

Meta-analysis on biomechanical properties of meniscus repairs: are devices better than sutures?

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Received: 2 October 2013 / Accepted: 19 March 2014 / Published online: 20 May 2014
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Abstract

Purpose Meniscal repair devices have been extensively tested during the past decades as reported in the literature. Reviewing the different meniscal repair devices and sutures with their respective biomechanical properties.

Methods For this meta-analysis, we conducted a systematic online search using PubMed, EMBASE, CCTR, and CINAHL using the search terms *Meniscus OR Meniscal AND Biomechanics AND Repair*. Load-to-failure (LtF), stiffness, and cyclic outcome measures were extracted independently and in duplicate. The systematic search revealed 841 manuscripts in total. After exclusion of duplicates and irrelevant publications, 41 studies remained

for final analysis. The studies were published in English and German from 1995 to 2013. Due to differing cyclic force protocols, cyclic outcomes had to be excluded.

Results Overall, sutures had a higher LtF [suture: 87.7 ± 0.3 N (weighted mean \pm standard error), device: 56.3 ± 0.1 N] and stiffness (suture: 8.9 ± 0.04 N/mm, device: 8.6 ± 0.04 N/mm) than devices, both $p < 0.05$. In LtF testing, PDS 0 Vertical (145.0 ± 8.1 N), OrthoCord 2-0 (143.6 ± 11.3 N), and Ethibond No 0 Vertical (133.4 ± 7.7 N) were the strongest sutures and Meniscal Viper (140.9 ± 5.1 N), MaxFire Vertical (136.2 ± 11.3 N), and FasT-Fix Vertical (115.2 ± 1.6 N) were the strongest devices. Second-generation devices were significantly stronger and stiffer than first-generation devices ($p < 0.001$).

Clinical relevance Suture repair remains the gold standard with a vertically oriented suture configuration showing superior LtF values compared to a horizontal configuration. Nevertheless, some meniscal repair devices

Patrick Sadoghi and Dan Buckland have contributed equally to this work.

Electronic supplementary material The online version of this article (doi:10.1007/s00167-014-2966-9) contains supplementary material, which is available to authorized users.

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have similar biomechanical properties to suture repairs. Both suture repairs and devices have a place in meniscal restoration.

Level of evidence None, meta-analysis of controlled laboratory studies.

Keywords Meniscus · Repair · Biomechanics · Load-to-failure · Stiffness · Devices

Introduction

The meniscus is mandatory for shock absorption, load distribution, proprioception, and the knee's overall joint function [2, 12, 45]. It aids in joint stability and protects the cartilage from axial loads, shear stress, and degeneration [2, 12, 26, 39]. However, trauma and joint degeneration may lead to meniscal tears and alter the joint's function, leading to acute symptoms and inferior long-term joint conditions [26, 28, 31, 39]. Therefore, the treatment of meniscal tears is one of the most challenging topics in orthopaedic research and sports medicine, and substantial contributions were achieved within the last years [30, 36]. Suturing the tissue of an acute tear in order to maintain its mentioned biomechanical properties has nowadays become the gold standard [3, 41]. Inside-out suture repairs remain the gold standard for meniscal repairs, although this technique is associated with an increased risk of neurovascular injury and is linked to augmented perioperative morbidity [10].

Rigid fixation with initially good clinical outcomes but high mid-term failure rates and damage to cartilage was found with the first-generation all-inside repair devices [4, 18]. Therefore, flexible suture- and anchor-based repair devices were introduced and are nowadays preferred in clinical practice.

It was shown that removal of the meniscus led to increased contact stress with biomechanical wear and permanent deformation of cartilage [29].

However, as the development of devices for meniscus suturing is a growing market, various different applications and techniques have been described in the literature and surgeons might therefore choose from all-inside, inside-out, and outside-in sutures as well as different technical devices [12]. As stability of the suture is a crucial outcome parameter, surgeons want to perform best in doing so while using the most adequate and accurate way of suturing. However, scientific literature lacks evidence for a most favourable suture device and technique with respect to biomechanical outcome.

The aim of this study was therefore to evaluate the pooled biomechanical outcome after different techniques

and devices for meniscus repair including load-to-failure (LtF) testing as well as stiffness measurements. The hypothesis was that modern devices show at least the same LtF forces as suture repairs.

