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A meta-analysis comparing active and passive rehabilitation protocols following flexor tendon surgery

Fleksör tendon cerrahisinden sonra aktif ve pasif rehabilitasyonun meta-analizle karşılaştırılması

Nader Paskima, D.O., M.P.H.,[1] Michael Walsh, PhD,[2]
Frank Lovecchio, D.O, MPH,[3] Anand Panchal, D.O.[4]

Department of [1]Orthopedic Surgery and [2]Division of Outcomes Studies, The New York University Hospital for Joint Diseases;
[3]Department of Emergency Medicine, Maricopa Medical Center;
[4]Department of Orthopedic Surgery, Grandview Hospital Medical Center

Objectives: The purpose of this meta-analysis was to determine which type of rehabilitation protocol (active versus passive) was superior following surgical repair of zone 2 flexor tendon lacerations.

Patients and methods: We searched Medline, the Cochrane Library, bibliographies of published texts, reviews, reports, and interviewed experts in the field. Three reviewers examined all sources of potential articles independently and compiled a list of potential articles. The reports were categorized into three groups: randomized controlled trials (RCT), clinical trials (CT) and case series (CS). Data were analyzed on Stata Intercool 7 using a random-effects model for meta-analysis.

Results: Following various steps of the exclusion process, three CTs and 25 CSs remained. Meta-analysis of three CTs showed a relative risk ratio of 1.2 (95% CI 0.78, 1.85) when comparing the active versus passive groups in terms of "good-excellent" outcomes. The pooled risk ratio for rupture rate in the clinical trials of active versus passive groups was 2.58 (95% CI 0.985, 6.759). Secondary to a scarcity of extractable information from CTs, case series using the active or passive protocol were also meta-analyzed individually. Using meta-regression, the differences in proportions of "good-excellent" outcomes and rupture rates between passive and active case series were found as -0.01 (95% CI -0.17, 0.15) and 0.029 (95% CI -0.033, -0.025), respectively.

Conclusion: Based on the review of three comparative series and the pooled estimates of the case series, there is a lack of robust evidence favoring active versus passive mobilization protocols with regard to outcomes and rupture rates.

Key words: Data collection; exercise therapy/methods; finger injuries/surgery/rehabilitation; meta-analysis; tendon injuries/surgery/rehabilitation.

Amaç: Bu meta-analizde, zone 2 fleksör tendon laserasyonlarının cerrahi onarımından sonra uygulanan rehabilitasyon protokollerinin hangisinin sonuçlarının daha iyi olduğu değerlendirildi.

Hastalar ve yöntemler: Çalışma için Medline, Cochrane Kütüphanesi, yayımlanmış yazılarla ilgili listeler, derlemeler, raporlar tarandı ve alanında uzman kişilerle görüşüldü. Üç yazar birbirlerinden bağımsız olarak makalelerle ilgili tüm kaynakları taradı ve olası makalelerin bir listesini hazırladı. Ortaya çıkan yayınlar üç grupta incelendi: Randomize kontrollü çalışma, klinik çalışma ve olgu sunumları. Veriler, meta-analiz için "random-effect" modeli kullanılarak Stata Intercool 7 programında değerlendirildi.

Bulgular: Makalelerin ayıklanması işleminden sonra üç klinik çalışma, 25 olgu sunumu kaldı. Klinik çalışmalarda aktif ve pasif gruplar "iyi-mükemmel" sonuçlar açısından karşılaştırıldığında, meta-analizde rölatif risk oranı 1.2 [%95 güven aralığı (GA) 0.78, 1.85) bulundu. Aktif ve pasif protokol için yırtılma oranına ait birleştirilmiş (pooled) risk oranı 2.58 (%95 GA 0.985, 6.75) idi. Klinik çalışmalardan elde edilebilir bilginin çok yetersiz olması nedeniyle, aktif veya pasif protokolün uygulandığı olgu sunumları da ayrı ayrı meta-analize alındı. Meta-regresyon modelinde, pasif ve aktif olgu sunumları için "iyi-mükemmel" sonuç ve yırtılma oranlarının dağılım farklılıkları sırasıyla -0.01 (%95 GA -0.17, 0.15) ve 0.029 (%95 GA -0.033, -0.025) bulundu.

