

Peer Review File

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<i>Reviewers' comments</i>	<i>Authors' Response</i>
<p>Reviewer: A</p> <p>I think you need to mention you are running the statistics for penile length at the start of Outcome Measures Line 190. You don't mention penile length until line 204. I think before you start discussing the REML it would be useful to mention what characteristic you are analyzing. This goes for all three penile length, curvature, and EF.</p>	<p>Thank you, we added two paragraphs in the beginning of the outcome measures (Line 217-225).</p> <p>"Our study aims to investigate the effects of certain factors on male sexual health. Specifically, we analyze three key characteristics: penile length, curvature, and erectile function (EF). In this paper, we present the results of our analysis using a random effects model and discuss the implications of our findings.</p> <p>To assess the impact of these factors on male sexual health, we utilized a random effects model. Before delving into the details of the statistical analysis, it is important to explicitly mention the characteristics we focused on: penile length, curvature, and EF. By examining these aspects, we aim to gain insights into the relationship between these variables and overall sexual health outcomes.</p>
<p>Reviewer: B</p> <p>Can the authors clarify the actual study numbers for this review? The results section states there were 52 studies and after reviewing abstracts, 31 were assessed further. Why wasn't the full text of all 52 checked?</p>	<p>Thank You for addressing these points: The actual studies number are corrected in both the PRISMA table as well as study search results. The total studies included in the manuscript are 5.</p>
<p>Reviewer: B</p> <p>This number 52 does not show up in Figure 1? How many studies were identified to begin with?</p>	<p>Thank you, Corrected in both the PRISMA table as well as study search results.</p>
<p>Reviewer: B</p> <p>Table 3 should include disease duration or at least acute vs chronic phase.</p>	<p>Done.</p>
<p>Reviewer: B</p> <p>Another limitation that should be pointed out is the lack of dividing the studies into acute or chronic stage treatment. Treatment timing can be crucial for PD and</p>	<p>Thank you, we added in limitation the lack of dividing the studies into acute or chronic stage treatment.</p> <p>We added a column in table 3 a time of intervention.</p>

<p>the authors indirectly alluded to that in the discussion but it would be worth highlighting this more clearly.</p>	
<p>Reviewer: C</p> <p>1. While no change in erectile function or length is noted, the trends in both appear beneficial and hampered by wide confidence intervals. Do you think the lack of statistical support is due to under-powering of the meta analysis?</p> <p>2. Can you calculate the mean degrees of improvement in curvature?</p> <p>3. Peyronie’s disease affects men’s quality of life to varying extents which may be studied using patient reported outcome measures. Is there PROM on overall satisfaction with traction therapy?</p>	<p>Thank You for addressing these points:</p> <ol style="list-style-type: none"> 1. We addressed this point in limitation Line (367-376). 2. We added this point in line (244-245): Based on the random-effects model analysis, we find a statistically significant effect of the degree of curvature ($p = 0.0373$) with mean improvement = 15.675 degrees. 3. Unfortunately, the included studies did not assess the quality of life and satisfaction level.
<p>Reviewer: D</p> <p>The results are educational to the reader: 1) understanding the limited literature available and 2) the MA results showing improvement for curvature only. Table 3 will benefit from two additional columns describing the type of device used and the setting in which traction was being applied - alone, combined with injection, after a primary therapy, etc. Tables 1 and 2 could be moved to supplementary.</p>	<p>Table 3, Done.</p>
<p>Reviewer: E</p> <p>I would make the title more clear. Instead of saying "The outcome of Penile traction device...", be more specific. Something likes "The effect of penile traction device in men with Peyronie's disease on penile curvature, penile length, and erectile dysfunction: A systematic review and meta-analysis."</p>	<p>Thank you for the suggestion , the titele has been changed.</p>
<p>Reviewer: F</p> <p>English should be improved with help of a native speaker.</p>	<p>Thank you, the English language was rechecked and edited from a native speaker.</p>
<p>Reviewer: F</p> <p>There is a recent SR on the penile modeling published on SMR: 10.1016/j.sxmr.2022.01.001 It includes other papers on PTT compared to studies included in this article. I would like know the reason of</p>	<p>Thank You, reasons for exclusion explained described below study by study.</p>