Materials and methods

This study was conducted following the PRISMA statement published by the CONSORT group [33, 34].

Systematic search and strategy

We conducted a systematic review of the literature using the online databases PubMed, MEDLINE, EMBASE, CINAHL (Cumulative Index of Nursing and Allied Health), and CCTR (Cochrane Controlled Trial Register). These electronic databases were searched online for “(Meniscus) OR (Meniscal) AND (biomechanics AND repair)” using these terms as keywords and exploded MeSH terms without restrictions in language or year of publication.

Only studies directly testing meniscus fixation devices in vitro using axial mechanical testing were included. In case of overlapping data, studies were merged as far as possible; completely overlapping studies were excluded. Human and animal studies were included as it has been shown that the tissue differences are minimal [23]. In total, the following studies were included testing human, porcine, and bovine menisci: 18, 28, and 44, respectively. Further exclusion criteria were duplicates and not using a generally accepted testing methodology that was comparable to the existing literature.

Extraction of relevant data

Eligibility of studies was assessed independently and in duplicate (DB, MDW) and crosschecked to avoid errors. Disagreement was resolved by discussion or, if necessary, with the help of the senior author (CR). The bibliographies of all included studies were reviewed for additional relevant studies. All searches were concluded by 1 January 2013.

The data extracted to categorize the studies were: number of samples, human or type of animal, type of suture or device, and test conditions (cyclic minimum [N], cyclic maximum [N]). Outcome data extracted were (when reported): LtF force [N], initial/1 cycle displacement [mm], 100, 300, 500, and 1,000 cycles displacement [mm], and stiffness that being defined as the slope of the LtF curve (unit N/mm). The crosshead speed was not considered.

Our search strategy generated 841 studies online and by citation tracking (PubMed: 137, EMBASE: 212, CINAHL:

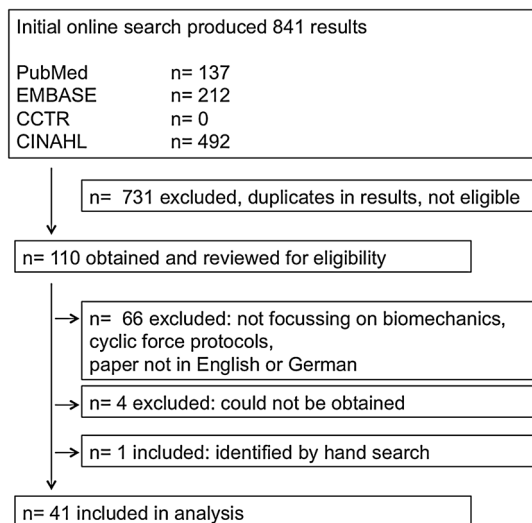


Fig. 1 Study flow chart. This flow chart depicts an overview over the studies in and excluded for this systematic review

492, Cochrane: 0) between 1 January 1995 and 1 January 2013. After exclusion of duplicates, studies not utilizing in vitro uni-axial tension mechanical testing of meniscal repair devices, studies not using comparable loading methods, 41 studies remained for analysis that tested human and animal menisci (Fig. 1). Those 41 studies tested 91 sutures or devices, respectively, out of which 59 % did not explicitly assess cyclic testing. After analysis of these studies, it was evident that cyclic testing was performed in many different manners such as testing at 1 Hz between 5 and 20 N [32, 40], 5 and 50 N [6], and 1 and 11 N [44], respectively. Due to these inconsistencies, cyclic testing was not included in the final analysis.

Quantitative data synthesis

To pool data, a weighted average and standard error was calculated for each device or suture based on number of samples and standard deviation derived from the studies.

It was attempted wherever possible to combine results from the same sutures and devices reported in different studies. However, due to the discrepancies in how some studies stated the suture used, there may be some results, which could be combined, but this was not done in our analysis. Results reported as a mean and standard deviation were used in meta-analysis. All results below are given as corrected mean [95 % confidence interval (CI) about weighted mean]. First- and second-generation devices were evaluated separately as well as a group (Tables 1, 2). First-generation devices were anchors or screws, while second-generation devices were sutures using an anchor. No IRB approval was needed for this meta-analysis on biomechanical tests.

