Early or Delay? The Most Suitable Rehabilitation Protocol for "No Man's Land" Injury: Meta-Analysis with Trial Sequential Analysis – 20 Years Trends

Precoce ou tardio? O protocolo de reabilitação mais adequado para lesão na região "terra de ninguém": Metanálise com análise sequencial de ensaios – Tendências de 20 anos

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Abstract

Objective The aim of this study is to analyze various rehabilitation protocol and determine which methods will yield a better outcome.

Methods The database reports were searched within 1990 until 2020, using PubMed, Cochrane library database, Ovid, Medline, and the other several published trials. A statistical analysis was made from Review Manager and Trial Sequential Analysis (TSA).

Result The mean of re-rupture rate is 3.3% ($n = 8$) in the combination protocol until 8% ($n = 48$) in CAM protocol. Meta-analyses found no significant difference between Kleinert vs CAM in re-rupture rate. Also no significant difference in Duran vs CAM in rerupture rate. In Trial Sequential Analysis (TSA), the z-curve does not cross both of the trial sequential boundaries, a further trial with larger sample will be required. The TSA of flexion contracture CAM vs Kleinert was indicated that CAM protocol may be superior than Kleinert to reduce the incidence of flexion contracture. For the range of mean flexion contracture 6.6% ($n = 18$) in CAM to 23.6% ($n = 76$) in Kleinert protocol.

Conclusion Current meta-analysis proposed that the combination technique will result less re-rupture incidence and better functional outcome in flexor zone II injuries

Keywords
- tendon injuries
- postoperative care
- surgical procedures, operative

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than other techniques. The CAM method also results less flexion contracture than others. However, a further meta-analyses with larger sample trials will be required to confirm this review's conclusion.

Resumo

Objetivo O objetivo deste estudo é analisar vários protocolos de reabilitação e determinar quais métodos produzem um melhor resultado.

Métodos Os relatórios dos bancos de dados foram pesquisados entre 1990 e 2020, usando PubMed, banco de dados da biblioteca Cochrane, Ovid, Medline e vários outros ensaios publicados. Uma análise estatística foi feita a partir do Review Manager e Trial Sequential Analysis (TSA).

Resultado A taxa média de re-ruptura é de 3,3% (n = 8) no protocolo combinado, e até 8% (n = 48) no protocolo de Movimento Ativo Controlado (MAC). As metanálises não encontraram diferença significativa entre Kleinert vs MAC na taxa de re-ruptura. Também não há diferença significativa entre Duran e MAC na taxa de re-ruptura. Na Trial Sequential Analysis (TSA), a curva z não cruza ambos os limites sequenciais de ensaio, será necessário um ensaio adicional com amostra maior. A TSA de contratura em flexão MAC vs Kleinert indicou que o protocolo MAC pode ser superior ao Kleinert para reduzir a incidência de contratura em flexão. Para a faixa de contratura média em flexão de 6,6% (n = 18) no MAC a 23,6% (n = 76) no protocolo Kleinert.

Conclusão A metanálise atual propôs que a técnica combinada resultará em menor incidência de re-ruptura e melhor resultado funcional em lesões da zona flexora II do que outras técnicas. O método MAC também resulta em menos contratura em flexão do que outros. No entanto, serão necessárias mais metanálises com estudos com amostras maiores para confirmar a conclusão desta revisão.

Palavras-chave
- lesões dos tendões
- cuidados pós-operatórios
- procedimentos cirúrgicos operatórios

Introduction

Previously, prior to 1970s, the preliminary studies considered the rehabilitation methods on flexor tendon injury post-surgical repair focused on keeping the flexor tendon immobilized for the earliest three weeks.[1] However, as shown in the previous researched, the tendon's tensile strength will be low at this stage. The purpose of this rehabilitation methods after surgical repair is to yield normal function and tendon gliding movement, yet, to avoid the tendon re-rupture, flexion contracture and scar adherence.[2,3] Flexor tendon injury can be a challenging process for most hand surgeon due to several clinical problems, for example; flexor tendon injury should be managed with operative treatments. Flexor tendon will not heal spontaneously without surgical because the end of tendon should bring together to promote healing. On the other hand, post-surgical problem may result re-rupture and stiffness, post-surgical rehabilitation should be meticulously planned.[4–6] The rehabilitation post-surgery has a function to prevent tendon adhesion and improve the gliding movement, even tough, if the rehabilitation managed too aggressively, the post-repair tendon has tendency to rupture or stiff.[7–9] Addressing injury in zone II flexor tendon may also become problematic, it needs to sustain the anatomic connection between FDS and FDP tendon. FDS tendon has two slips that it has to roll around the FDP tendon, to permit FDP pass through FDS and lie down in the superficial champers chiasma. When the hand surgeon fails to remake this anatomical relationship, it will restrain tendon to glide, increase the risk to adhesion and restrict the digital movement.[10,11]