<p>exclusion for each of the following papers. It is obvious that even just one paper excluded by mistake compromises all the results of the meta-analysis! Why the authors excluded these papers?</p> <p>Capoccia E, Ziegelmann M, Emmerson J, et al. Long-term patient-reported outcomes in men with Peyronie's disease undergoing nonsurgical and nonintralesional injection management. <i>Int J Impot Res</i> 2021;33:75–81.</p>	<p>The reason of exclusion: (no comparator “placebo”)</p>
<p>Reviewer: F</p> <p>24. Fernandez-Pascual E, Manfredi C, Cocci A, et al. A novel penile splint as early traction therapy after grafting techniques for Peyronie's disease. <i>J Sex Med</i> 2020;17:1819–1824.</p>	<p>The reason of exclusion: (no comparator “placebo”)</p>
<p>Reviewer: F</p> <p>25. Ziegelmann M, Savage J, Toussi A, et al. Outcomes of a novel penile traction device in men with Peyronie's disease: a randomized, single-blind, controlled trial. <i>J Urol</i> 2019;202:599– 610.</p>	<p>The reason of exclusion: no access on full text</p>
<p>Reviewer: F</p> <p>26. Alom M, Sharma KL, Toussi A, et al. Efficacy of combined collagenase clostridium histolyticum and RestoreX penile traction therapy in men with Peyronie's disease. <i>J Sex Med</i> 2019;16:891–900.</p>	<p>The reason of exclusion: no comparator “placebo”</p>
<p>Reviewer: F</p> <p>27. Wymer K, Kohler T, Trost L. Comparative cost-effectiveness of surgery, collagenase clostridium histolyticum, and penile traction therapy in men with Peyronie's disease in an era of effective clinical treatment. <i>J Sex Med</i> 2019;16:1421–1432.</p>	<p>The reason of exclusion: Different comparator and outcomes.</p>
<p>Reviewer: F</p> <p>30. Yafi FA, Pinsky MR, Stewart C, et al. The effect of duration of penile traction therapy in patients</p>	<p>The reason of exclusion: The treatment approach involves the use of penile traction therapy alongside intralesional injection of interferon α-2b.</p>

<p>undergoing intralesional injection therapy for Peyronie's disease. J Urol 2015;194: 754–758.</p>	
<p>Reviewer: F</p> <p>32. Rybak J, Papagiannopoulos D, Levine L. A retrospective comparative study of traction therapy vs. no traction following tunica albuginea plication or partial excision and grafting for Peyronie's disease: measured lengths and patient perceptions. J Sex Med 2012;9:2396–2403.</p>	<p>The reason of exclusion: Contradicted to PICO</p>
<p>Reviewer: F</p> <p>33. Abern MR, Larsen S, Levine LA. Combination of penile traction, intralesional verapamil, and oral therapies for Peyronie's disease. J Sex Med 2012;9:288–295.</p>	<p>The reason of exclusion: penile traction therapy (PTT) when added to intralesional verapamil injections (IVI) combined with oral L-arginine 1g bid and pentoxifylline 400 mg in men with PD) “Different treatment”</p>
<p>Reviewer: F</p> <p>35. Levine LA, Newell M, Taylor FL. Penile traction therapy for treatment of Peyronie's disease: a single-center pilot study. J Sex Med 2008;5:1468–1473.</p>	<p>The reason of exclusion: (noncontrolled pilot study) “should not be involved in meta-analysis”</p>
<p>Reviewer: F</p> <p>Abstract should be improved in the Results and Methods section. These sections are too vague. Results section of Abstract should be more concrete by entering numerical values, percentages, p-values, etc.</p>	<p>Thank you, changes has been made.</p>
<p>Reviewer: F</p> <p>The authors include studies on patients in acute and chronic phase of PD. Sub-analyses are mandatory.</p>	<p>Thank you, unfortunately no sufficient input for sub-analysis.</p>
<p>Reviewer: F</p> <p>Line 86: lack of reference.</p>	<p>Thank you, the reference has been added.</p> <p>Segal RL, Burnett AL. Surgical Management for Peyronie's Disease. World J Mens Health. 2013;31(1):1-11.</p>

