A Pilot Study of ARP Wave Electromyostimulation:
Management of Adolescent Anterior Knee Pain

Eric W. Edmonds, MD; Amelia M. Lindgren, MD; Liane Chun, MD;
Raghav Badrinath, MD; James D. Bomar, MPH; Roland Howard, MD

Objectives: Accelerated Recovery Performance (ARP) Wave therapy is an electromyostimulation therapy designed to enhance neuromuscular control to rehabilitate patients with musculoskeletal pathology. The purpose of the study was to compare ARP Wave therapy and standard physical therapy (PT) in the setting of adolescent knee pain, assessing the duration of treatment and ability to improve knee function without complications.

Methods: A prospective pilot study was conducted randomizing adolescent patients into two therapy groups: 1) standard PT or 2) ARP Wave therapy. Patients crossed over to the other treatment type if symptoms persisted after their first course. The Pedi-IKDC, Hospital for Special Surgery Pediatric Function Activity Brief Scale (HSS Pedi-FABS), and Kujala outcome scores were recorded at baseline, after the initial treatment course, and upon conclusion of the crossover treatment course.

Results: Six patients were randomized into the ARP Wave group and three patients were randomized into the PT group. Pedi-IKDC, HSS Pedi-FABS, and Kujala were similar at baseline among the two groups ($p>0.25$). The PT group did not improve their outcome scores with just PT ($p>0.25$); however, the ARP Wave group improved in all three outcomes after only ARP Wave treatment ($p<0.05$).

Conclusions: Although a small sample size, this pilot study demonstrates the potential impact of ARP Wave therapy on the management of adolescent anterior knee pain with improvements in outcome scores. Further study of ARP Wave therapy is warranted for common benign knee pathologies, and perhaps even for children recovering from surgical intervention.

Level of Evidence I: Randomized controlled trial or systematic review of Level-I randomized controlled trials

INTRODUCTION

Accelerated Recovery Performance (ARP) Wave therapy utilizes direct current (DC) compounded with a high frequency double exponential background waveform that creates electromyostimulation. This has characteristics that contrast with more conventional therapeutic neuromuscular electrical stimulation, including: interferential, microcurrent, galvanic, Russian stimulation, and iontophoresis1–3. ARP Wave therapy is a class II FDA medical device that has been approved for muscle re-education, relaxation of muscle spasms, increased neovascularization, prevention of disuse atrophy, and maintaining/increasing joint range of motion. The ARP Wave Rx100 uses a main electrostimulation pulse of 40 to 500 cycles per second that is coupled with a background high-frequency carrier

signal at 10,000 cycles per second. The polarity direction of electron flow is reversible within the unit and this is utilized as part of the therapy. Reversing the polarity during therapy is intended to create a deeper and more effective muscle contraction with the stimulation, which in turn can help to activate more muscle fibers. This in hypothesis would stimulate a natural healing processes, but there is currently limited scientific evidence for this concept.

Recent literature for major knee injuries such as anterior cruciate ligament tears, or patella instability, suggests that poor motor control of the core musculature is a root problem that increases the odds of sustaining one of these injuries4–6. In fact, many prevention programs have been developed to address the problem in hopes that the incidence of injury can be decreased. The results of these programs have been met with mixed success7,8. The ARP Wave technology could add a clinically beneficial modality that may enhance the results of preventing these injuries, if the claims regarding success are upheld. The underlying concept behind ARP Wave therapy is that it educates the patient at multiple levels regarding neuromuscular control. By either holding a specific position or moving the afflicted limb through a discrete and controlled range of motion during electromyostimulation, the patient develops strength, endurance, and more importantly muscle memory regarding the functional position of the adjacent joints.