In the middle of 1970s, duran and house[12] delineate their method which involved "controlled passive motion" and reported that the restrictive adhesions tendon may be prevented with 3 until 5 mm of length tendon excursions. Concomitantly, Kleinert et al.[13] investigated the promising outcome using direct passive motion post-surgical with a rubber band as an orthosis to pull back the finger and permit active finger extension, with producing passive flexion movement of finger. His study revealed that the mobilized tendon post-operative showed less adhesion and faster healing rate than prolonged immobilized tendon.

The progression of modification rehabilitation protocols following flexor tendon injury grows rapidly since then, accompanying with furtherance in surgical methods and materials. On the other hand, there is still a debatable area to determine the ideal rehabilitation methods to achieve a functional outcome post-tendon repair, although, many previous publishing reports have declared a novel rehabilitation protocol.[14,15]

There are many variety of rehabilitation methods regarding flexor tendon injury, yet, the principal methods are "active extension-passive flexion" by Kleinert et al.[13] using rubber band orthosis. In the second place, "controlled passive movement" (Duran and Houser protocol) used a passive

motion within range 3 to 5 mm of the involved digits followed with active digit flexion. The last protocol is the combination between Kleinert and Duran protocol, Chesney et al.[16] study has compared those three protocols overview following post-surgical repair in zone II flexor tendon injury and generated that the combined technique resulted less incidence of tendon re-rupture and more tolerable range of motions.[17]

Formerly, there has been several published systematic review and meta-analysis which has been compared, one of them is published by Thien et al.[18] in Cochrane library. This study has only included the Randomized Controlled Trial report, there were three full text reports of RCT and the other three were just abstract. It concluded that the best regimen method may not be defined due to insufficient verification of trial studies.

Our review comprehensively included RCT and observational reports of the past 20 years published data, we specified our search filtered on to rehabilitation methods in flexor zone II injury "no man's land." This review is deliberately to give the answer of "which the rehabilitation protocols in "no man's land" injury to generate the best functional outcome post-surgical repair."

Materials and Methods

Search Strategy

The author seeks the relevant articles according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. We used this guideline as a set of evidence-based items to improve our systematic reviews and meta-analyses. At first, the database reports were collected thorough fastidious search within range 1990 until 2020, using PubMed, Cochrane library database, Ovid, Medline, and the other several published trial registries. We included all of studies with evidence based ranging from level I to level IV. The criteria of this review's study emphasized on clinical assessment, with the subject matter of the tendon rupture prevalence, flexion contracture and functional outcome scoring using Strickland Criteria, The Buck-Gramcko Classification and DASH (Disabilities of the Arm, Shoulder, and Hand) Questionnaire following the early phase rehabilitation protocol (3 weeks) post-surgical repair in zone II flexor injury, categorized as a passive motion (Kleinert and Duran type protocol), controlled active motions and combination of those protocols. We analyzed each study for odds ratio (OR) for dichotomous models with 95% Confidence Interval (CI), it was measured using Review Manager (RevMan) [Computer program, Version 5.3. Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration, 2014]. The result's heterogeneicity was elaborated as a fixed effect model if heterogeneity was $< 50\%$ and the random effect model if heterogeneity was $> 50\%$. Our initial search keywords are using "rehabilitation" and "flexor tendon" resulted 263 articles. Furthermore, we add more keywords following the Boolean operators: Kleinert protocol OR controlled active motion OR modified kleinert rehabilitation AND duran protocol OR duran houser rehabilitation OR early passive mobilization OR early passive motion OR combination active-passive motion AND flexor tendon injury zone 2 OR hand flexor tendon rupture zone 2. 16 articles were included with total sample is 1.321 populations (►**Fig. 1**).

