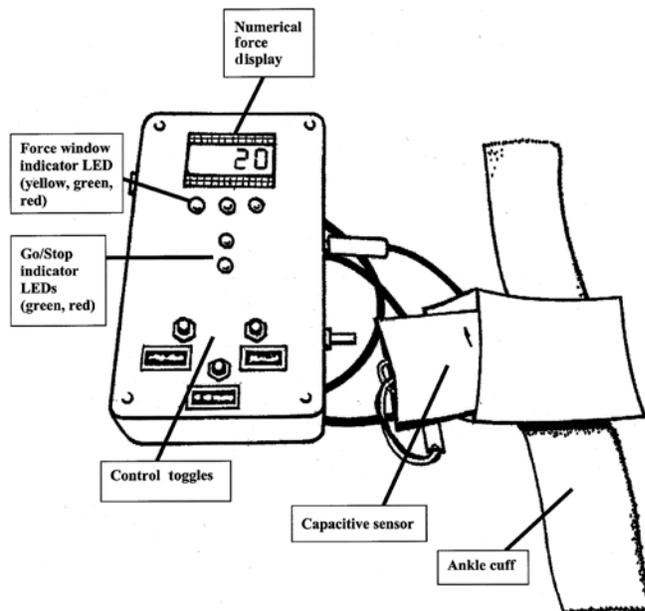


Figure 5.

Isopad device placed between ankles measures force generated by isometric hamstring-quadriceps cocontraction. Visual and audible feedback of force improves success in attaining preset isometric strength goals. Several control toggles set contraction time and rest time, set target threshold, and defined a “window” of desired contraction response as delineated in Methods section (of main paper) on prototype device design. A green LED cues user when to contract and a red LED cues start of rest period. One audible and two visual feedback cues are designed to generate desired contraction-response. For visual feedback, a liquid crystal display (LCD) provides instantaneous numeric feedback of force in relative units. LEDs in three colors relate to applied force: amber indicates force is being applied well below target, green indicates correct amount of force is being applied, and red signals too much force is being applied. Audible feedback accompanies amber, green, or red LED, with variable volume generated at frequencies of 1,250, 2,500, or 3,750 Hz, respectively. Keeping force within “green” and sound on “middle” tone are the goals.

nominal window span of ± 20 percent of the target, the window span can be increased to ± 30 percent to increase the apparent ease in maintaining the required force.

Muscle Reeducation Format with Isopad

Participants always were seated in the same platform (not a chair), with feet dangling in the 90° position and with feet positioned on a footstool in the 20° flexion position. Knee position was verified by the physical therapist, who then placed the Isopad sensor cuff on the patient’s left lower limb on the anterior lateral side of the tibia. The Isopad was turned on, which initiated a self-

calibration routine of the scale to zero (a tare procedure). The patients then crossed their right lower limb over the sensor cuff so that the sensor was in maximum contact between the posterior and anterior ankles to ensure greatest contact with the sensor pad and most consistent force feedback. On cue from the device (green LED), patients pressed back with the front ankle and forward with the back ankle. Then 6 s later, the LED changed from green to red (i.e., “stop”). For each new position (right ankle over left, etc.), the physical therapist had to optimally reposition the sensor on the leg.

Clinical Assessment

Patient Entry Criteria

Inclusion and exclusion criteria are modeled on those published by Maurer and colleagues for another OA protocol [35]. Patient inclusion criteria were—

1. Ability to give informed consent.
2. Age of 40 to 81 years.
3. Pain symptoms provoked by activity in the more symptomatic knee of 4/10 or greater on the visual analog scale.
4. During manual muscle testing, extension strength of 4+ or less on a 0 to 5 scale of the more symptomatic knee in 10° of flexion.
5. Independent ambulation without an assistive device.
6. Knee pain present for at least 6 mo.
7. Fewer than 30 min of morning stiffness.
8. No current participation in a lower-limb strengthening program.

Exclusion criteria were—

1. Participation in a strengthening program of the knees in the past month.
2. Functionally limiting cardiac disease or dyspnea on exertion.
3. Exercise-induced angina.
4. Uncontrolled hypertension.
5. Moderate-to-severe peripheral neuropathy.
6. Knee flexion contracture of 10° or greater.
7. Administration of intraarticular steroids in the past 3 mo or hyaluronic acid in the last 9 mo.
8. Poor health that would impair compliance or assessment.
9. Arthroscopy of either knee in the past year.
10. Lateral instability of more than 15° or posteroanterior instability of greater than 1 cm.
11. Knee pain caused by pes anserine bursitis.