Sonuç: Üç karşılaştırmalı çalışmaya ve olgu sunumlarından elde edilen birleştirilmiş değerlere göre, sonuçlar ve yırtılma oranları açısından aktif protokolün üstünlüğünü gösteren güçlü bulguya rastlanmadı.

Anahtar sözcükler: Veri toplama; egzersiz tedavisi/yöntem; parmak yaralanması/cerrahi/rehabilitasyon; meta-analiz; tendon yaralanması/cerrahi/rehabilitasyon.

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- *Correspondence: Nader Paksima, DO, MPH . NYU-Hospital for Joint Diseases, Department of Orthopaedic Surgery, 530 First Ave. Suite 8U, New York, NY, 10016 USA. Tel: +00-1-212-263-2192 Fax: +00-1-212-263-0231 e-mail: npaksima@yahoo.com*

Progress in the treatment of flexor tendon lacerations in the last 30 years has included the development of new suture materials and microsurgical techniques that have allowed atraumatic re-approximation of the severed tendon. However, the optimal postoperative rehabilitation protocol following flexor tendon repair, especially in zone 2 remains controversial.[1-3]

The two most common rehabilitation protocols differ in the type of flexion allowed. While both protocols allow active extension, active protocols allow active flexion while passive protocols use passive mobilization of the tendon. The theoretical advantage of the active flexion protocol is increased tendon glide which results in a greater final range of motion. The theoretical advantage of the passive flexion protocol is that it allows the tendon to glide in the tendon sheath while protecting it from undue stress at the repair site.

The purpose of this meta-analysis was to systematically review the literature available on zone-2 flexor tendon lacerations in an attempt to determine a superior treatment regimen.

PATIENTS AND METHODS

We searched Medline®, The Cochrane Library Database, bibliographies of published texts, reviews, reports, and interviewed experts in the field. The MEDLINE search included the following MeSH Terms (key words, not full text): flexor tendon, surgery, repair, reconstruction, rehabilitation, laceration, and treatment. Additional search criteria included English language reports (1960 to July 2001), human, and all ages. The Cochrane Library website and the Musculoskeletal Injuries Group Trials Registry were searched entering the same text words as above. A "snowballing" technique was employed in which potentially relevant references in review articles and retrieved articles were harvested. Following this process, three board-certified hand surgery experts were contacted and inquiries were made about additional references.

Three researchers completed the searches independently and a potential article list was compiled. The articles were then reviewed for compliance with previously developed inclusion and exclusion criteria. Inclusion criteria for the meta-analysis were: *(i)* English language, *(ii)* human trials, *(iii)* published articles from 1960-2001, *(iv)* report on an outcome of interest, *(v)* utilization of a treatment of interest, *(vi)* follow-up for >3 months, and *(vii)* acute repair <2 weeks following the injury. Exclusion criteria were: *(i)* failure to meet inclusion criteria, *(ii)* ipsilateral hand injuries (amputations, etc.), *(iii)* animal studies, *(iv)* tendon grafts or *(v)* flexor tendon lacerations of the thumb, and *(vi)* biomechanical studies.

The outcome of interest was defined as the percentage recovery of range of motion (ROM) as measured after more than three months following repair. Articles reporting the outcome as percent return of ROM of the proximal interphalangeal joint (PIP) plus distal interphalangeal joint (DIP), or having results convertible to this measure were selected. The percentage return of ROM was subsequently converted to a 4-point grading scale: excellent (85-100%), good (70-84%), fair (50-69%), and poor (<50%). In addition, rupture rates with specified techniques were recorded.

For validity assessment purposes, two reviewers evaluated only the methods section of each potential article to be used in the analysis. Data extraction was performed independently using pre-formulated data collection forms.

The study characteristics were reviewed in detail and, after this filtering process, each study was categorized into three groups: randomized controlled trials, clinical trials and case series.

