Accepted Manuscript (Uncorrected Proof)

Title: Effects of Kinesio Taping on Pelvic Floor Dysfunctions: A Systematic Review of RCTs

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To appear in: Physical Treatments

Received date: 2024/12/1

Revised date: 2025/01/4

Accepted date: 2025/02/01

First Online Published: 2025/08/03

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Please cite this article as:

Mohamadi S, Boozari S, Delshad V, Esmaeeli M. Effects of Kinesio Taping on Pelvic Floor Dysfunctions: A Systematic Review of RCTs. *Physical Treatments*. Forthcoming 2025. DOI: http://dx.doi.org/10.32598/ptj.16.1.473.2

DOI: http://dx.doi.org/10.32598/ptj.16.1.473.2

Abstract

Objectives: Objectives Pelvic floor disorders span a broad spectrum of common illnesses that impact the pelvic floor

area in various ways. These conditions have a substantial financial, emotional, and physical impact on people, families,

and society as a whole. Several pelvic floor disorders are managed and prevented with kinesio taping (KT). There is

not enough research on KT in pelvic floor disorders. The precise impact of this therapy approach on different pelvic

floor issues is therefore unclear. To gain a clearer understanding the effects of KT in the treatment of various pelvic

floor dysfunctions, the current study set out to conduct a systematic evaluation of all relevant randomized controlled

trials (RCTs).

The following keywords were used to search databases such as PubMed, Scopus, Science Direct, Medline, and Web

of Science: kinesio-taping, kinesiology taping, pelvic floor physiotherapy, pelvic floor conservative treatment, pelvic

floor dysfunction, pelvic floor disorder, vaginal dysfunction, anal or defecatory dysfunction, urethral dysfunction,

urge incontinence, stress incontinence, overactive bladder, constipation, sexual dysfunction, vaginismus, pelvic floor

dyssynergia, erectile dysfunction, pelvic organ prolapse, voiding dysfunction, and chronic pelvic pain syndrome as of

March 2024. The checklist from the Critical Appraisal Skills Program (CASP) was utilized to evaluate the articles'

quality and bias risk. There were six RCTs that satisfied the inclusion/exclusion criteria and and reviewed.

Results: There was insufficient evidence to suggest that incorporating KT is more clinically effective than

placebo or some of other physiotherapy treatment modalities at urinary and defecatory dysfunctions and

pelvic girdle pain including significant decrease in the frequency of incontinence occurrences and

depression test results have positive effects on defecation frequency, duration, consistency, strain, pain and

ultimately improvement of quality of life.

Discussion: The findings revealed that the KT alone or in combination of other physiotherapy treatment

modalities, have beneficial effects on some pelvic floor dysfunctions but because of limitations of studies,

this research area needs more valuable evidences.

Keywords: kinesio taping, pelvic floor dysfunction, incontinence, constipation

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Highlights:

- Kinesio-taping can be an effective complementary modality for management of pelvic floor dysfunctions
- Kinesio-taping has low cost and easy application for treatment of pelvic floor dysfunctions
- Kinesio-taping can be effective alone in some cases of pelvic floor dysfunctions

Plain Language Summary:

There are various treatments for pelvic floor disorders that can be costly and time-consuming, making them unpleasant for the patient. Kinesiotherapy is a physiotherapy treatment that is costeffective, requires very little time commitment, and has no adverse effects on the patient. Research indicates that the use of this therapeutic method alone or in combination with other methods can be effective as a complementary treatment for common cases of pelvic floor dysfunctions for example constipation, urinary incontinence, and even post-surgeries, aiming to reduce pelvic and menstrual pain. However, Given the scarcity of research in this field, additional studies are Accepted Manuscri

Background

Pelvic floor dysfunctions are highly common clinical problems, with wide variety range of disorders¹. In addition to pelvic organ prolapse, these dysfunctions include defecatory and sexual systems, lower urinary tract sensory and emptying abnormalities, intestinal and urinary incontinence, and a number of chronic pain syndromes ^{1,2}. These significantly influence the quality of life., especially in woman population ^{1,2}

