

Review

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Biomechanical testing of osteosynthetic locking plates for proximal humeral shaft fractures – a systematic literature review

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Abstract: Proximal humeral shaft fractures can be treated with helically deformed bone plates to reduce the risk of iatrogenic nerve lesion. Controversially to this common surgical technique that was first established in 1999, no biomechanical investigation on humeral helical plating is recorded by other reviews, which focus on proximal fractures exclusively. Does an additional scope for shaft fractures reveal findings of helical testing?

The present systematic literature review was performed based on guidelines by Kitchenham et al. to systematically search and synthesize literature regarding biomechanical testing of osteosynthetic systems for proximal humeral shaft fractures. Therefore, a systematic approach to search and screen literature was defined beforehand and applied on the findings of the database PubMed®. Synthesized information of the included literature was categorized, summarized and analyzed via descriptive statistics.

Out of 192 findings, 22 publications were included for qualitative synthesis. A wide range of different test methods was identified, leading to a suboptimal comparability of specific results between studies. Overall, 54 biomechanical test scenarios were identified and compared. Physiological based boundary conditions (PB-BC) were referenced in 7 publications only. One study of testing straight and helical

dynamic compression plates without PB-BCs was identified, showing significant differences under compressional loading.

The absence of test standards of specific fields like humeral fractures lead to a high variance in biomechanical testing of osteosynthetic locking plates for proximal humeral shaft fractures. Physiological approaches offer realistic test scenarios but need to be uniformed for enhanced comparability between studies. The impact of helically deformed locking plates under PB-BC was not identified in literature.

Keywords: biomechanical testing; helical plating; humeral shaft fractures; locking plates

Introduction

According to the Federal Statistical Office of Germany (Destatis) 81,166 humeral fractures got registered in Germany in the year 2019 [1]. Locking type osteosynthetic systems are due to its adjustability to different fracture types one of the most frequently used osteosynthetic devices to treat humeral fractures [2]. These osteosynthetic systems lock the screw angle-stable relative to the bone plate and therefore the position of the fractured bones to one another to reinforces the fracture zone. Thereby, the implanted system needs to withstand postoperative, physiological loads to avoid a biomechanical failure in use.

Humeral shaft fractures (about 15 % of all humeral fractures) are commonly treated with long internal locking plates, such as the PHILOS® Long by DePuy Synthes (Johnson & Johnson, USA). A critical complication of that treatment is iatrogenic radial nerve damage with cited rates from 2.7 to 20 % [3–8]. To reduce the risk of nerve lesion, helical shaped plates are implanted to bypass the anatomical path of the radial nerve, resulting in 0 % cases of iatrogenic nerve damage [8–11]. This method was first introduced by Gill et al. in the year 1999 [12]. Up until now, the helical shape of the bone plate is created mostly manually by the surgeon

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using two bending iron tools prior to implantation. The straight bone plate is thereby plastically deformed and consequently changed in its material properties at the section of deformation. A pre-shaped, helical implant is not available on the market so far.

Short-term clinical studies did not find relevant differences in stability-related complications between groups of patients treated with a straight or helical PHILOS plate. Nevertheless, a change of the biomechanical performance of a helical deformed osteosynthetic system is to be expected and may influence the long-term performance of the whole system.

An ongoing research project by the author's research group investigates the changes of the biomechanical performance and durability due to the plastic deformation of helical shaped PHILOS® Long plates under physiological static and cyclic loading. Biomechanical testing of a complete osteosynthetic system with cadaver bone or bone substitute, also called implant system testing (IST), relies on the state of the art of test methods in this field.

Systematic literature reviews of biomechanical tests of osteosynthetic plate-screw-devices for humeral fractures are rare. Only two systematic reviews by Jabran et al. [13] and Cruickshank et al. [14] were identified, which focus on biomechanical analysis of osteosynthetic devices for proximal humerus fractures exclusively. Both reviews record no testing on helically deformed plates for humeral fracture treatments. But is there no testing on helical plates for humeral fractures done? Or does a search focus of proximal fractures only prevent findings of helical testing in literature?