<p>Reviewer: F</p> <p>Lines 96-99: the relatively high cost and the need to use the extenders for several hours a day limiting personal freedom and stressing the patient should be underlined as disadvantages of PTT. Besides, I suggest to add a reference</p>	<p>Thank you, the reference has been added.</p> <p>Toussi A, Ziegelmann M, Yang D, Manka M, Frank I, Boorjian Stephen A, et al. Efficacy of a Novel Penile Traction Device in Improving Penile Length and Erectile Function Post Prostatectomy: Results from a Single-Center Randomized, Controlled Trial. Journal of Urology. 2021;206(2):416-26.</p>
<p>Reviewer: F</p> <p>Line 101: I suggest to replace “its use for curvature correction prior to penile prosthesis insertion” with “its use for curvature correction before surgery or to attempt to avoid surgery”</p>	<p>Thank you, the sentences has been replaced.</p>
<p>Reviewer: F</p> <p>Line 119-120: Authors PTT wrote “studies evaluating penile traction therapy as a secondary therapy following the primary intervention or before surgery for Peyronie's disease”. Then in lines 127-129 they wrote “In addition, studies were included if they met the following criteria: either all included men who received special primary treatment for PD (injection or surgical treatment) or a group of men who underwent adjunct penile traction after primary treatment or PTT as primary treatment”. The two sentences contradict each other and above all the second seems confused. I recommend clarifying this important point</p>	<p>Thank You, We paraphrased the whole paragraph to make sure there is no contradictory, Line (132-141)</p>
<p>Reviewer: F</p> <p>Search strategy should be clarified. Were chronological or language restrictions applied? How were searched the keyword (full-text, title/abstract? How was used the Boolean operators?). I suggest to add as Supplementary material the exact search string and search setting used for each database.</p>	<p>Thank you, the search strategy that has been updated and the supplementary material of the exact search string and search setting used for each database has been added in the attached file.</p>
<p>Reviewer: F</p> <p>The authors should use the PICOS model to explicit the inclusion criteria.</p>	<p>Thank you, PICOS model has been added , line (132-136).</p>

<p>Reviewer: F</p> <p>The authors wrote: “comparison was matched placebo or follow-up” I recommend to add “or no treatment”</p>	<p>Thank you, “or no treatment.” Has been added , line 135 and 141.</p>
<p>Reviewer: F</p> <p>Lines 131-132: This seems a sentence a random meaningless sentence. The authors should check.</p>	<p>Thank You, the sentence has been deleted.</p>
<p>Reviewer: F</p> <p>Line 134: The authors exclude case series. So I suppose that all studies included had a comparative group (otherwise they are by definition case series). For example Gontero et al seems to be a non comparative study . The authors should check this point.</p>	<p>Thank you for the valid point. We checked this point case series has been removed from the paragraph.</p>
<p>Reviewer: F</p> <p>Line 145: I suggest to add “follow-up”</p>	<p>Thank you, “follow-up.” Has been added , line 159.</p>
<p>Reviewer: F</p> <p>Line 148: the primary outcome should preferably be only one. The others may be secondary outcomes</p>	<p>Thank You, We added the primary outcome is the penile length before and after the intervention, while secondary outcomes include the degrees of curvature and various parameters related to erectile function. Line (167-170).</p>
<p>Reviewer: F</p> <p>Authors should specify whether erectile function was extracted only when assessed with validated tools.</p>	<p>Thank You, We added Erectile function was evaluated using the International Index of Erectile Function (EF-IIEF) scores. Line (170-171).</p>
<p>Reviewer: F</p> <p>Line 160: the last sentence is redundant</p>	<p>Line (175-176) also the reference were added</p>
<p>Reviewer: F</p> <p>NOS is valid only for nonrandomized COMPARATIVE studies. If any study has no comparative group this score</p>	<p>Thank you, the non-comparative study is deleted so NOS can be used.</p>