Pelvic floor physiotherapy is regarded as a primary, low-risk, minimally invasive therapy for both management and also prevention of pelvic floor dysfunctions ^{3,4}. It includes pelvic floor muscle training, electric impulse therapy, magneto therapy, manual therapy, Laser, acupuncture, behavioral therapy (bowel and bladder training), biofeedback and kinesio taping (KT) ⁴⁻⁶. However, Studies using KT as a simple, safe, non-invasive and inexpensive modality in the pelvic floor conditions are insufficient and its effects in different conditions, have not known sufficiently ⁴.

The lower urinary tract's sensory and emptying problems, the defecatory and sexual systems, pelvic organ prolapse, urine and bowel incontinence, and seThere are several possible causes for KT, such as lowering compression brought on by the skin, fascia, and subcutaneous tissues being raised, which increases bloodlymph circulation and, in turn, reduces inflammation and pain-related chronic pain syndromes ^{4,7,8}. Another possible mechanisms are fascial correction and therefore increment of range of motion, improvement of neuromuscular control and joint position by mechanoreceptor stimulation and kinesthetic awareness ^{5,7,8}. Also we can point to the facilitation or inhibition of muscle activity and injury prevention ⁷. Additionally, various studies suggest that KT application may activate the cutaneous-visceral reflex mechanism associated with Head's zones ⁴⁻⁶.

Despite contradictory data about kinesiology tape's (KT) efficacy in treating different ailments and in healthy people, KT is still a common and widely utilized physiotherapy technique. ^{5,9}. This is because,

that the results of limited studies about therapeutic effects of KT, suggest that KT can be clinically beneficial ⁷. However, Collecting and reviewing the results of valid studies in this area can still pave the way for clinical work and future research. Therefore, despite the potential positive effects of kinesiotaping on pelvic floor dysfunctions, there is limited and unclear research on the topic. This study search for the effects of KT on pelvic floor dysfunction management, evaluating a range of outcomes, in comparison to sham or certain conservative non-KT therapies. Summarizing and analyzing strong and credible studies in this field can create opportunities for future research to conduct more comprehensive and accurate studies

Methods/Design

2.1. Search strategy

The standards of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) served as the foundation for our search approach. ¹⁰. Articles were included which examine the effects of KT alone or combined with other treatment modalities in different pelvic floor dysfunctions. Accessible databases comprising PubMed, Scopus, Science Direct, Medline and web of science were searched from the earliest records to the March 2024. Following syntaxes were used to search relevant articles: (kinesio-taping OR kinesio tape OR kinesiology taping) AND (pelvic floor physiotherapy OR pelvic floor physical therapy OR pelvic floor treatment OR nonpharmacological pelvic floor treatment OR pelvic floor conservative treatment) AND (pelvic floor dysfunction OR pelvic floor disorder OR vaginal dysfunction OR anal dysfunction OR urethral dysfunction OR urinary incontinence OR anal incontinence OR urge incontinence OR stress incontinence OR overactive bladder OR constipation OR sexual dysfunction OR vaginismus OR pelvic floor dyssynergia OR erectile dysfunction OR pelvic organ prolapse OR defecatory dysfunction OR voiding dysfunction OR chronic pelvic pain syndrome). We searched each of the words within

each parentheses (totally, three sets of parentheses) that were separated by OR with each of the word in the next two parentheses which separated with AND, using the "plus sign" so that with each search, we had three words or phrases, and in this way, we found all relevant articles (e. g. kinesio-taping + pelvic floor physiotherapy + pelvic floor dysfunction,. ...). In addition, the references at the end of the selected articles were checked.