Statistical analysis

All data were entered into Microsoft Excel (Microsoft, Redmond, WA, USA) and analysed with STATA 10 (StataCorp LP, College Station, TX, USA). The level of significance for pooled estimates was set at 5 %.

Results

Overall results

Overall, sutures had a higher LtF (mean \pm standard error, SE) suture: 87.7 ± 0.3 N, device: 56.3 ± 0.1 N), and stiffness (suture: 8.9 ± 0.04 N/mm, device: 8.6 ± 0.04 N/mm) than devices, both with $p < 0.05$.

This section mentions the top three sutures and/or devices in the respective section. Further below, for each suture and device LtF (Table 1) and stiffness (Table 2) with the current evidence references are noted. These figures also depict the different first- and second-generation devices. Second-generation devices were significantly stronger and stiffer than first-generation devices ($p < 0.001$). In the next paragraphs, weighted mean \pm SE are given. Please consult Tables 1 and 2 for CI.

Strongest suture repair (highest load-to-failure)

Listed are the top three suture repairs with respect to LtF. Data are formatted as weighted mean \pm SE.

1. PDS 0 Vertical with 145.0 ± 8.1 N [20]
2. Orthocord 2-0 with 143.6 ± 11.3 N [6, 8]
3. Ethibond No 0 Vertical with 133.4 ± 7.7 N [15]

Strongest device (highest load-to-failure)

1. Meniscal Viper with 140.9 ± 5.1 N [15, 20, 21]
2. MaxFire Vertical with 136.2 ± 11.3 N [5, 8]
3. FasT-Fix Vertical with 115.2 ± 1.6 N [5, 7, 14, 15, 24, 47, 48]

Highest stiffness of all repairs stating an SD

1. FiberWire 2-0 Vertical with 28.7 ± 4.2 N/mm [40]
2. Ultrabraid No. 0 with 26.1 ± 8.1 N/mm [40]
3. Ultra FasT-Fix with 25.6 ± 1.6 N/mm [32, 40]

Strongest repair with respect to orientation of the repair

Those studies explicitly stating the orientation of the repair were analysed for the load-to-failure.

Table 1 Load-to-failure summary

	Studies	Trials	Mean ± SE (N)	95% CI			
Sutures	Ethibond 2-0 Horizontal [35, 47, 48, 50]	4	35	73.9 ± 1.3	(72.7 - 75.2)		
	Ethibond 2-0 Vertical [6, 16, 35, 44, 47, 48, 50]	7	66	82.6 ± 0.8	(81.9 - 83.4)		
	Ethibond 3-0 Horizontal [38]	1	11	29.3 ± 5.0	(24.3 - 34.3)		
	Ethibond No 0 Vertical [15]	1	7	133.4 ± 7.7	(125.7 - 141.1)		
	Fibre Wire 2-0 Vertical [5, 8, 40]	3	37	126.3 ± 3.9	(122.4 - 130.2)		
	OrthoCord 2-0 [6, 8]	2	20	143.6 ± 11.3	(132.3 - 154.9)		
	PDS #1 Horizontal [17, 19]	2	20	105.4 ± 6.5	(98.9 - 111.8)		
	PDS 0 Vertical [20]	1	10	145.0 ± 8.1	(136.9 - 153.1)		
	PDS II Horizontal [25, 43]	2	14	84.6 ± 4.2	(80.4 - 88.8)		
	PDS II Vertical [25, 43]	2	14	123.9 ± 7.4	(116.4 - 131.3)		
	Ti-Cron 2-0 Vertical [13, 22]	2	28	69.9 ± 1.9	(68.0 - 71.8)		
	Ultrabraid No. 0 [8, 40]	2	23	113.0 ± 7.5	(105.4 - 120.5)		
	Suture Total	29	285	87.7 ± 0.3	(87.4 - 87.9)		
1st Gen Devices	Biofix Arrow 10 mm [13, 22, 47]	3	37	43.9 ± 0.6	(43.4 - 44.5)		
	Biofix Arrow 13 mm [1, 13, 14, 16, 17, 19, 22, 35, 43, 44]	10	97	44.8 ± 0.5	(44.3 - 45.4)		
	Biofix Arrow 16 mm [13, 22]	2	27	58.3 ± 3.1	(55.2 - 61.4)		
	Clearfix Screw [17, 20]	2	18	25.6 ± 2.2	(23.4 - 27.8)		
	H-Fix [17, 20]	2	18	24.2 ± 1.0	(23.3 - 25.2)		
	1st Gen Device Total	19	197	39.9 ± 0.2	(39.7 - 40.1)		
	2nd Gen Devices	FasT-Fix Horizontal [5, 7, 24, 47, 48]	5	48	85.6 ± 1.4	(84.2 - 87.1)	
		FasT-Fix Vertical [5, 7, 14, 15, 24, 47, 48]	7	59	115.2 ± 1.6	(113.6 - 116.8)	
		MaxFire Horizontal [5, 6, 32]	3	25	70.7 ± 5.9	(64.8 - 76.6)	
		MaxFire Vertical [5, 8]	2	18	136.2 ± 11.3	(124.9 - 147.5)	
		Meniscal Cinch [6, 32, 40]	3	39	74.8 ± 2.7	(72.0 - 77.5)	
		Meniscal Viper [15, 20, 21]	3	24	140.9 ± 5.1	(135.8 - 146.0)	
		OmniSpan [6]	1	10	87.6 ± 33.9	(53.7 - 121.5)	
Rapid Loc [5, 7, 8, 20, 24, 47, 48]		7	66	46.9 ± 0.4	(46.5 - 47.3)		
TFix Anchor [19, 35]		2	18	74.3 ± 3.4	(70.9 - 77.7)		
Ultra FasT-Fix [8, 32, 40]		3	38	94.5 ± 2.6	(91.9 - 97.1)		
2nd Gen Device Total		36	345	73.0 ± 0.2	(72.8 - 73.2)		
Device Total		55	542	56.3 ± 0.1	(56.2 - 56.3)		
Grand Total		84	827	64.9 ± 0.1	(64.8 - 64.9)		