<p>is not valid and should be replaced with another. For example Gontero et al seems to be a non-comparative study. The authors should check this point.</p>	
<p>Reviewer: F</p> <p>I suggest to add references to justify the proposed cut-off of Jadad, NOS scores, I² statistic</p>	<p>Thank you, the reference added in line 178.</p> <p>Thorlund K, Imberger G, Johnston BC, Walsh M, Awad T, Thabane L, et al. Evolution of heterogeneity (I²) estimates and their 95% confidence intervals in large meta-analyses. PLoS One. 2012;7(7):e39471.</p>
<p>Reviewer: F</p> <p>Line 168: I suggest to justify this sentence with a reference</p>	<p>Thank you, the sentence has been removed because I did not find any reference corresponding to it.</p>
<p>Reviewer: F</p> <p>The discovery of so few papers (39) for the research strategy adopted is strange. The authors should justify it adding as Supplementary material the exact search string and search setting used for each database and the exact number of papers found with each database.</p>	<p>Thank you, the search strategy that has been updated and the supplementary material of the exact search string and search setting used for each database has been added in the attached file.</p>
<p>Reviewer: F</p> <p>I suggest to add the mean number of patients and mean follow-up in the Results section</p>	<p>Thank you, the mean number has been added, line 212.</p>
<p>Reviewer: F</p> <p>The authors should replace Figure 1 with PRISMA 2020 flow diagram. The authors used a previous version.</p>	<p>Thank you, PRISMA diagram has been updated (Figure 1).</p>
<p>Reviewer: F</p> <p>The authors should add the reasons of exclusion of full-texts</p>	<p>Thank you, edited</p>
<p>Reviewer: F</p>	<p>Thank you, the meaning of all abbreviations has been used and are added.</p>

<p>The authors should add the meaning of all abbreviations used in the legend of each Table</p>	
<p>Reviewer: F</p> <p>Table 4: The author should specify that erectile function was reported as IIEF-EF. Besides, the author should check that all scores correspond to the same variant of IIEF (IIEF, IIEF-5, IIEF-EF). If not, the meta-analysis on IIEF could be not valid.</p>	<p>Thank You, We mention that clearly, Erectile function was evaluated using the International Index of Erectile Function (EF-IIEF) scores. Line (170-171).</p>
<p>Reviewer: F</p> <p>Table 6: I suggest to add the related percentage close to each adverse event. Besides, I suggest to remove the column on side effects in Table 4 (it is redundant)</p>	<p>Done.</p>
<p>Reviewer: F</p> <p>Table 5 is useless due to the performed meta-analysis. I suggest to remove it</p>	<p>Thank You, Table 5 has been removed upon your recommendation.</p>
<p>Reviewer: F</p> <p>The authors should a table with the device for PTT and the protocol of application of PTT in each study.</p>	<p>Thank You, We added Study objectives and protocols in Table 5</p>
<p>Reviewer: F</p> <p>The authors should add the references of papers in each Table</p>	<p>Thank you, the references of papers in each table has been added</p>
<p>Reviewer: F</p> <p>I suggest to report the p-values for the total estimated effect in each figure</p>	<p>Thank you, the p-values for the total estimated effect in each figure has been added.</p>
<p>Reviewer: F</p> <p>Outcome measures subsection in Results section should be rearranged to make it clearer. Too many useless</p>	<p>Thank you, the changes have been made, line (191-199).</p>