All of the literature's component including the report's eligibility, qualification, critical appraisal, the selection studies and trial object, also bias risk assessment were judged by independent authors. Critical appraisal of literature is using CASP (Critical Appraisal Skill Program) question checklist on each included study.[19]

Statistical Analysis

The author also measured mean difference for continuous outcome and OR (odds ratio) for dichotomous outcome, using 95% CI (Confidence Interval). It was enumerated using Review Manager (RevMan) [Computer program, Version 5.3. Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration, 2014]. A heterogeneicity interstudy was assessed by $\chi 2$ test, each studies heterogeneicity will be assumed if $I^2 > 50\%$ and P value <0.1. The result data will be categorized as a significant if P value <0.05. To create the threshold in our meta-analysis, yet, to determine the reliable significance based result and this review's impact of the information amount due to small sample size and low study's quality, we used trial sequential analysis by the statistical software, TSA version 0.9 β (User Manual for TSA, Copenhagen Trial Unit 2011). The reports will be considered to have a sufficient level evidence if the Z-curve cross the upper and lower boundaries or futility line. However, if the Z-curve doesn't cross the boundaries, the required information size had not been reached and there will be insufficient evidence to have the conclusion.

Methods

The Specification Criteria for this Review

Types of Studies

The author incorporated all type studies; included case-series, cohort studies, quasi-randomized and non-randomized study, Randomized Controlled Trial (RCT) with range of evidence level varies from level I-IV (►**Table 1**).

Type of Populations

The author particularizes the literature on human study related to early stage rehabilitation post-surgical repair in zone II flexor tendon injury.

Type of Interventions

The variation of surgical method regarding zone II flexor tendon injury is well accepted on included studies followed by early stage rehabilitation:

- Active extension-passive flexion (Kleinert method)
- Controlled passive movement (Duran Houser protocol)
- Controlled active movement
- Combination technique (Kleinert, Duran Houser and controlled active movement)