12. Active fibromyalgia.
13. History of alcohol or substance abuse (because this might affect compliance with the study protocol).
14. Presence of arthritis other than OA in the more symptomatic knee (note a patient could have OA in bilateral knees that are equally symptomatic without violating entry criteria).
15. Pregnancy.
16. History of cancer other than skin cancer.
17. Symptomatic spine, hip, ankle, or foot disease other than OA that would interfere with assessment of the knee.

Patient Assessment

If deemed an appropriate candidate based on a screening telephone conversation, the subject signed an informed consent form, duly approved by the Institutional Review Board (IRB) at the Philadelphia Veterans Affairs Medical Center. After receiving a detailed history and performing a physical assessment, we obtained baseline knee films. Patients who had Kellgren II OA or above on radiography began an 8 wk isometric muscle reeducation protocol. (The protocol initially called for Kellgren II and III only. However, one patient with Kellgren III+ was included to increase overall enrollment.) At the beginning and end of each visit (three a week), the physical therapist recorded any adverse events and change of chronic knee pain on a visual analog scale.

At the end of each week, the patient's maximum knee flexion force was determined to establish the biofeedback force target for the following week. The patient was asked to exert maximum force three times, and the average was calculated to determine the three-repetition maximum. The biofeedback target for the subsequent week was set at 80 percent of the three-repetition maximum. At 0 wk, 4 wk, and 8 wk into the protocol, a symptom self-report questionnaire was completed (WOMAC). Additionally, computerized dynamometer absolute isometric strength assessments were determined at baseline (weeks -1 and 0), 4 wk, and the end of the program. The physiatrist and physical therapist conducted exit interviews that contained the same components as the initial evaluation and together comprised a comprehensive history (including functional history) and physical examination. The purpose of a comprehensive entry and exit evaluation was to assure that medical status had not changed and adverse events were recorded.

Prestudy weight-bearing anteroposterior knee films of the more clinically involved knee (or both knees if equally involved) were obtained on all candidates and

interpreted by the radiologist consultant according to Kellgren and Lawrence criteria for osteophytes, joint space narrowing, and subchondral sclerosis [36]. All study participants had Kellgren stage II or greater disease.

The WOMAC is a multidimensional, validated, widely accepted, self-administered instrument for individuals with OA of the knee. The WOMAC assesses symptoms quantitatively in three dimensions: pain, stiffness, and function [37,38]. The physical therapist at the study site administered the WOMAC to subjects at the beginning, middle (4 wk), and end of the 8 wk protocol using a standardized method.

Isolated quadriceps and hamstring torques were quantified at 90° and 60° of knee flexion bilaterally for eight total isometric torque determinations with a Biodex 2AP computerized dynamometer (Biodex Medical Systems, Inc., Brookhaven R&D Plaza, 20 Ramsay Road, Box 702, Shirley, New York 11967-0702). The dynamometer assessments were supervised by the physical therapist after careful positioning of the patient. Investigators determined reliability by measuring torque at two time points, 1 wk apart before beginning the strengthening protocol. Biodex assessments were also obtained at the middle (4 wk) and end (8 wk) of the strengthening protocol.

Data Analysis

Descriptive statistics were obtained for (1) sensor accuracy and repeatability; (2) Isopad-measured relative strength, (3) torque measured with the Biodex dynamometer, and (4) symptoms measured by the WOMAC survey instrument.

RESULTS

Engineering Testing

Accuracy was determined for the resilient capacitive sensor with polyurethane dielectric according to the single-set method A and step-set method B (see Methods section). Grand average accuracy across the force range (method A) was 4.9 percent (range 0.3 to 13.0 percent) (see **Table 1**). Grand average accuracy across the range (method B) was 9.5 percent (range 0.2 to 26.8 percent). Accuracy error was greatest at the lowest force tested (109.0 N, 24.5 lb). Overall, accuracy was considered good.

Repeatability was likewise determined according to the single-set method A and step-set method B (see Methods section). Grand average repeatability (method A)

across the range was 1.5 percent (range 0.0 to 3.2 percent) (see **Table 2**). Grand average repeatability (method B) across the range was 4.0 percent (range 0.1 to 9.9 percent). Repeatability is better than 10 percent in all cases, which is considered quite good.