Second-generation devices were significantly stronger compared to the first-generation devices ($p < 0.001$). Dots indicate weighted mean load-to-failure for each device or suture configuration tested. Bars indicate 95 % confidence interval of the mean. Studies = number of studies that tested the device, Trials = number of samples tested. Total study number includes number of studies counted multiple times for each repair method tested

1. Inside-out with 95.5 ± 2.2 N ($n = 5$ studies)
2. Outside-in with 72.7 ± 1.2 N ($n = 7$ studies)

Strongest repair with respect to positioning of the repair

Those studies explicitly stating the positioning of the repair were analysed for the LtF.

1. Vertical with 97.1 ± 0.8 N ($n = 26$ studies)
2. Horizontal with 60.2 ± 0.8 N ($n = 19$ studies)

The following sutures and devices were tested. Please consult Tables 1 and 2 for details.

Sutures

Resorbable sutures tested were: PDS #1™, PDS 0™, PDS II™ (Ethicon, Inc., Somerville, NJ, USA)

Non-resorbable sutures tested were: Ethibond™ No. 0, Ethibond™ 2-0 and Ethibond™ 3-0 (Ethicon, Inc., Somerville, NJ, USA), FibreWire® 2-0 (Arthrex, Inc., Naples,

FL, USA), Orthocord® 2-0 (DePuy Mitek, Raynam, MA, USA), Ti-Cron™ 2-0 (Covidien, Inc., Mansfield, MA, USA), Ultrabraid® No. 0 (Smith&Nephew, Andover, MA, USA), Nitinol® 2-0 and Nitinol® 3-0 (Clarimed, Los Gatos, CA, USA), Nylon 2-0 and Nylon 3-0 (Assut Medical SARL, Pully-Lausanne, Switzerland)

Devices tested were: Biofix Arrow® 10, 13, and 16 mm (Biofix, Blue Bell, PA, USA), Clearfix® Screw (Innovative Devices, Marlborough, MA, USA), H-Fix®, OmniSpan™ and Rapid Loc® (DePuy Mitek, Raynam, MA, USA), TFix® Anchor, FasT-Fix® and Ultra FasT-Fix® (Smith&Nephew, Andover, MA, USA), MaxFire™ (Biomet, Inc., Warsaw, IN, USA), Meniscal Cinch® and Meniscal Viper™ (Arthrex, Inc., Naples, FL, USA).