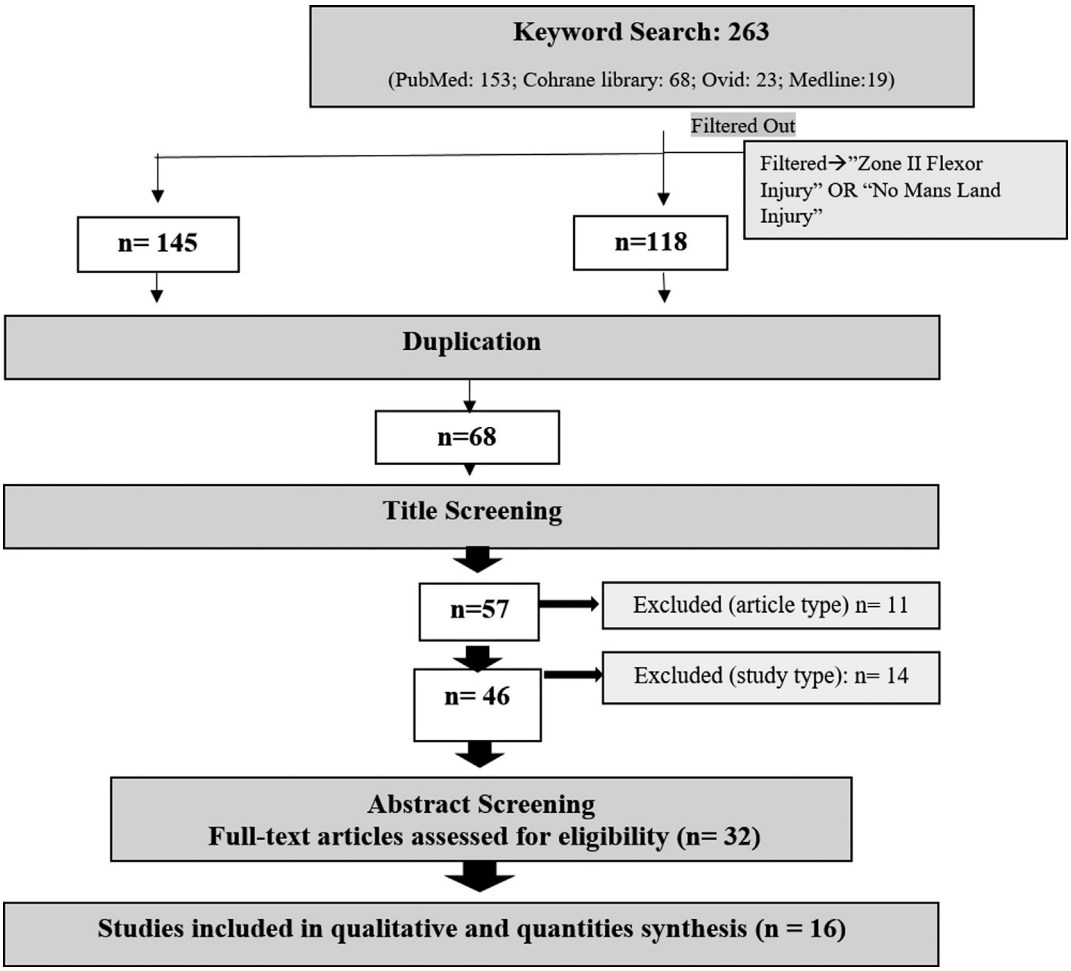

Fig. 1 Article Selection Scheme.

Table 1 Validity Search Methods

Authors	Journal	Country	Model	Study Design	Level of Evidence
Scheffler, 2008	The Arthroscopy Association of North America	Germany	Sheep	Prospective Comparative Study	II
Dustmann, 2008	Knee Surgeon Sports Traumatologic Arthroscopic	Germany	Sheep	Prospective Comparative Study	II
Mayr, 2011	Knee Surgeon Sports Traumatologic Arthroscopic	Germany	Sheeps	Prospective Comparative Study	II
Bhatia, 2012	The American Journal of Sports Medicine	Chicago, Illinois	Rabbits	Randomized Controlled Trial	I
Jackson, 1993	The American Journal of Sports Medicine	California	Goats	Prospective Comparative Study	II

The time duration regarding injury-to surgical repair and rehabilitation duration may vary on each literatures.

Type of Result Assessment

- Post treatment complication
  - Re-rupture incidence
  - Flexion contracture
- Functional outcome assessment
  - Strickland criteria
  - The Buck-Gramcko classification
  - DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire.20

Study Quality Assessments

All of the published studies were assessed and analyzed for its title and abstract as it were matched with this study's specifications. Furthermore, all of the filtered studies will be extracted to the inclusion basis. We did the critical appraisal

study using checklist of CASP (clinical skill appraisal program), then it will be finalized with the high qualification and study eligibility will be reviewed. All of the literature's section, comprising a study's methodological, the data variables, and risk of bias has been reviewed by the author.

Results

Study Descriptions

Our electronic database summed several inclusion studies with total sixteen literatures and 1.321 participants, it was divided in to four meta-analyses and descriptives. Studies level varies from level IV evidence in 6 case series, 8 prospective cohort studies (Level II evidence), 1 retrospective comparative study (Level III evidence), and 1 randomized controlled trial study (Level I evidence) (►**Table 1**). None of the included studies were compared altogether of those included protocols. There were 6 studies which outlined only one specific rehabilitation protocol and 10 other studies compared between Kleinert, Duran, CAM and the combined rehabilitation protocol.

Surgical Technique

Most of the studies (10 reports) used a tendon repair technique which involved two-suture strands across the tendon. Two studies used a four-strands suture and one study used six-strands core suture. Two studies did not explain the repair tendon technique. In this review, we did not identify the correlation between suture strands number and the re-rupture rate (Table 2).

Primary Outcome: Re-rupture Rate

We summarized the average rate of re-rupture per rehabilitation protocol with the highest mean of re-rupture rate is the CAM protocol at 8 percent ($n = 48$, $N = 593$). The mean range of re-rupture is 3.3 to 8 percent across all of the studies. The lowest of mean rate followed by the combination protocol (kleinert and duran type) at 3.3 percent ($n = 8$, $N = 241$) (Table 2). From the meta-analyzes calculation between the comparison of Kleinert rehabilitation protocol versus CAM which used fixed effect model for dichotomous outcome, it was found there was no significant difference in terms of re-rupture rate between those two models rehabilitation (Heterogeneity, $I^2 = 40\%$; OR = 1.64 95% Confidence Interval (CI), 0.55 to 4.92; $p = 0.37$). It was also found there was no statistically different between Duran and CAM protocol in re-rupture rate (Heterogeneity, $I^2 = 0\%$; OR = 1.37 95% Confidence Interval (CI), 0.40 to 4.74; $p = 0.62$). In trial sequential analysis, the z-curve does not cross both of the trial sequential boundaries, the calculation of required information size was 169, yet, a further trial with larger sample will be required (►**Fig. 2**).