Data were analyzed on Stata Intercool 7™ (2001) using a random-effects model. We chose the risk ratio of good or excellent versus fair or poor outcomes as our primary measurement of effect. Statistical heterogeneity was assessed using the Q-statistic. In addition, the risk ratio (RR) for rupture in the active versus passive group was assessed as a secondary measurement of outcome.

If initial collection of randomized controlled trials was insufficient, clinical trials would be further reviewed as would the case series. Because of the heterogeneous nature of these data, analysis would occur separately within each study type.

With regard to the case series, the active and passive case series were analyzed separately. The standard deviations together with 95% confidence interval (CI) were calculated for each study. We then sorted the cases using Stata and performed a meta-analysis using a random-effects model. The summary estimate was obtained for the case series that used the active protocol and also for those using the passive protocol. We analyzed the two sets of case series for both the "good-excellent" outcomes and rupture rate data.

We also obtained an estimate of the difference (and corresponding 95% CI) in proportions of good-excellent outcomes between the active and passive case series by performing a meta-regression. This was performed by regressing the proportion of good and excellent outcomes using a dummy variable (active=1, passive=0) to arrive at an estimate for the difference in proportions and its corresponding 95% CI. A similar technique was used to estimate the difference in rupture rates between active and passive protocols.

RESULTS

A total of 1,822 articles were initially reviewed, with 1,688 being eliminated because they failed to meet the inclusion or exclusion criteria. Of the remaining 134 manuscripts, 37 were excluded because of biomechanical (cadaveric) nature, and 71 were excluded because no follow-up or suitable outcome data were reported. In the end, there remained 26 trials. There were no randomized controlled trial that compared the active versus passive protocols. There were three nonrandomized comparative trials and 23 case series. Agreement of validity was obtained on all the articles between the two reviewers.

The three comparative trials are summarized in Table I.[1-3] The data was extracted and a RR of active versus passive for the development of a favorable outcome (excellent or good) was computed. By convention, a crude RR greater than 1 would suggest a more favorable outcome in the active group in comparison to the passive group, whereas a number less than 1 would represent the opposite effect. The pooled RR using the random-effects model was 1.2, 95% CI 0.78, 1.85. A calculation for heterogeneity generated a Q-statistic of 4.25 on df=2 with p=0.12, indicating no evidence for heterogeneity. However, we chose to use the random-effects estimate because we did not feel that a single true value existed for the relative risk. The studies were merely sampled from a distribution of possible results.

With regard to the risk for rupture with the active versus passive protocols, the random-effects pooled estimate of RR was 2.58, 95% CI 0.985, 6.759. A calculation for heterogeneity using a Q-statistic was equal to 1.664 on df=2 with p=0.435. Once more, there was no evidence for heterogeneity, but we chose to use the random-effects model for the same reasons stated above.

Since there were only three comparative trials, we decided to analyze the case series data to see if any additional information could be obtained. A total of seven case series employed the active protocol and 16 reported on the passive technique (Table II).[4-26] The case series by Silfverskiold and May[22] was excluded because their report of 100% for good or excellent results aroused suspicion.

When the active and passive case series were taken separately, we obtained a random-effects pooled estimate of 69.7% (95% CI 59.5, 79.9) for excellent or good outcomes for the passive series. The corresponding value for the active case series was 68.6% (95% CI 61.3, 75.8). The Begg and Mazumdar test did not show any evidence for publication bias for the passive (p=0.499) and active (p=0.348) case series, respectively (Table III).

TABLE I

Nonrandomized clinical trials comparing the active and passive protocols

Authors	Year	Postoperative rehabilitation	Total digits	Good-excellent Results (%)	Rupture rate (%)
Baktir et al.[1]	1996	Passive	41	78.0	4.9
		Active	47	85.0	4.3
Bainbridge et al.[2]	1994	Passive	58	53.5	3.4
		Active	49	94.0	10.2
Peck et al.[3]	1998	Passive	26	84.6	7.7
		Active	26	69.0	46.0