Discussion

The most important finding was that the vertically oriented repair remains the gold standard in biomechanical testing by virtue of the highest LtF and stiffness.

Table 2 Stiffness summary

		Studies	Trials	Mean ± SE (N/mm)	95% CI		
Sutures	Ethibond 2-0 Horizontal [27, 47, 48, 50]	4	42	11.0 ± 0.3	(10.6 - 11.3)		
	Ethibond 2-0 Vertical [6, 47, 48, 50]	3	30	15.0 ± 0.4	(14.6 - 15.3)		
	Ethibond 3-0 Horizontal [27]	1	12	6.2 ± 0.7	(5.5 - 6.8)		
	Ethibond No 0 Vertical [15]	1	7	9.8 ± 0.3	(9.5 - 10.1)		
	Fibre Wire 2-0 Vertical [40]	1	13	28.7 ± 4.2	(24.5 - 32.9)		
	Nitinol 2-0 Horizontal [27]	1	12	8.5 ± 1.0	(7.5 - 9.5)		
	Nitinol 3-0 Horizontal [27]	1	12	6.7 ± 1.3	(5.4 - 8.0)		
	Nylon 2-0 Horizontal [27]	1	6	5.2 ± 1.0	(4.2 - 6.2)		
	Nylon 3-0 Horizontal [27]	1	6	2.8 ± 0.4	(2.4 - 3.1)		
	PDS #1 Horizontal [19]	1	8	3.1 ± 0.5	(2.6 - 3.6)		
	PDS II Horizontal [25]	1	7	15.3 ± 3.5	(11.8 - 18.8)		
	PDS II Vertical [25]	1	7	15.6 ± 3.7	(11.9 - 19.3)		
	Ti-Cron 2-0 Vertical [13, 22]	2	28	9.4 ± 0.6	(8.8 - 10.0)		
	Ultrasraid No. 0 [40]	1	13	26.1 ± 8.1	(18.0 - 34.2)		
Suture Total	20	203	8.9 ± 0.04	(8.8 - 8.9)			
Devices	1st Gen Devices	Biofix Arrow 10 mm [13, 22, 47]	3	37	7.6 ± 0.6	(7.0 - 8.2)	
		Biofix Arrow 13 mm [13, 14, 17, 22]	4	41	4.7 ± 0.1	(4.6 - 4.8)	
		Biofix Arrow 16 mm [13, 22]	2	27	10.0 ± 0.7	(9.4 - 10.7)	
		Clearfix Screw [17]	1	8	3.1 ± 0.4	(2.7 - 3.5)	
		H-Fix [17]	1	8	3.1 ± 0.2	(2.9 - 3.3)	
	1st Gen Device Total	11	121	4.8 ± 0.1	(4.7 - 4.8)		
	2nd Gen Devices	FasT-Fix Horizontal [24, 48, 49]	3	26	20.9 ± 0.7	(20.2 - 21.5)	
		FasT-Fix Vertical [14, 15, 24, 48, 49]	5	39	13.3 ± 0.2	(13.1 - 13.5)	
		MaxFire Horizontal [32]	1	9	16.3 ± 3.2	(13.1 - 19.5)	
		Meniscal Cinch [6, 32, 40]	2	29	22.2 ± 1.7	(20.5 - 23.9)	
		Meniscal Viper [15]	1	7	14.6 ± 1.8	(12.8 - 16.4)	
		Rapid Loc [24, 47, 48]	3	26	12.6 ± 0.7	(12.0 - 13.3)	
		Ultra FasT-Fix [32, 40]	2	29	25.6 ± 1.6	(24.0 - 27.2)	
		2nd Gen Device Total	17	165	16.0 ± 0.1	(15.9 - 16.1)	
Device Total		28	286	8.6 ± 0.04	(8.5 - 8.6)		
Grand Total	48	489	8.7 ± 0.02	(8.7 - 8.7)			

Second-generation devices were significantly stiffer than first-generation devices ($p < 0.001$). Stiffnesses for the Orthocord 2–0 and the OmniSpan have been reported to be 27.0 and 27.5 N/mm, respectively, without stating an SD [6]. Thus, those repairs were not taken into the calculations. Dots indicate weighted mean stiffness for each device or suture configuration tested. Bars indicate 95 % confidence interval of the mean. Studies = number of studies that tested device, Trials = number of samples tested. Total study number includes number of studies counted multiple times for each repair method tested

As shown by McCann et al. [29], removal of the meniscus leads to cartilage degeneration with its final stage: osteoarthritis.