Primary Outcome: Flexion Contracture

The range mean of flexion contracture is 6.6 to 23.6 percent, with the highest mean of flexion contracture rate is Kleinert protocol at 23.6 percent ($n = 76$, $N = 322$) and the lowest mean rate is Controlled Active Motion (CAM) at 6.6 percent ($n = 18$, $N = 273$). The meta-analyses between Kleinert and CAM used random effect model for dichotomous outcome, found statistically significant in flexion contracture rate. (Heterogeneity, $I^2 = 0\%$; OR = 4.48 95% Confidence Interval (CI), 2.48 to 8.07; $p < 0.00001$) (►**Fig. 2**). For trial sequential analysis in term of flexion contracture between CAM and Kleinert was illustrated that the Z-score crossed the upper boundary line indicated that CAM protocol may be superior than Kleinert to reduce the incidence rate of flexion contracture (►**Fig. 2**).

Secondary Outcome: Functional Outcome

The functional outcome for this review were divided in to three outcomes. First, we identified the comparative between Kleinert – Modified Kleinert type, Duran Type, Combination protocol (Kleinert, Duran and CAM), and Controlled Active Motion (CAM) based from the Original Strickland Criteria. Eleven studies had used the Strickland criteria. For meta-analyses between Kleinert rehabilitation protocol and CAM used random effect model for dichotomous outcome, found no significant difference in Strickland score. (Heterogeneity, $I^2 = 79\%$; OR = 0.49 95% Confidence Interval (CI), 0.14 to 1.71; $p = 0.26$) (►**Fig. 2**).

For strickland criteria's sum average on each study was found the highest excellent - good score (%) at the combination technique with mean 80 percent ($n = 167$), the lowest mean excellent - good score (%) is 53 percent ($n = 138$) in Duran type. The average of Strickland criteria in all protocols is 53 to 80 percent. Three studies had been used the Buck-Gramcko criteria. The highest excellent - good score in Buck-Gramcko criteria was found 97 percent ($n = 74$) in combination type protocol. The lowest mean is Kleinert-modified Kleinert type at 69 percent ($n = 205$). The mean of Buck-Gramcko outcome is 69 to 97 percent. The third outcome is DASH questionnaire, only three studies analyzed the DASH outcome which only compared Kleinert-modified Kleinert, Duran type, and CAM protocol. The highest mean score is 53.8 ($n = 184$) at Duran type, the lowest mean value is CAM at 36.7 ($n = 77$). The mean of DASH questionnaire is 36.7 to 53.8.

Discussion

Kleinert et al.[13] introduced the first protocol method with passive flexion and active extension, since then, there were plentiful published experimental studies about rehabilitation novel protocol. There are many hypothesis regarding to this rehabilitation protocol in flexor zone II injury appear to be questionable.[21] One of the hardest challenge to assess this rehabilitation program is not only due to the technique of rehabilitation itself, yet, it also depends on the variation of surgical technique and the functional outcome of the patient. In this review, we reveal most studies (ten reports) were using two-strands suture technique compared with the four and six-strands.[22]

Hung et al.[2] analyzed that he has used early active mobilization on zone II and other zone flexor tendon injury and achieved good-excellent result in 71% zone II repairs and