Durability was determined by comparing accuracy and repeatability before and after accelerated life testing. The most rigorous testing occurred for sensor 3, compressed

Table 1.

Accuracy (% error) of three resilient capacitive sensors: Accuracy = ((calculated force – actual force)/actual force)•100%. Force is calculated from second-order calibration curve.

Method	Force (N)	Sensor			Average
		1	2	3	
Single-Set (A)	109.0	7.8	0.5	0.3	2.8
	220.2	13.0	9.2	6.6	9.6
	331.4	1.3	5.0	2.3	2.8
	442.6	2.1	5.6	5.1	4.3
Grand Average	—	—	—	—	4.9
Step-Set (B)	109.0	26.8	15.0	4.6	15.4
	220.2	19.0	13.9	4.6	12.5
	331.4	5.4	8.9	0.2	4.8
	442.6	3.7	6.4	5.1	5.1
Grand Average	—	—	—	—	9.5

Table 2.

Repeatability (% error) of three resilient capacitive sensors. Repeatability = ((max force – min force)/2)/mean force)•100%. Force is calculated from second-order calibration curve.

Method	Force (N)	Sensor			Average
		1	2	3	
Single-Set (A)	109.0	3.2	0.0	0.0	1.1
	220.2	2.8	1.3	1.4	1.8
	331.4	2.6	1.7	2.9	2.4
	442.6	0.8	0.6	0.3	0.6
Grand Average	—	—	—	—	1.5
Step-Set (B)	109.0	4.1	9.9	8.7	7.6
	220.2	3.1	8.0	2.6	4.6
	331.4	4.4	3.0	2.2	3.2
	442.6	1.1	0.6	0.1	0.6
Grand Average	—	—	—	—	4.0

20,000 times (see **Table 3**). Accuracy across the force range via the single-set method A was 7.4 percent (range 4.2 to 10.1 percent) and for the step-set method B was 15.8 percent (range 11.1 to 28.5 percent). Repeatability via the single-set method A was 3.3 percent (range 2.2 to 4.6 percent) and via the step-set method B was 1.8 percent (range 0.7 to 3.0 percent). The capacitive sensor substantially retained its accuracy and repeatability properties and proved itself very durable.

Additionally, the capacitive sensor could be calibrated if compressed on a flat surface. However calibration of an Isopad would require additional accuracy and repeatability tests with sensors sandwiched between “dummy” ankles compressed with the use of known forces. Because the investigators did not have this capability for Phase I, they decided to express force as a relative measure (Isopad units) rather than absolute force (Newtons or pounds) for the clinical evaluation.

Clinical Evaluation of Isopad

Of the more than 40 individuals assessed, about half met the entry criteria. However, of those that met criteria only five were willing to travel to the study site 3 days a

Table 3.

Accuracy and repeatability of resilient capacitive sensors after accelerated life testing were similar to before life testing. Shown is durability performance of sensor 3 after 20,000 compressions at 442.6 N (99.5 lb). Accuracy degraded somewhat: For single-set method A, accuracy degraded from 3.6% to 7.4%, and for step-set method from 3.6% to 15.8%. However, accuracy of sensors 1 and 2 actually improved after accelerated life testing: For sensor 1, average accuracy after 6,667 compressions was 4.3% (single-set method A) and 4.4% (step-set method B). For sensor 2, average accuracy after 13,334 compressions was 4.4% (single-set method A) or 5.2% (step-set method B).

Parameter	Force (N)	Single-Set Method A	Step-Set Method B
Accuracy (% error)	109.0	8.3	28.5
	220.2	4.2	12.2
	331.4	7.0	11.1
	442.6	10.1	11.5
Average	—	7.4	15.8
Repeatability (% error)	109.0	2.8	2.3
	220.2	4.6	3.0
	331.4	2.2	0.7
	442.6	3.5	1.0
Average	—	3.3	1.8

week for 8 wk. Of those that agreed to participate, median age was 68 ± 8 standard deviation (SD) years, median height was $173 \text{ cm} \pm 20 \text{ cm}$ ($68 \text{ in.} \pm 8 \text{ in.}$), and median weight was $106.1 \text{ kg} \pm 14.1 \text{ kg}$ ($234 \text{ lb} \pm 31 \text{ lb}$). Subjects were generally obese. All were right-handed. Two subjects were African-American females, one African-American male, one Caucasian male, and one Caucasian female. The diagnosis of knee OA had been made a median of $12 \text{ yr} \pm 11 \text{ yr}$ earlier. Three of the participants demonstrated pronounced OA symptoms in the left knee, one in the right knee, and one with equal symptoms in both knees. (Having equal bilateral symptoms did not exclude a subject as long as the pathologic process was OA, confirmed by X-ray.)