TABLE II

Case series of active and passive rehabilitation protocols

	Authors	Year	Digits	Good or excellent results (%)	Rupture rate (%)
Passive protocol	Duran and Houser[4]	1975	29	74	14
	Strickland and Glogovac[5]	1980	25	56	4
	Lister et al.[6]	1977	79	75	3
	Gault[7]	1987	25	72	12
	Chow et al.[8]	1987	78	98	3.9
	Saldana et al.[9]	1991	60	93	5
	Tang et al.[10]	1994	51	76.5	4
	Karlander et al.[11]	1993	85	77.6	6
	Creekmore et al.[12]	1985	18	27	?
	Pho et al.[13]	1978	23	87	?
	Schenck and Lenhart[14]	1996	25	48	?
	May et al.[15]	1992	159	73	3.1
	Gelberman et al.[16]	1991	60	56.6	1.6
	Edinburg et al.[17]	1987	17	64	0
	Early and Milward[18]	1982	54	55.5	?
	Ejeskar[19]	1984	60	62	5
Active protocol	Small et al.[20]	1989	117	77	9.4
	Cullen et al.[21]	1989	38	78	6.4
	Silfverskiold and May[22]	1994	55	100	3.6
	Becker et al.[23]	1979	68	51.5	10
	Elliot et al.[24]	1994	63	79.4	4.8
	Hester et al.[25]	1984	35	43	?
	Kitsis et al.[26]	1998	87	89	5.7

The difference in proportions between the passive and active case series, as estimated from the meta-regression, was –0.01 (95% CI –0.17, 0.15), indicating the passive group had 1% more "good-excellent" results, which was not significant.

The same procedure was used when comparing rupture rates. The meta-analysis of the passive and active case series showed pooled estimate rupture rates of 5.2% (95% CI 4.4, 6.0) and 7.3% (95% CI 5.2, 9.3), respectively.

In summarizing the case series data, the crude difference in proportions was 3.69% (0.0369) and the difference obtained from meta-regression was –0.029 (95% CI –0.033, –0.025), demonstrating significantly that the rupture rate was 2.9% higher in the active group.

TABLE III

Random-effects pooled estimates for excellent or good outcomes and rupture rates

	Good & excellent outcomes		Rupture rates	
Group	Pooled estimate	95% CI	Pooled estimate	95% CI
Case series				
Passive	0.697	0.595, 0.799	0.052	0.044, 0.060
Active	0.686	0.613, 0.758	0.073	0.052, 0.093
Difference	0.011		-0.021	
Difference from meta-regression	-0.012	-0.179, 0.155	-0.029	-0.033, -0.024
Clinical trials	1.203	0.784, 1.845	2.58	0.985, 6.759

DISCUSSION

The treatment of flexor tendon lacerations has undergone major advances over the past few decades.[27] Although there is universal agreement that mobilization of the tendons postoperatively is beneficial, an optimal rehabilitation program has not been established. Literature reports typically only describe a specific treatment protocol and report on its success. Unfortunately, little evidenced-based information can be extracted from these reports. This formed the basis of our meta-analysis in order to answer the question of what the best postoperative treatment protocol was following the repair of zone 2 flexor tendon injuries.

A detailed systematic search of the literature revealed no randomized randomized controlled trial comparing active versus passive protocols. Randomized trials increase the likelihood that the two comparative groups will be similar and that selection bias will be minimized. Three clinical trials were identified that compared active and passive flexion postoperative protocols. Of these, two[2,3] began with the passive protocol for approximately 12-18 days and then switched to an active protocol. When an uncontrolled nonblinded protocol is used to generate two comparative groups, the groups may potentially be treated differently. For example, the experience level of the surgeon and therapist may improve over time, hence favoring the latter group. In the third clinical trial,[1] the authors did not report the selection criteria used to assign patients to different treatment groups. The retrospective design of this study might have resulted in selection bias in that a surgeon might have decided that a certain patient had characteristics that better suited for a particular treatment. This would result in differences between the two groups, making them even not comparable.

These three comparative studies used the Kessler suture technique and Strickland criteria for outcome measurement.[5] The Strickland criteria is based on the final degrees of ROM attained for active PIP and DIP flexions, with results being excellent, good, fair, or poor. We preferred this outcome measurement because it is objective. The Strickland criteria do not consider complications, rupture rate, need for reoperation, or subjective factors.