Adolescent knee pain is believed to develop secondary to this same poor neuromuscular control that risks ligamentous injury, and stems from recent accelerated growth with slow adaption of muscle to acquired skeletal length in adolescence9. The objective of this pilot study is to elucidate either a benefit or detriment of electromyostimulation via ARP Wave therapy in the outcomes of patients presenting with one of the many diagnoses included in the umbrella term: anterior adolescent knee pain. The null hypothesis is that ARP Wave therapy utilized in lieu of standard physical therapy will not decrease the duration of necessary treatment to achieve normal (symptom free) knee function. The primary aim was to determine if ARP Wave therapy would improve patient reported outcomes (PROs) during treatment in a shorter amount of time then a standard course of physical therapy. If this technology can be utilized to help neuromuscular control in adolescents with knee pain without major injury, then perhaps it might also be beneficial in the management of adolescents that present with a major injury (first-time patella dislocations, first-time traumatic anterior glenohumeral dislocations, ankle instability, et cetera), or even in the surgical rehabilitation of patients.

MATERIALS AND METHODS

After Institutional Board Review approval, this study utilized a prospective randomized cohort of adolescent patients who presented to the orthopedic sports center (age restriction greater than 12 years old) with a diagnosis under the umbrella of “adolescent anterior knee pain”. This knee pain included: Osgood-Schlatter disease, Sinding-Larsen-Johanssen syndrome, patellofemoral syndrome, symptomatic medial plicae, and Hoffa fat pad syndrome/impingement. Exclusion criteria included: abnormal readings of 4 view (anteroposterior, lateral, merchant, and tunnel view) radiographs of bilateral knees other than possible apophyseal fragmentation by a pediatric musculoskeletal radiologist, skeletal maturity, previous surgery, history of hemarthrosis, previous physical therapy (PT), and/or diagnosis of ligament, meniscus, cartilage, or tendon injury. Failure to attend either treatment modality per study protocol was also a subsequent exclusion criteria, though this was recorded as a means of understanding perceived ease of attending treatment visits by the patient and their parents.

During the consenting process, patients and their families agreed to computer randomization into one of two treatment arms: 1) ARP Wave therapy 5 days a week for 4 weeks (a standardize protocol for ARP Wave therapy), or 2) physical therapy within the institution’s PT department (for standardization of the PT protocol) 2 days a week for 6 weeks. Additionally, subjects were willing to cross-over if pain continued after the first round of treatment.

Patients in the PT group, and patients in the ARP Wave group who crossed over to PT, underwent physical therapy utilizing a protocol for atraumatic knee pain that focuses on flexibility and development of hip/core strength over a 6-week period, visiting the therapist twice per week and encouraged to maintain a daily home exercise program (HEP). They received a handout with basic exercises to use at home to ensure that progress with their HEP was maximized, but there was no accounting for the amount of HEP performed. The handout included basic core exercises including, but not limited to: planks, bridges, and other patient-specific directed exercises. Line drawings of basic stretches for the hamstring and quadriceps muscles were also provided.

Patients in the ARP Wave group, and patients in the PT group who crossed over to ARP Wave, underwent a standardized ARP Wave program (following the protocols established for the device as a FDA approved class 2

medical device). The treatment protocol consisted of 20 sessions completed by each individual over a period of 30 days. During that time frame the athletes are not allowed to undergo directed PT, HEP or their normal athletic endeavors to avoid any potential interference with the neuromuscular training particular to this therapeutic modality.

Both cohorts of patients were evaluated weekly, for up to 10 weeks (if crossover occurred), by an independent team of observers who were blinded to the treatment arm. These independent observers administered PROs, including: Pedi-IKDC, Hospital for Special Surgery Pediatric Function Activity Brief Scale (HSS Pedi-FABS), and Kujala scores. Independent observers were not involved with the ARP wave therapy or the physical therapy, and the assessments occurred at the location of convenience and preference for the family (such as the child's school, home, local park, or our gait lab).

An interim analysis for each patient was performed once they completed their first arm of the study by the managing orthopedic surgeon. At that visit, the collected outcome variables (Pedi-IKDC, HSS Pedi-FABS, Kujala) were reviewed to confirm and ensure safety in treatment. Along with outcome collection, all subjects underwent a clinical exam. Those with continued symptoms crossed over to the other treatment group, regardless of outcome scores. Those that crossed over were re-evaluated at the conclusion of their subsequent treatment modality.