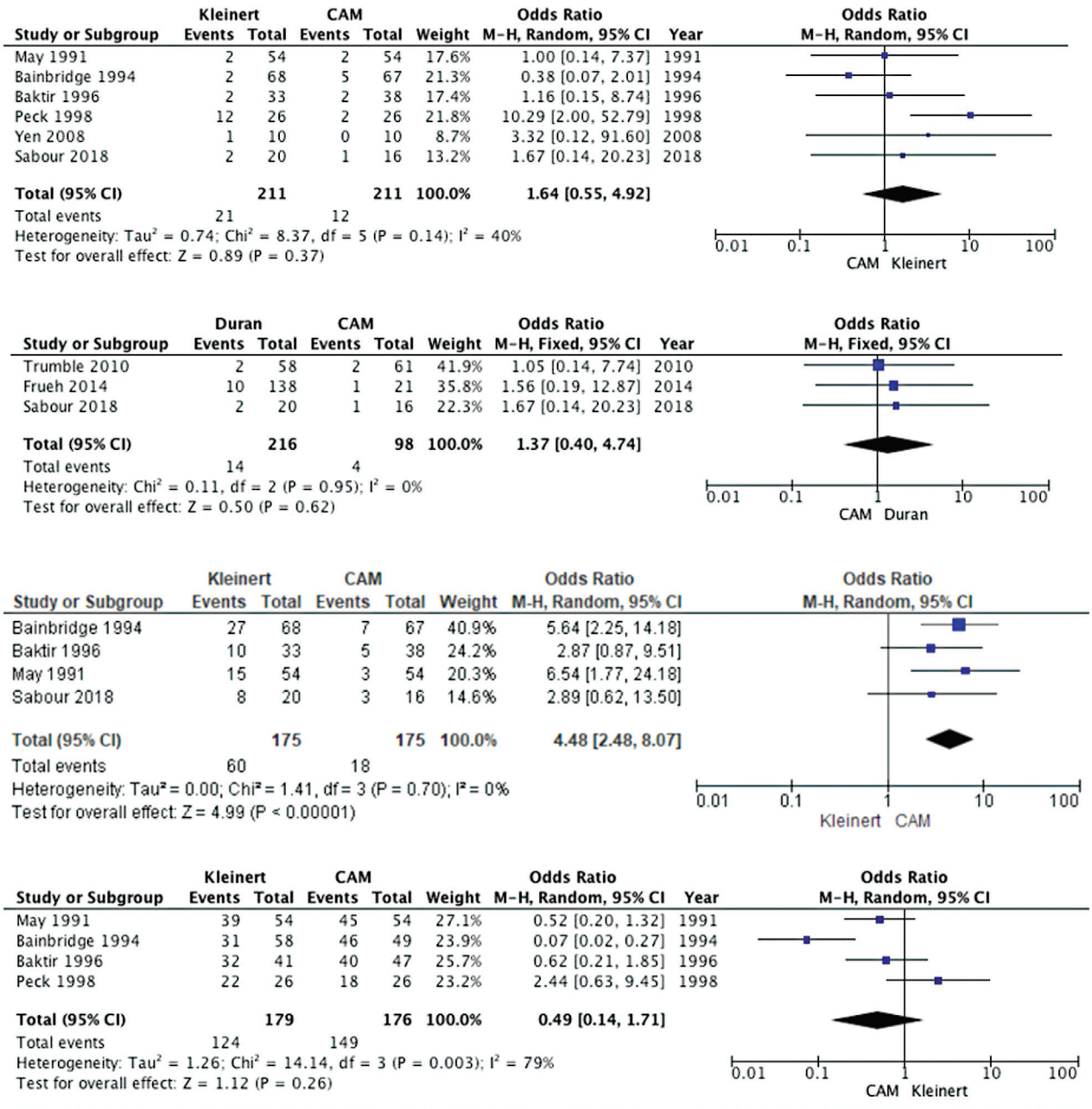

Fig. 2 Comparison: Kleinert Rehabilitation Protocol vs Controlled Active Motion; Outcome: Re-rupture (digits); Duran Rehabilitation Protocol vs Controlled Active Motion; Outcome: Re-rupture (digits); Kleinert Rehabilitation Protocol vs Controlled Active Motion; Outcome: Flexion Contracture (digits); Kleinert Rehabilitation Protocol vs Controlled Active Motion; Outcome: Strickland Criteria (Excellent-good).