Four patients reported an increase in pain over the past year; the fifth noted no change in pain during the previous year. Kellgren ratings in the more symptomatic knee were II (three individuals), III (one), and III+ (one). In addition, all participants were weaker in the symptomatic knee by more than 1 SD below the mean for isolated quadriceps and/or hamstrings torque compared with age-adjusted norms for quadriceps and hamstrings torques [34,39,40].

Weekly determinations of 80 percent three-repetition maximal voluntary contraction and measured in Isopad units over the 8 wk of the study are depicted in **Figure 6**. The forces recorded represent the contraction force applied to the sensor cuff in the right-over-left and left-over-right 90° and 20° positions of the knee. While strength improvement was documented in all positions of the knee, the variability was relatively high. The variability can be attributed to the differences between the male

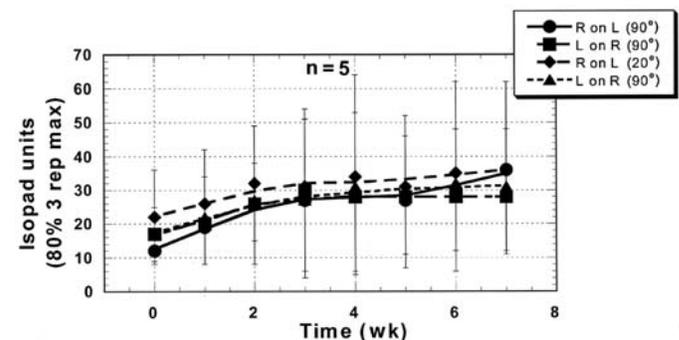


Figure 6.

Isopad-measured progressive isometric strength tends to increase in all patients at each of four positions over 8 wk. For each position, a weighted curve fit algorithm is used to connect points. R = right and L = left.

and female mean relative strength and the small number of study subjects. During the period of data collection, the women demonstrated a mean strength increase from 13 ± 2 to 16 ± 2 Isopad units, and men increased from 23 ± 8 to 54 ± 7 Isopad units. A relative strength improvement (force data/subject divided by the subject's preprogram strength) revealed a 50 to 200 percent increase in isometric strength.

Three of the five subjects quickly adapted to and used the feedback aspect of performance provided by the Isopad, reliably applying contractile force within the target window span within the first week of the program. All subjects demonstrated a significant upward slope in Isopad-measured force generated over the 8 wk study. The other two subjects required several weeks to develop reliable performance with feedback and neither demonstrated a linear increase in strength testing. One participant was not able to produce controlled contractions accurately until week 5 and only after the window span was increased from 20 to 30 percent of the force target. The other participant who had difficulties with feedback displayed cognitive deficits related to medications (haloperidol and benzotropine mesylate), but these symptoms resolved in the last 2 wk of the study. During this improved performance phase, the participant responded more consistently to the feedback and did not require verbal cueing by the supervising physical therapist.

Computerized dynamometer testing revealed a trend of strength improvement in all eight positions (**Figure 7**). However, the variance again was large (50 percent of the mean) because of the absolute strength difference between men and women, the trend away from dominance of right knee extension toward symmetric strength, and patient-specific patterns of torque improvement. Three of the participants disproportionately increased flexor torque, and two increased extensor torques. Strength increased more for subjects with quadriceps and/or hamstrings weakness than those subjects whose strength approached that of age-matched normals who are not diagnosed with knee OA [34,39,40].

The WOMAC was administered at the beginning, middle, and end of the training period to quantify symptoms of pain, stiffness, and functional deficit. All patients reported improvement in all three categories: 33 percent pain and stiffness reduction and 15 percent functional improvement (**Figure 8**). Subjects with Kellgren II disease had 56 percent pain decrease, whereas Kellgren III subjects had virtually no pain decrease. This difference in symptom response according to the extent of radiologically evident OA contributed to variability of the WOMAC pain score.