Basic descriptive statistics are presented. Due to the low patient number and uneven randomization into the two study groups, data was analyzed with non-parametric tests. The Mann-Whitney U was used to evaluate differences among our groups. The Wilcoxon signed ranks test was used to evaluated changes over time. No a priori power analysis was performed (since this is the first study of ARP Wave therapy), but a post-hoc analysis was done to determine the full extent of sample size needed after the pilot results were evaluated. Statistical analysis was conducted using SPSS (version 28; IBM, New York, NY). Statistical significance was defined as $p<0.05$.

RESULTS

Seventeen patients were enrolled in the study but only 9 patients completed the treatment protocol as outlined by the study design (4 patients dropped out of each group). Of those completing the study, 3 patients were randomized to the PT group and 6 patients were randomized to the ARP Wave group. Two patients in the PT group crossed over into the ARP Wave treatment arm and 1 patient in the ARP wave group crossed over into standard PT. The mean age of patients included was 15.4±1.8 years (median: 15.7, range 12.8 to 17.4 years), with a breakdown between cohorts of mean 16.1 years in the PT group, and mean 15.0 years in the ARP Wave group (p=0.548). All three patients in the PT group were female, and 2/6 patients in the ARP Wave group were female (p=0.167). The PT group included adolescents participating in Dance, Water polo and Running; whereas, the ARP Wave group included: Soccer, Basketball, Volleyball, and Running. Duration of management (inclusive of time with the crossover) was 15.0 weeks in the PT group and 10.9 weeks in the ARP Wave group, p=0.262.

Baseline outcome scores did not differ significantly among the two treatment groups, nor did they differ significantly at the conclusion of the first treatment course (Table 1). Patients treated with ARP Wave therapy im-

Table 1. Distribution of outcomes scores

			N	Mean±SD	Median	Range	p value
Baseline	Pedi-IKDC(%)	ARP	6	54.3±26.9	50.55	23.9 to 96.7	0.548
		PT	3	63.8±7.8	65.20	55.4 to 70.7	
	HSS-Pedi-FABS	ARP	6	21.5±11.1	27.50	2.0 to 29.0	0.548
		PT	3	17.3±3.2	15.99	15.0 to 21.0	
	Kujala (%)	ARP	6	65.8±18.3	63.50	44 to 98	0.262
		PT	3	72.3±3.1	73.00	69 to 75	
End of 1st Tx Course	Pedi-IKDC(%)	ARP	6	80.8±15.9	87.50	53.3 to 96.7	0.262
		PT	3	64.8±8.2	65.20	56.5 to 72.8	
	HSS-Pedi-FABS	ARP	6	61.6±29.4	55.00	26.0 to 96.7	0.262
		PT	3	30.4±28.5	15.99	12.0 to 63.3	
	Kujala (%)	ARP	6	87.2±13	89.00	63 to 100	0.167
		PT	3	77.3±9.1	81.00	67 to 84	

proved in all three scores from baseline to the end of the first course of treatment. Patients treated with PT did not see a statistically significant improvement in any of the outcome measures from baseline to the end of the first course of treatment (Table 2). When looking at the patients who crossed over, we observed no statistically significant difference in any of the three outcome measures when comparing baseline scores to the scores obtained at the end of the first treatment course ($p>0.1$), or from the end of the first treatment course to the end of the crossover sessions ($p>0.1$), or from baseline to the end of the crossover session ($p>0.1$)(Table 3).

Using our observed effect size, the post-hoc power analysis indicated that 32 subjects would be needed to have an 80% chance of detecting a significant difference in HSS Pedi-FABS between outcomes in adolescents undergoing ARP Wave versus traditional PT.

DISCUSSION

Although a small sample size, this pilot study demonstrates the potential impact that ARP Wave therapy may have on the management of adolescent anterior knee pain, especially considering that ARP Wave therapy takes only 4 weeks compared to the standard 6-week PT protocol.