77% zone with statistically significant. Riaz et al.[3] who has also evaluated using Kleinert methods on his prospective comparative study and found that 75% digits were graded excellent using AASH scoring. According to Thien et al.[18] on his meta-analyses using 6 RCT, there were no significant difference between the comparison on early active motion, Continuous Passive Motion (CPM), Kleinert and Duran protocol. He also stated that early mobilization protocol is well accepted in flexor tendon injury, yet the best regiment has not been concluded. On the other hand, Khan et al.[23] used Kleinert method on his prospective study, he analyzed 50 populations, with statistically significant, 94% patients had excellent result. Trumble et al.[24] who also reported his analysis through active motion protocol compared with passive motion, he reported the flexion contracture and range of motion were better achieved than passive protocol. On the other terms, patients with more improved joint movement stated a higher satisfaction than immobilized joint post-srugical. However, article by Peck et al.[25] compared the active motion protocol and modified kleinert, 46% tendon ruptures were achieved by active motion protocol.[13]

This meta-analysis have been made to overcome the complication rate post-surgical flexor tendon injury zone II. Thus, we met some challenge of the long interval on

Table 2 Study characteristics

	Scheffler, 2008		Dustmann, 2008		Mayr, 2011		Bhatia, 2012		Jackson, 1993	
	Allograft	**Autograft**	**Allograft**	**Autograft**	**Allograft**	**Autograft**	**Allograft**	**Autograft**	**Allograft**	**Autograft**
Sample Size (Populations)	24	24	27	27	21	21	32	16	20	20
Animal Models	Female merino sheep		Female merino sheep		Sheep		Male New Zealand White Rabbit		Female Skeletally Mature Spanish Goats	
Age Range of Animal models	2 – 3 years old		N/A		N/A		N/A		4 – 5 years old	
Primary Surgery: ACL Reconstruction										
Graft Type	Superficial Flexor Tendon Graft	Superficial Flexor Tendon Graft	Flexor Tendon M. Digitalis Superficial is Graft	Flexor Tendon Graft	Patellar Tendon	Flexor Digitorum Superficial is Tendon	Semitendinosus Tendon	Semitendinosus Tendon	Fresh Frozen Patellar Tendon Allograft	Patellar Tendon Autograft
Surgical Techniques	Medial Arthrotomy		Medial Arthrotomy		Ventromedial Longitudinal Arthrotomy		Medial Parapatellar Arthrotomy		Anterolateral Surgical Approach	
Graft Fixation	Femoral cortex: fixation button		Femoral cortex: fixation button		Transtibial techniques		Krakow Stitch		Femoral cortex: cancellous screw with metal washer	
Secondary Surgery: Biopsy Procedure										
Independent Examiner	Independent researcher, blind		Independent researcher, blind		Independent researcher, blind		Independent researcher, blind		Independent researcher	
Biopsy Interval	6 wks, 12 wks, 52 wks		6 wks, 12 wks, 52 wks		0 wks, 6 wks, 12 wks, 24 wks		2 wks, 8 wks		6 wks, 6 months	
Biopsy Sites	Midsubstance tissue → subsynovial (SUB), an intermediate (MED), and a central (CNT)		Tissue from undamaged, intraarticular graft		Central Section (midsubstance tissue)		Graft Insertion Sites, midsubstance tissue		Central Cross Section	
Biopsy Speciment Size	4 µm		N/A		7-8 µm		N/A		Cut Free	
Study Methods	High Resolution Microscope		Polarizarion Microscope		Light Microscope		High Resolution Microscope		Polarized Light Microscopy Zeiss Transmission Electron Microscope	
Speciment Staining Techniques	H&E Masson-Goldner trichrome Staining Immunohystochemistry		ASMA Stain Neofuchsin Immunohystochemistry		Giemsa Staining		H&E Masson-Goldner trichrome		H&E Uranyl Acetate	
Quantitive Histology	Cell distribution Cell morphology Appearance of foreign body giant Inflammatory cells. Cellularity and Vascular Density		Cell distribution Cell morphology Collagen crimp Myofibroblasts expression		Cellular Morphology Cellular Organization Cellular Type Total Cell Count Ratio of necrosis to cells		Cell distribution Cell morphology Matrix Blood Vessel		Cell histology Collagen Fibril Size Area Distribution Vascularity	

report's trends, the repair technique may vary on each study and multitude report's variable including sample populations, the tendon injury pattern and length of rehabilitation protocol. As we know, none of the recent study did the comparative study which used all of the rehabilitation method protocols. Nevertheless, through this review and meta-analyses, our expectation is to answer the question of "what type of rehabilitation is the most suitable for no man's land injury." We analyze the combination protocol which combined active and passive technique is the best protocol. Through our review, the lowest rate of re-rupture incidence was achieved by the combination technique, yet, the flexion contracture is minimal on the digits which were treated by controlled active motion (CAM).

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Conflict of Interest
The authors have no conflict of interests to declare.

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