Although meniscus repair has evolved during the last decades, meniscal repair devices are still compared to the gold standard of inside-out repairs. Meniscal repair devices are mostly used for posterior horn tears as well as intermediate part tears while suture techniques are preferred for anterior horn tears or detachments. Still, for the anterior horn, suture techniques are commonly used due to the ease in this area. To date, 841 studies have been found that report on meniscus repairs and its biomechanical properties. This impressive amount of studies makes it difficult for orthopaedic surgeons to choose the right repair device. With this comprehensive meta-analysis, we are trying to help in this difficult decision-making process.

Summary of evidence

In this meta-analysis, we tried to include all relevant biomechanical evaluations of meniscal repair devices since the year 1995 up to 1 January 2013.

Higher LtF measurements are considered to be superior in the evaluation of devices and sutures for meniscal repair. Nevertheless, a threshold has never been established and there is still dispute on the amount of in vivo loads to the human meniscus [11, 37]. This makes the final evaluation of the different LtF measurements difficult to interpret.

Another value that has been frequently reported is stiffness. Again, there has been no consensus as to the appropriate threshold value. Regarding biomechanical characteristics, the stiffness of a construct should not be too high (rigid) in order not to have too high shear forces between the repair and the construct, but the agreement as

to what too a high a value might does not exist. In our belief, stiffness is not as important as LtF testing. Stiff materials are considered to be stronger than elastic materials. Nevertheless, stiff materials might more easily cut through soft tissue due to the difference in stiffness. Cyclic testing, which has not been performed in 59 % of the studies analysed, seems to be even more important. We strongly believe that this is the best way to measure the quality of a repair. As reported, two biomechanical factors influence the quality of a repair: (1) initial gapping between the torn meniscus parts at cycle 1 and (2) increase in gapping during cyclic loading [40]. If initial gapping is too high, there is too little contact area between the meniscus parts. On the other hand, if the increase in gapping during cyclic loading is too excessive, initial contact area might be lost. In a worst-case scenario, a 30-year-old man in a walking intensive profession (postman) takes about 12,000 steps a day [42]. Excessive cyclic gapping might thus impair postoperative healing. This makes biomechanical testing, although uni-axial, important.

Although healing rates of up to 83 % with repeat arthroscopies have been reported [9, 46], we do not know if a meniscus completely heals after having undergone repairs. The most commonly used sutures are non-resorbable sutures. It is not known if these are used due to their higher LtF rates or in order to keep the meniscus stable over an extended time span. Second-generation meniscal repair devices show similar biomechanical properties compared to inside-out suture repairs and could thus be used in daily clinical work [6]. Our study has potential shortcomings. Like any meta-analyses, the validity of our findings depends on the validity of the primary studies. Another shortcoming is the heterogeneity of the included primary studies. This is the reason why we did not perform any statistical analysis but to state the large amount of biomechanical outcomes. Although we tried to include comparable studies, several donor species and slight variation in testing methods were included, which might significantly contribute to the error in comparing biomechanical testing [23]. As stated in practically all biomechanical meniscus studies, the uni-axial loading recreates a worst-case scenario and does not reproduce shear forces. We did not consider different crossheads speeds. Most studies use speeds at 3.15 mm/s, but this speed was not consistently used and might thus alter stiffness and LtF values.

Conclusions

Suture repairs remain the gold standard in terms of biomechanical characteristics. A vertically oriented repair seems to be superior to the horizontal orientation based on higher LtF and stiffness values. Meniscal repair devices are

nevertheless evolving with respect to LtF testing. Cyclic testing should always be performed when evaluating the biomechanical properties of meniscal repairs.

Acknowledgments We thank all the authors whose studies we analysed for their contribution. Dr. Buckland thanks the Whitaker International Foundation for fellowship support.

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