2.2. Eligibility criteria for study selection

First, two independent authors (SM and SB) considered the eligibility of the obtained studies by their titles and abstracts to identify which one can be included for peer review. PICOS (population, intervention, comparison, outcomes, and study design) criteria were used to assess whether a study was eligible. In the present systematic review the PICOS was as follows: **P**: patients with pelvic floor dysfunctions, **I**: kinesio taping, **C**: comparison with other conservative treatment modalities, **O**: improvements in quality of life, pelvic floor muscle strength, bowel and bladder symptoms, discomfort, disability, and other aspects S: controlled clinical trials that are randomized.

The two researchers reviewed full-text papers if titles or abstracts did not contain sufficient information for eligibility. Duplicates were eliminated, and if the two investigators could not agree on whether any included studies were eligible, a third investigator (VD) made the final decision based on the precise inclusion and exclusion criteria, results, and research design (PICOS). In the current study, the inclusion criteria were noticed as: (1) the papers should compare KT with sham KT or other conservative treatment modalities (2) the studies investigated the pelvic floor dysfunctions (3) the studies reported any parameters related to improvement in the pelvic symptoms (pain, pelvic floor muscle performance disability, bowel and bladder symptoms, quality of life and etc.) (4) Randomized controlled clinical trials only and (5) full-text original articles were published in the English language.

The articles were excluded if: they were published in the other languages, if the articles were published or presented in a conference, seminar or thesis and researches published in a summarized form.

2.3. Quality assessment

Studies that included in the current systematic review were evaluated using the Critical Appraisal Skills Program (CASP) checklist for clinical trial studies in terms of methodological quality ¹¹. This checklist consisted of 11 questions for Randomized Controlled Trial studies in the four sections. The section **A**, comprises 3 questions indicating "Is the study design appropriate for a randomized clinical trial? The section **B**, include 3 questions indicating "whether the study methodologically sound?" The section **C**, comprises 3 questions and is about "what are the results?" Finally section **D**, comprises 2 questions and indicate "whether the results help locally?" The questions can be answered with "yes", "no" or "can't say". All studies were scored by the same two independent investigators that assessed the eligibility of the studies. If there was found any disagreement about answering to any question in each article, the two investigators discussed the differences to reach a final decision. If the disagreement was not solved, the third researcher involved in the discussion panel in order to achieve the consensus. The final agreement was reached based on the majority opinion.

2. 4. Data extraction

Information from all included studies was extracted and summarized in form of table as follows: authors and year of publication, study design, diagnosis, participant's characteristics (group type and sample size), outcome measures (pelvic pain, pelvic floor muscles strength, questionnaires, voiding diaries) and main results.

Results:

A total of 1545 possible articles were discovered in the first search using the databases listed in the search strategy. Once duplicates were eliminated, 986 records were left. Following the title, abstract, and full test screenings, if required, in accordance with the inclusion and exclusion criteria, there were only 27 acceptable articles left. Nine research were found to be eligible after taking the CASP checklist into account. Ultimately, six studies were chosen for examination after receiving moderate to high quality ratings.

A flow chart of PRISMA ¹⁰, is displayed in Figure 1.

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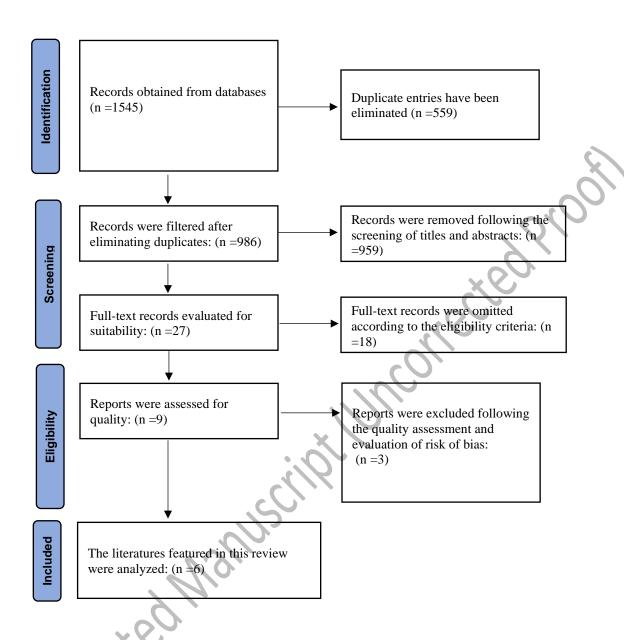


Fig. 1. PRISMA diagram of the literature explore

3.1. Results of included studies

A summary of the relevant articles, presented in Table 1.