Table 2. Change in outcomes from baseline to end of 1st course of treatment

			N	Mean±SD	Median	Range	p value
ARP Wave	Pedi-IKDC(%)	Baseline	6	54.3±26.9	50.55	23.9 to 96.7	**0.043**
		End of Tx*	6	80.8±15.9	87.5	53.3 to 96.7	
	HSS-Pedi-FABS	Baseline	6	21.5±11.1	27.495	2.0 to 29.0	**0.046**
		End of Tx*	6	61.6±29.4	55	26.0 to 96.7	
	Kujala (%)	Baseline	6	65.8±18.3	63.5	44 to 98	**0.028**
		End of Tx*	6	87.2±13	89	63 to 100	
PT	Pedi-IKDC(%)	Baseline	3	63.8±7.8	65.2	55.4 to 70.7	0.655
		End of Tx*	3	64.8±8.2	65.2	56.5 to 72.8	
	HSS-Pedi-FABS	Baseline	3	17.3±3.2	15.99	15.0 to 21.0	1.0
		End of Tx*	3	30.4±28.5	15.99	12.0 to 63.3	
	Kujala (%)	Baseline	3	72.3±3.1	73	69 to 75	0.285
		End of Tx*	3	77.3±9.1	81	67 to 84	

*end of first course of treatment, this does not include crossover scores
Bold indicates statistically significant values

Table 3. Change in outcomes over time for those that crossed over (n=3)

		Baseline	End of 1st Tx Course	End of Crossover
Pedi-IKDC(%)	Mean±SD	74.3±20.9	75.3±20.2	90.2±10.4
	Median	70.7	72.8	91.3
	Range	55.4 to 96.7	56.5 to 96.7	79.3 to 100
HSS-Pedi-FABS	Mean±SD	21±6	18±7.2	58.9±32
	Median	21	16	53.3
	Range	15 to 27	12 to 26.01	30 to 93.3
Kujala (%)	Mean±SD	80.7±15.3	88.3±10.2	93.3±8.3
	Median	75	84	96
	Range	69 to 98	81 to 100	84 to 100

Comparisons between baseline and 1st treatment course, baseline and final treatment course, and 1st treatment course and final treatment course had a p-value >0.1

The loss of approximately 50% of the patients/families who enrolled into the study suggests that either the intensity of the ARP wave program was too much of a time commitment or that the benign diagnoses were not worrisome enough for families to follow through with prescribed management. Further study is warranted to identify the utility of ARP Wave therapy for these common benign knee pathologies and its potential use in other childhood musculoskeletal injuries; however, these early results of improved PROs with ARP Wave therapy appear to at least rival traditional PT.

Although the technology of ARP Wave therapy has been available for nearly 20 years, there is very little clinical research supporting its utilization. The only clinical trial performed to date is a published report on ARP wave therapy to improve muscle strength after disuse atrophy following anterior cruciate ligament surgery in adults10. This previous work suggests that the electromyostimulation evoked by ARP Wave therapy produces minimal inhibitory protective muscle contractions allowing active range of motion during therapy and training, permitting eccentric contractions to occur that potentiates the ability to mobilize and build muscle. The previous results suggested that quadriceps muscle could be developed in less time when ARP Wave was utilized in conjunction with physical therapy.

The present prospective randomized study identified that ARP Wave therapy could both shorten duration of therapy and significantly improve patient-derived outcome scores within the pilot study sample size, but without disproving our null hypothesis. The intensive process of undergoing ARP Wave therapy is time prohibitive for busy families, especially with students in-season for sports. Patients are instructed that for the duration of the ARP Wave therapy sessions, the patient is not supposed to continue in regular activities or physical therapy, as these may affect the re-education of the muscle groups being treated. This is in contrast to other forms of adjunct electrostimulation that are performed in order to augment standard physical therapy. In fact, it is the greater level of electromyostimulation of ARP Wave (compared to other modalities) that allows this therapy type to be used in isolation to standard physical therapy. Five day-a-week visits, although of shorter duration at each visit, is time consuming for families, and may be counter-indicated as our study did demonstrate a failure to attend visits in 40% of patients in the ARP Wave cohort. However, there was also a 57% dropout rate for the PT group. Therefore, it is difficult to attribute the time-commitment of ARP Wave therapy as the primary reason for failure to complete the assigned treatment regimen. Another possible explanation is that the benign nature of the diagnoses may have relieved patients and their families of any fears, allowing them to return to sport without any therapeutic modality being applied once they were educated on the benign nature of their pain.