<p>numbers (especially due to heterogeneity data), repetitive sentences.</p>	
<p>Reviewer: F</p> <p>Lines 198-201: the authors should specify that they referred to penile length</p>	<p>Thank you, has been referred to penile length, line 234.</p>
<p>Reviewer: F</p> <p>I suggest to add among the limitations the low-to-intermediate quality of included studies</p>	<p>Thank you, added in line 366.</p>
<p>Reviewer: G</p> <p>this is well designed and performed metanalysis informing the role of PTD in the treatment of PD Here are my comments:</p> <ol style="list-style-type: none"> 1. Three areas of improvement in penile length, erectile function and curve need to be highlight and I do recommend separate them into three section to shows the clinical improvement. Lumping together could be confusing and difficult to review 2. It appears that three PTD devises reviewed- RestoreX, Andropenis and Penimaster? Is there other devises that need to be included? Please ensure you cover this area and may indicate any future devise development in this area 3. Patient selection and underlying causes of PD could play part of how PD respond to PTD. Please specify different causes of PD in each category like post radical prostatectomy vs traumatic vs congenital. Could you elaborate more. I assume the most studies area is post radical prostatectomy/penile rehab? 4. Coupling PTD with PD medical treatment such as Injectable could improve efficacy in PD curve correction and length? I was not clear on this. Could you please clarify? 5. Cost of PTD in USA could be an issues and supply issues worldwide. Can you please elaborate on this matter 6. Please provide future directions on PTD devise development and innovation 	<p>Thank You for addressing these points:</p> <ol style="list-style-type: none"> 1. penile length, erectile function and curve has been separated into three sections. 2. we found only mentioned devices and have been discussed. 3 Thank You, the aim of this review to is assess the PTD in general on PD without take in concern the underlying cause. Moreover, we added in table 5 summary of the objectives for each study. 4. We added a section abouth combining the treatment , Line (273-289). 5. we added about that fact of the cost effectiveness of PTD, Line (108-112). However the cost effectiveness of PTD was not among study scope of interest other than focus on its clinical impact on PD treatment. 6. we added below section of limitation: Future direction and recommendation: line (374-399).

<p>Reviewer: H</p> <p>Line 42: delete "finally"</p>	<p>Done.</p>
<p>Reviewer: H</p> <p>Line 55, Line 81, Lne 120, Line 125: please use PD after Peyronie's disease once has been spelled out in full. Look through the whole script to secure this, there are several</p>	<p>Done.</p>
<p>Reviewer: H</p> <p>Line 74: AND after (ED)</p>	<p>Done.</p>
<p>Reviewer: H</p> <p>Line 95: What other symptoms. Either mention them, write THE other symptoms (if it applies all or delete last paragraph.</p>	<p>Thank you, the paragraph deleted.</p>
<p>Reviewer: H</p> <p>Line 125, use PTT after it has once been written in full. Look through whole script.</p>	<p>Done.</p>
<p>Reviewer: H</p> <p>Line 149: sexual function or just erectile dysfunction?</p>	<p>Done.</p>
<p>Reviewer: H</p> <p>Line 184: does not make sence, please rephrase.</p>	<p>Done, line (209-210).</p>
<p>Reviewer: H</p> <p>Line 186, 187: please use just past: NOT HAVE REPORTED; but just reported - you have used past-time untill now.</p>	<p>Done</p>
<p>Reviewer: H</p>	<p>Done.</p>

Line 219: Add “THESE” are presented in Table 5.	
Reviewer: H Line 241: USE, not uses	Done.
Reviewer: H Line 250: why is just Clostridium with capital letter? I would say all or none. XIAFLEX uses small letters.	Done.
Reviewer: H Line 274: Its double. IIEF stands for international index of erectile function delete Erectile Function	Done, line 309
Reviewer: H Line 290: its double: IIEF-EF In Prisma Checklist.	Thank you, IIEF-EF related to (erectile function domain) and written clearly . Line (309 and 325).
Reviewer: H Number 6: a date for each source at last search is not stated. They only write a month and year for all.	Done
Reviewer: H Number 7: a full search strategy has not been presented. It may not be appropriate to add to the article but at least have it as supplementary for others to reproduce the search. I think this is a very important thing to add. There are several articles that illustrate how to do so. Many also use a librarian or equal educated person to make sure they don't miss a study.	Thank you, the search strategy has been updated, line (190-198).