According to the above-mentioned results, of 6 studies, the urinary system conditions was investigated in three studies ⁴⁻⁶, defectory conditions was assessed in three studies ^{12,13}, coccydynia was assessed in one study ¹⁴.

Due to the scattered and inconsistent outcome measures in the studies, it was not possible to calculate the effect size or conduct a meta-analysis.

Table 1: summary of the study's results in details by type of dysfunctions (chronologically)

Row	Authors	Study design	Diagnosis	Participants	Outcome	Main results
	(year)			and	variables	
				intervention		
1	Orhan	RCT	chronic	CTM (13)	7-day bowel	Significant
	(2016)	•	constipation	KT (14)	diaries,	differences
				Control	BSFS,	were
		20		(13)	VAS,	observed in
		19			PEDsQL	the changes
						of
						defecation
		11.0				frequency,
						defecation
						duration,
						BSFS, VAS,
	v (),					and total
						PEDsQL
	U					scores.
2	Azam	RCT	Bowel	KT+IF+Tra	DF,	There was a
(0)	(2017)		control	ditional PT (15)	VAS,	notable
			problem	Traditional	CSS	reduction in
				PT (15)		the
•						constipation
						scores and
						abdominal
						pain
						following
						treatment

3	Krajczy	RCT	urinary	KT (31)	Number of	The
	(2018)		incontinence	ST (29)	incontinenc	research
	,			` ,	e	group
					Incidents,	revealed a
					depression	significant
					test	reduction in
						incontinenc
						e incidents
						and an
						improvemen
						t in mental
						well-being
						in
						comparison
					9,	with the
					. 00	control
					XC	group
4	Celena	RCT	OAB	PFMT+KT	OAB-V8	The
	у	1.01	0.10	(16)	PPIUS	PFMT+KT
	(2020)			PFMT+ST	diary	group
	(2020)			(16)	MOS	showed a
					KHQ	significant
					bladder	reduction in
					function	daily
					with a 3-day	incontinenc
			X		voiding	e episodes,
					, ording	daily voids,
						nightly
		. (voids, and
		, (2)				scores in the
						KHQ
		Mo.				compared to
						the
						PFMT+ST
						group
5	Celena	RCT	OAB	KT+ PFME	voiding	There was a
	v	,	- 	(25)	diary	notable
	(2021)			ES + PFME	OAB-V8	decrease in
				(25)	PFMS with	the number
-6	7.			PFME(25)	perineomete	of voids
(6)				, ,	r, KHQ	along with a
NO						decline in
						KHQ and
•						OAB-V8
						marks, and
						an enhanced
						perception
						of
						improvemen
						t.
						ι.

6	Mosad	RCT	post-	KT+CT(14)	PNRS	Overall, the
	(2023)		colonoscopy	PFE+CT(14	ODI	CT-KT
			coccydynia)		group
				CT(14)		showed
						notable
						improvemen
						t.
						Considering
						impact on
						ODI, there
						was no
					- 4	significant
					0'	difference
					7 /	between the
					0	groups

Abbreviations: randomized controlled trial (RCT), connective tissue manipulation (CTM), Kinesio Taping (KT), Bristol Stool Form Scale (BSFS), Visual Analog Scale (VAS), and Pediatric Quality of Life Inventory (PEDsQL), Interferential current stimulation (IF), Physical Therapy (PT), defectation frequency test (DF), constipation score system (CSS), sham tape (ST), overactive bladder (OAB), pelvic floor muscle training (PFMT), Overactive Bladder Assessment Form (OAB-V8), Patients' Perception of Intensity of Urgency Scale (PPIUS), Modified Oxford Scale (MOS), quality of life with the King's Health Questionnaire (KHQ), external electrical stimulation (ES), pelvic floor muscle exercise (PFME), pelvic floor muscle strength (PFMS), conventional therapy group (CT), pelvic floor exercise group (PFE), Pain Numeric Rating Scale (PNRS), Oswestry Disability Index (ODI).