Using a random-effects model, we pooled the information for the comparative trials and calculated a pooled relative risk of good or excellent results in the active versus passive groups. The pooled estimate was 1.203 (95% CI 0.784, 1.845), which indicated that the active flexion group had a 20% better chance of having a good or excellent outcome. The 95% CI clearly encompassed 1, showing no statistical difference between the two groups.

When comparing rupture rates for the comparative trials, the active treatment group had a higher incidence of rupture with a pooled relative risk of 2.58 (95% CI 0.985, 6.759). This association was not statistically significant, but the lower bound of the CI was very close to 1, suggesting a trend of higher rupture with the active protocol, which suggested a probability of statistical significance with a larger data set. Since only three trials were analyzed, a beta error may have occurred in that we were underpowered to detect a difference in the groups.

In an attempt to gain further information, the data from the case series were meta-analyzed. Conducting a meta-analysis on case series is unconventional and is subject to inherent potential errors. Pooled data from case series that report on different outcomes and use dissimilar treatment techniques must be interpreted with caution. Of 23 case series, seven employed the active and 16 utilized the passive protocol.

The outcomes in the case series were based on the Strickland criteria except for nine series which used different scales.[10-13,17-19,23,25] Despite the differences in outcome scales, they all reported outcomes as excellent, good, fair, poor, based upon the final ROM. Although some flaws existed - in one paper[23] there was no way to separate thumb injuries from the rest of the finger injuries - we felt that this gave us a basis to compare the results.

The case series also employed different repair techniques. Four suture types were utilized by six cases series that used the active protocol. In those using the passive protocol, the majority of the studies reported the use of the Kessler suture technique, with four articles reporting different suture techniques. Despite these limitations, we proceeded with our meta-analysis.

The results of the meta-analysis revealed no significant proportion difference between the pooled estimates for the active (68.6%) and passive (69.7%) case series for good and excellent results.

It is difficult to draw conclusions when comparing relative risk (estimated for the clinical trials) and proportion difference (estimated for the case series). The higher level of heterogeneity noted in the passive (Q=174.087, 15 df, p<0.001) and active (Q=95.517, 7 df, p<0.001) case series showed much variability. The heterogeneity was much lower for the clinical trials (Q=1.664, 2 df, p=0.435) because these trials were more similar, and, by reporting relative rates, the results became more comparable.

We noted, however, that both groups of data revealed no statistically significant difference with regard to postoperative treatment regimens and final outcomes of ROM. When rupture rates of case series were considered, we noted a significantly higher rupture rate associated with the active technique.

When the overall data are surveyed, certain trends in outcomes can be noted. In both the clinical trials and case series, higher rates of "good and excellent" outcomes and lower rupture rates were observed in the passive rehabilitation groups. These results fall in line with the theory that passive flexion and extension cause less intratendinous strain than a protocol employing active extension. Tendon excursion is also an integral component of postoperative care. It has been shown that a moderate amount of tendon excursion (2-9 mm) is sufficient to prevent postoperative adhesions and to promote healing.[28,29] The passive protocol, which allows for a moderate level of tendon excursion while minimizing tendon rupture, theoretically should provide better outcomes.

When employing both the passive and active protocols, as in the Washington regimen, excellent outcomes have been noted.[30,31] Additionally, the modified rehabilitation protocol utilizing both protocols has been shown to be more effective than the active protocol alone.[31]

At present, sufficient data on the individual merits of each rehabilitation protocol are lacking. Even though the results of this study seem to favor the outcomes of the passive protocol, the interstudy variability amongst the case series diminishes its clinical applicability.

The limitations of this meta-analysis arise from the deficiencies in the literature. Ideally one should perform a meta-analysis only on randomized controlled trials.[27,30] This would allow us to compare odds ratios and confidence intervals. We had no randomized controlled trial, and few clinical trials, and so the results obtained from this study must be interpreted with caution. In conclusion, after systematic review of the literature, we have not found sufficient evidence to guide our treatment decisions. There is a need for a well-designed randomized controlled trial to evaluate the postoperative protocols. Additional case series describing a technique for postoperative treatment of flexor tendon lacerations would add little to the literature.

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