It is notable that one patient developed a left hamstring sprain, type I, during week 7 of the protocol. (This device-related nonserious adverse event of severe intensity was

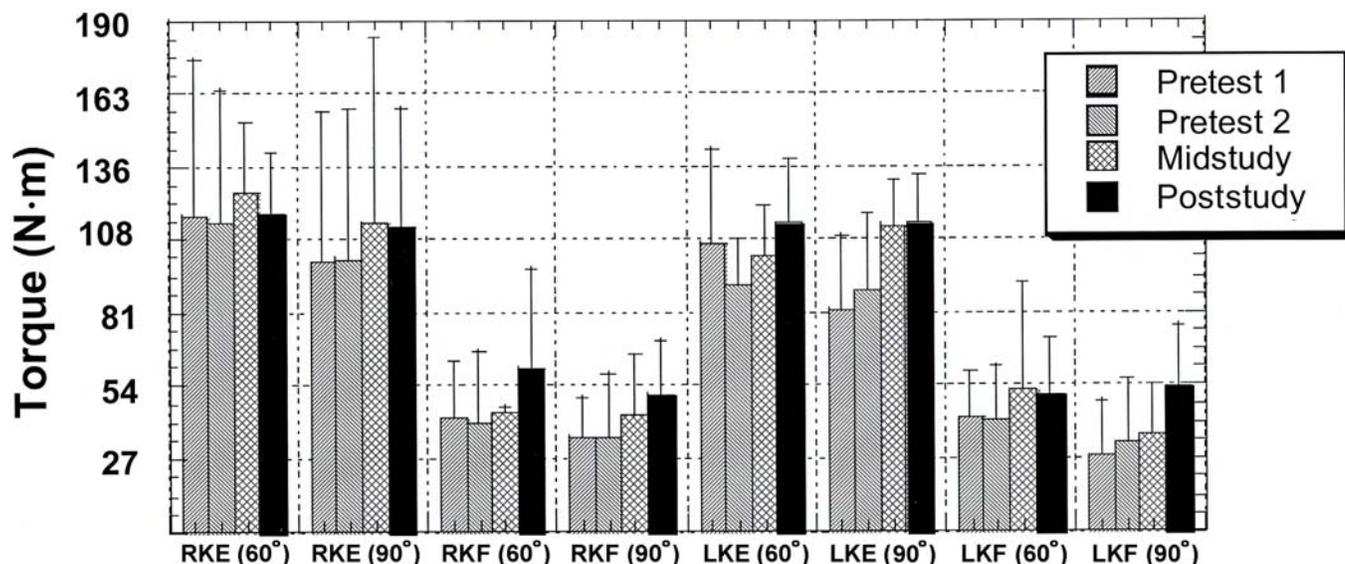


Figure 7.

Measurements of muscle-specific torque on Biodex dynamometer before, during, and after study in four study participants. R = right, L = left, KE = knee extension, and KF = knee flexion.

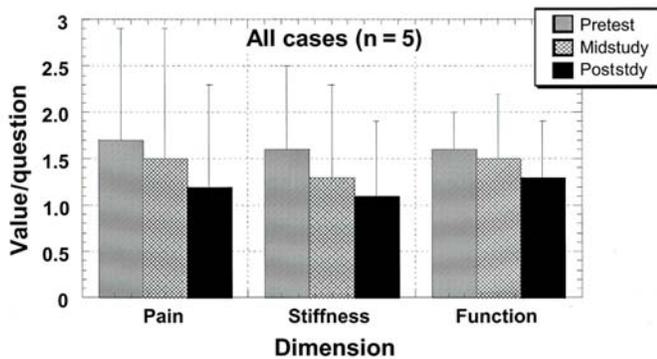


Figure 8. Measurements of pain, stiffness, and function on WOMAC validated instrument before, during, and after study in five study participants.

reported to the IRB.) Apparently, the sprain occurred when she attempted to press harder when the Isopad failed to register her force during two contractions. She felt the pain immediately after the session and stopped Isopad training. However she completed the program's final evaluation (without the Biodex determination). Application of moist heat, administration of an NSAID, and reduction in activity (cane recommended for support during ambulation) resolved the sprain in 4 to 6 weeks. Most of the subjects complained of a minor level of hamstring soreness at some point during their muscle reeducation program, but none reported increases in joint pain.