3.2. Quality assessment

All of the featured articles had an average quality that was rated as moderate to high. Table 2 provides a summary of the CASP findings. High applicability has been shown by the included randomized controlled trial trials.

Table 2. Critical Appraisal Skill Program (CASP) to assess the methodological quality for the case-control studies

Questions	Orhan (2016)	Azam (2017)	Krajczy (2018)	Celenay (2020)	Celenay (2021)	Mosad (2023)
1. Did the study tackle a well-defined research question?	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the allocation of subjects to interventions done randomly?	Yes	Yes	Yes	Yes	Yes	Yes
3. Were all subjects who joined the study take for at its conclusion?	Yes	Yes	Yes	Yes	Yes	Yes
4. • Were the subjects unaware of the intervention they received?	Can't tell	Can't tell	Can't tell	No	No	No
• Were the examiners 'blind' to the intervention they were giving to subjects?	Yes	No	No	No	No	No
• Were the individuals evaluating the outcomes blinded?	Yes	No	No	Yes	Yes	Yes
5. Were the groups of study comparable at the beginning of the randomized controlled trial?	Yes	Yes	Yes	Yes	Yes	Yes
6. Aside from the investigational intervention, did each study group obtain comparable levels of care (that is, were they treated equally)?	Yes	Yes	Yes	Yes	Yes	Yes
7. Was the impact of the intervention	Yes	Yes	Yes	Yes	Yes	Yes

presented in a thorough way?						
8. Was the	Yes	Yes	Yes	Yes	Yes	Yes
accuracy of the						
estimated						
intervention or						
therapy influence						
provided?						
9. Do the	Yes	Yes	Yes	Yes	Yes	Yes
advantages of the						
investigational						~>
intervention						9
surpass its risks					, V '	
and expenses? 10. Can the	Yes	Yes	Yes	Yes	Yes	Yes
findings be	1 68	168	1 68	168	Tes	168
relevant to your						
local community						
or situation?				36		
11. Would the	Yes	Yes	Yes	Yes	Yes	Yes
investigational				.0)		
intervention offer						
more benefits to			11/1			
subjects compared			1//),			
to the current						
interventions?						
Total score	11	10	10	10	10	10
Applicably	Highly	Highly	Highly	Highly	Highly	Highly

Discussion:

This systematic review was conducted on previous studies that investigated improvement of pelvic floor dysfunction with KT compared with other conservative treatment modalities by different outcome measures. The KT combined with other conservative treatments showed better therapeutic results for pelvic floor dysfunctions. Regarding the findings of the reviewed studies, most studies reported positive outcomes with KT, but methodological limitations and inconsistent results warrant caution.

4. 1. Outcome measures among the three groups of the studies based on affected system

4. 1. 1. Effect of KT on Urinary system conditions (lower urinary tract symptom)

Urinary system conditions encompass a range of symptoms and refer to certain types of functional disorders affecting the lower urinary tract, which are highly prevalent syndromes ⁵. Physiotherapeutic methods including KT have recommended and recognized treatment methods for urinary incontinence but there have been very few studies in this area ⁶.

In a survey by Krajczy et al (2018), which examine the effects of 4 days of KT in two groups (KT and placebo KT), of children with urinary incontinence, on the number of incontinences and their mental state ⁶. The frequency of incontinence episodes and depression test results, have reduced significantly which demonstrated that KT had a positive impact on patients' mental health. ⁶. The mechanism behind this effect can be explained as follows: the reflex action from KT applications in the lower abdominal and sacral areas may enhance proprioception and help regulate the tone of the musculofascial bladder and urinary tract system ⁶. The limitations of this study was the lack of a quantitative assessment of incontinence, such as urine volume, as well as other factors like somatic characteristics. Additionally, the lack of blinding in the Krajczy study could introduce bias into the study results in the intervention group ⁶.