There are a few limitations of this study, predominately related to the nature of it being a pilot (small sample size to determine the number to treat), and the lack of controlling for the consistency and effort of the adolescents performing the exercises prescribed. Despite the small sample size, there was an unexpected significant finding related to the primary aim of improved PROs after completing the ARP Wave therapy. The null hypothesis cannot be refuted however, despite a 4-week difference in treatment duration, since the small sample size did not find a statistical difference in the treatment groups. Moreover, since the pilot was performed on non-surgical patients, the commitment of the patients/families to the rehabilitation process is in question. However, perhaps the 5 times a week of ARP Wave therapy is merely akin to patients actually participating in HEP that they obtain from PT. Because compliance with HEP was not monitored, conclusions cannot be drawn regarding this possibility. In reality, the low sample size of our pilot study limits any conclusions that we can draw regarding outcomes; however, the statistical improvement in PROs despite being a low sample size pilot study is encouraging for the utility of ARP Wave therapy.

ARP Wave therapy uses electromyostimulation therapy to safely improve knee pain via strength training and engages the adolescent athlete to participate in their rehabilitation exercises. Our null hypothesis that ARP Wave would not significantly improve the duration of treatment compared to traditional PT is upheld in the small sample size of this pilot study. Notwithstanding, evidence gleaned from our primary aim that ARP Wave therapy would improve PROs suggests that this intense near-daily therapy program is at least as safe and effective as traditional PT. Future studies based on this pilot data may be performed that include both non-surgical and surgical outcomes as no deleterious effects of ARP Wave were noted during the study. For families with the time and means to fully engage with the ARP Wave program, it appears to be worth consideration amongst the various treatment modalities available.

REFERENCES

1. Gould N, Donnermeyer D, Pope M, Ashikaga T. Transcutaneous muscle stimulation as a method to retard disuse atrophy. Clin Orthop Relat Res. 1982;(164):215-220.
2. Laughman RK, Youdas JW, Garrett TR, Chao EY. Strength changes in the normal quadriceps femoris muscle as a result of electrical stimulation. Phys Ther. 1983;63(4):494-499. doi:10.1093/ptj/63.4.494
3. Selkowitz DM. Improvement in isometric strength of the quadriceps femoris muscle after training with electrical stimulation. Phys Ther. 1985;65(2):186-196. doi:10.1093/ptj/65.2.186
4. Antich TJ, Brewster CE. Osgood-schlatter disease: review of literature and physical therapy management. J Orthop Sports Phys Ther. 1985;7(1):5-10. doi:10.2519/jospt.1985.7.1.5
5. Brushøj C, Hölmich P, Nielsen MB, Albrecht-Beste E. Acute patellofemoral pain: aggravating activities, clinical examination, MRI and ultrasound findings. Br J Sports Med. 2008;42(1):64-67; discussion 67. doi:10.1136/bjsm.2006.034215
6. Maffulli N, Longo UG, Spiezia F, Denaro V. Sports injuries in young athletes: long-term outcome and prevention strategies. Phys Sportsmed. 2010;38(2):29-34. doi:10.3810/psm.2010.06.1780
7. Noyes FR, Barber-Westin SD. Neuromuscular retraining intervention programs: do they reduce noncontact anterior cruciate ligament injury rates in adolescent female athletes? Arthroscopy. 2014;30(2):245-255. doi:10.1016/j.arthro.2013.10.009
8. Swart E, Redler L, Fabricant PD, Mandelbaum BR, Ahmad CS, Wang YC. Prevention and screening programs for anterior cruciate ligament injuries in young athletes: a cost-effectiveness analysis. J Bone Joint Surg Am. 2014;96(9):705-711. doi:10.2106/JBJS.M.00560
9. Slotkin S, Thome A, Ricketts C, Georgiadis A, Cruz AI, Seeley M. Anterior Knee Pain in Children and Adolescents: Overview and Management. J Knee Surg. 2018;31(5):392-398. doi:10.1055/s-0038-1632376
10. Wright AR, Richardson AB, Kikuchi CK, Goldberg DB, Marumoto JM, Kan DM. Effectiveness of Accelerated Recovery Performance for Post-ACL Reconstruction Rehabilitation. Hawaii J Health Soc Welf. 2019;78(11 Suppl 2):41-46.