DISCUSSION

Investigators determined from engineering tests that the capacitive sensor with resilient polyurethane dielectric was repeatable, accurate, and durable enough to use as part of a program of isometrics to provide feedback of performance. Performance compared favorably to specifications of force sensors used for rehabilitation and/or wound care diagnostics [41]. Most participants were able to use feedback of isometric force to reach a target force, the target being presented by means of readout sound and light displays. As one would expect from an evaluation of an isometric routine for subjects with OA, strength tended to improve and symptoms to diminish for participants. As a clinical evaluation only, no general conclusions can be drawn from these results.

As the first prototype of a future home-based Isopad, areas for improvement became evident after clinical evaluation, with sensor size being the most critical. The sensor

in the ankle cuff was too small (it is suspected) to accurately present force to the subject who on week 7 was discharged because of an adverse event. This nonserious adverse event of severe intensity was a muscle sprain. This sprain could be traced to inaccurate placement of the sensor-cuff to measure contraction force, even though a therapist adjusted the pad on the ankle.

For the cause underlying this adverse event to be substantially eliminated, the Isopad employed for Phase II trials will be redesigned with a single wraparound sensor that will be at least 10 times the area of the Phase I sensor. It will have an elastic strap around the plantar foot to ensure a snug repeatable fit and eliminate the need for repositioning during the isometric routine.

Isopad-measured strength gain was noted only among those individuals who were able to understand and respond to biofeedback. However, even those who did not initially understand the biofeedback concept and did not demonstrate monotonic strength increases with the Isopad tended not to show symptom reduction on the WOMAC and a trend toward strength increase on the computerized dynamometer. However, it is not clear if this second group would respond to the Isopad in the home setting, because biofeedback probably would be necessary to maintain an independent, sustained program of isometric contractions.

All study participants exhibited an increased strength profile from baseline to discharge evaluation when using the Isopad muscle reeducation device to improve precision of isometric exercise. Functional complaints associated with knee OA tended to decrease in study participants, who reported less pain upon rising in the morning and less overall knee pain. Four participants subjectively reported greater ease in stair climbing and descending and improvement in ambulation performance. Four of the five participants expressed an interest in continuing the muscle reeducation program on their own but felt that it would be more difficult to get the full effect of the protocol using the Isopad without professional supervision.

A potential adverse effect of isometric exercise protocols among the elderly, although not reported in this investigation, is rising of blood pressure, which is of particular concern for those who have hypertension. Greer and associates have suggested that a transient 15 percent increase in blood pressure does occur with isometric exercise [42], but it resolves after 60 s of rest. Other researchers have shown that the transient increase in blood pressure caused

by brief exercise, if it indeed occurs, is well tolerated even by very old subjects (e.g., >85 yr) without active cardiac disease [43]. As an additional precaution, participants can be trained not to perform the valsalva maneuver during isometric contractions, which can blunt any potential blood pressure increase [44].

In future models, the Isopad used at home will monitor adherence to the muscle reeducation program through its internal data storage and downloading capability. These electronic features will enable the therapist to monitor session frequency, duration, and energy exertion without being physically present. When the Isopad is cleared for home use, it may help improve compliance with isometric exercise. Compliance is a major factor governing whether or not an isometric exercise program is effective in reducing pain and increasing functionality of those who have knee OA [16].

Since force generated by muscle is proportional to its integrated electromyographic (EMG) signal [33], the Isopad essentially is an EMG-biofeedback muscle reeducator that does not require EMG electrodes or assignment of one-on-one supervision.

CONCLUSIONS

This Phase I study determined that the resilient capacitive sensor has adequate accuracy and repeatability to be used in rehabilitation therapeutics and that the Isopad is feasible for use with patients, with some modifications (e.g., increased sensor size in the ankle cuff). Most subjects can benefit from immediate and continuous feedback of muscle strength. Although one can draw no conclusions from the clinical assessment of the Isopad (since there was no control group), improvements were found in strength and reduction in symptoms (trends) that would suggest that the Isopad was working as intended. A Phase II study will be conducted over a longer time period and involve more patients. Its goal will be to identify statistically significant findings and refine the design of the Isopad for home use.

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