In a study by Celenay et al. (2020) the effects of pelvic floor muscle training (PFMT) with KT (per Kenzo Kase's KT Method) were assessed. ¹⁵ with PFMT plus sham tape (ST) in women with overactive bladder (OAB) syndrome for 6 weeks ⁵. In comparison to PFMT+ST, they find that PFMT+KT was more successful in lowering OAB symptoms and the sense of urgency, as well as in improving PFM strength, bladder function, and quality of life. Additional improvements in the PFMT+KT group over the PFMT+ST group may be due to KT's ability to regulate the tone of the musculofascial system in the area associated with the bladder reflex. Based on these findings, KT may be a further treatment option for

OAB symptoms. ⁵. However, the weaknesses of this study were only evaluating short-term effects of KT and lack of blindness. Also, .the current study did not include urodynamic evaluation ⁵. In a different study, Celenay et al. (2021) compared the effects of external electrical stimulation (ES) or Kenzo Kase's KT Method in addition to pelvic floor muscle exercise (PFME) with solitary PFME in three groups of women with OAB over a 6-week period using the same outcome measures as their earlier study. ⁴. They discovered that when combined with PFME, KT and ES were more successful than PFME alone at reducing OAB symptoms, improving quality of life, and creating a sense of improvement. ⁴. The control of myofascial tone may be the cause of these improved outcomes when KT is applied in the bladder reflex area. This trial, like the previous ones, did not assess the long-term effects of KT, blindness, or urodynamic assessment.

Incorporating KT, a simple, non-invasive, and secure technique, into the treatment regimens for patients with urinary system problems could enhance the effectiveness of the programs in alleviating related symptoms and enhancing quality of life by affecting Enhancing bladder tone and boosting proprioception by heightening patients' bladder awareness. However, we need evidences that are more decisive.

4. 1. 2. Effect of KT on Defecatory system conditions

There is a lack of adequate research utilizing KT in bowel problems. Based on the studies conducted on the bowel dysfunctions in children, KT has a positive effect on bowel symptoms including constipation and bowel control ¹³.

In relation to constipation, in the study by Orhan (2016), in cerebral palsy (CP) children which survey the impact of connective tissue manipulation (CTM), compared with two model of KT group and control group for 4 weeks ¹³. This study showed that both CTM and KT are similarly

effective approaches for managing pediatric constipation. The CTM and KT were found to have positive effects on defecation frequency, duration, consistency, discomfort, strain and overall quality of life in CP children with chronic constipation. ¹³. The likely mechanisms of KT involve stimulating the reflex zone of the bowel, reducing abdominal bloating and discomfort and promoting bowel movements, through the application of KT on the abdominal area ¹³. The robustness of this study include the utilization of reliable measurement tools to evaluate bowel symptoms and the application of the non-invasive intervention known as KT. However, inability of a double blind, placebo-controlled trial and absence of long term follow up, were limitation of this study ¹³.

In another study by Azam (2017), the researcher examined the impact of combining lower abdominal KT, interferential (IF) electrical stimulation, and routine traditional physiotherapy (PT), compared to a control group that received only routine traditional physiotherapy, over a period of 12 weeks. He found in the enhancement of bowel control among children with meningomyelocele in the research group as opposed to the control group. ¹². The assessment of defecation frequency per week (DF), the use of the visual analog scale (VAS) to measure abdominal pain, and the constipation score system (CSS) to evaluate changes in bowel control all demonstrated significant improvement in the group that received KT plus IF plus PT ¹². Through the application KT on the lower abdomen and sacral region, blood and lymph circulation in these areas improve, alongside stimulating cutaneous mechanoreceptors like free nerve endings, Pacini corpuscles, and Ruffini endings within the fascia. This process provides the central nervous system (CNS) with data regarding pain and position. The activation of mechanoreceptors via KT results in a reduction in sympathetic nervous system activity and an elevation in parasympathetic activity, leading to better bowel control by increase intestinal tone and intestinal peristalsis movements ¹⁶. However, there

is insufficient studies about the effects of KT on defecatory system in general population and high quality methodology, which makes drawing definitive conclusions difficult.

4. 1. 3. Effect of KT on pelvic girdle pain

In a related study organized by Mosaad et al. (2023) on the management of post-colonoscopy coccydynia, the researchers compared the effects of adding KT to conventional therapy (CT) with pelvic floor exercise (PFE) and CT in both groups. The study involved a 4-week training period. The results indicated that CT-KT demonstrated greater effectiveness than CT-PFE in decreasing pain linked to coccydynia following a colonoscopy. Nevertheless, there was no notable difference between their impacts on functional disability, as assessed by the Oswestry Disability Index (ODI)

Numerous studies have revealed that kinesiology tape (KT) is effectual in alleviating pain and enhancing functional ability ¹⁷⁻¹⁹. KT is considered a highly effective technique to enhance blood and lymphatic circulation, restore muscle tension and realign joints ²⁰⁻²². One proposed mechanism is that KT application offers cutaneous stretch stimulation, which lead to pain inhibition by gait control theory ²³. Additionally, it is supposed that the application of kinesiology tape (KT), will enhanced afferent feedback which may stimulate the neuromuscular pathways ²⁴.

A possible explanation for the lack of improvement in functional disability following the use of KT and PFE may be insufficient treatment duration and inadequate loading of these modalities to promote the enhancement of patients' functional abilities. Therefore, it is possible that a longer duration of treatment and higher loading will be necessary to improve the patient's functional disabilities and ODI scores.

4. 2. Outcomes of the three groups of the studies

Taking everything into account, KT has become one of the most commonly utilized physiotherapy methods. Nevertheless, to our current understanding, there aren't many studies examining the effects of KT alone on pelvic floor conditions in the literature, and the ones that do exist are of a moderate caliber and produce inconsistent, ambiguous findings. Furthermore, it is challenging to compare, for instance, bowel and bladder dysfunctions, children and adults, or men and women. Another factor that makes this comparison challenging is that few research evaluate the impact of KT application as a stand-alone technique in comparison to sham or placebo effects, and the majority of studies combine KT applications with other conservative treatment techniques.

Limiting the reviewed sources to only English language articles, excluding theses, presentations, etc., and the inability to conduct a meta-analysis or calculate effect sizes due to the small number of studies and the diverse, scattered variables examined, were limitations of our review study.

To enhance the applicability of the findings, it is advised that future research with a sufficient sample size look into additional parameters, such as the quantitative assessment of incontinence (urodynamic outcomes, such as urine volume) or other parameters, like the somatic characteristics (the demographic and physical characteristics of subjects). ⁶. It appears that it is possible to identify the traits that are beneficial for treatment by looking at other factors. Additionally, studies that examine the durability and Future research is needed to explore the long-term outcomes of kinesio taping on patients with various pelvic floor issues.

5. Conclusion

According to the scant research that is currently available, KT by alone or in conjunction with other conservative therapy approaches may benefit people with pelvic floor dysfunctions both physically and psychologically. In order to enhance pelvic floor symptoms and Patients with pelvic floor dysfunction may experience an improved quality of life through the incorporation of kinesiology taping (KT), a

straightforward, non-invasive, safe, and effective adjunctive technique. Therefore, KT could be considered a complementary therapy for urinary incontinence and defecatory disorders, but further high-quality RCTs with standardized protocols and larger, multi-center trials are needed.

Ethical Considerations and Ethical Approvals:

Not related

Conflict of interest

There are no conflicts of interest of any type in this study

Funding and Supporting:

VCC66/169/N/9/

None, We had not any funding for doing this research

Acknowledgment:

None

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