Consequently, a systematic literature review was performed covering proximal and diaphyseal fracture types to add knowledge to the existing reviews and therefore to answer the following three research questions:

- (1) What is the current state of the art in biomechanical *in vitro* testing of osteosynthetic plate-screw-systems for humerus fractures?
- (2) Are physiological boundary conditions regarding the support and loading of the IST considered and applied to the test method?
- (3) Are test methods applied to helical shaped humerus plates?

Review methodology

This systematic literature review is based on guidelines and procedures by Kitchenham et al. for performing systemic reviews [15]. Hence, a specific search and selection process for investigating publications in the PubMed® database was defined.

Selection criteria

The timeline of published articles was set from the year 2000 to October 2022 to identify potentially relevant publications. Additionally, only articles in English language and available as full text were considered in the search strategy. The search string was applied to all fields as follows:

(biomechanic*) AND (humerus) AND (test*) AND ((bone plate) OR (plate) OR (helical plate) OR (twisted plate)).

Data extraction and synthesis

All findings of the initial search were surveyed in three steps according to a systematic methodology as seen in Figure 1.

Therefore, inclusion and exclusion criteria were defined beforehand and applied in each step. Articles were excluded

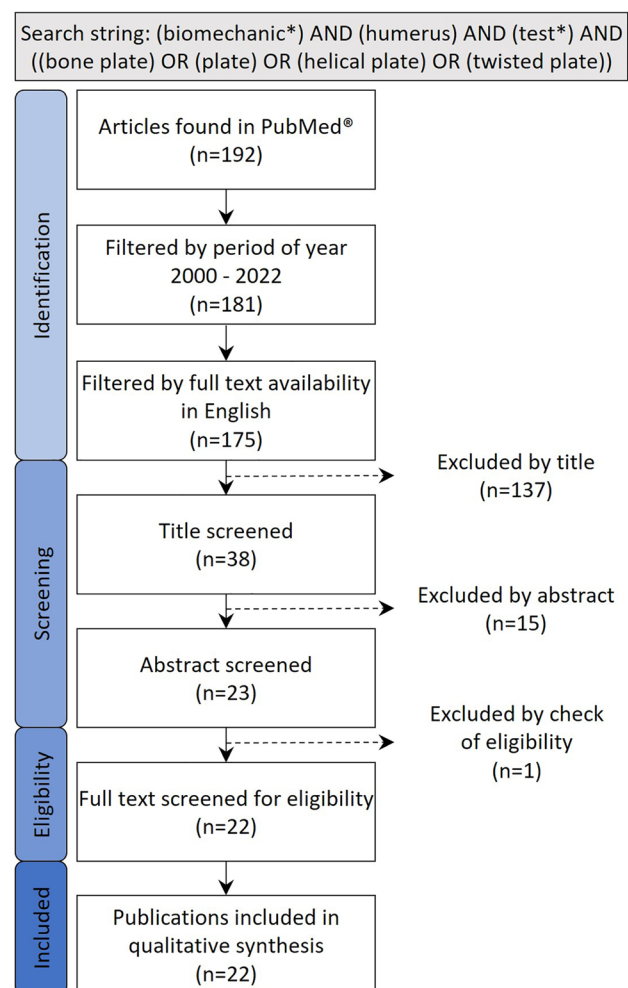


Figure 1: Flow-chart of the applied methodology for the systematic literature review.

if they did not or partly comply with the inclusion criteria or matched a single exclusion criterion.

Exclusion criteria:

- Title shows no evidence to research questions.
- Scope of the article is unclear in terms of the research aims, the applied methods or materials.
- Test setup not specifically developed for testing osteosynthetic systems for humeral shaft fractures.
- Boundary conditions of the test setup in terms of the specimen support and loading is unstated.
- Tested osteosynthetic system is different to a plate-screw-system type (e.g., external fixation, intramedullary nail).

Inclusion criteria:

- Test setup for testing osteosynthetic systems for humeral fractures is identified.
- Straight or helical shaped bone plates were tested biomechanically via an IST.

After the systematic survey methodology was applied to the initially found 192 articles, a total of 22 articles remained and were included for conducting the review.

Synthesized information of all articles was labeled and grouped in the following categories:

Loading scenario: static (S) or cyclic (C).

Type of loading: axial loading tension (AL+), axial loading compression (AL–), axial torque (AT), inclined loading tension (IL+), inclined loading compression (IL–), bending (B), mixed (M:*,*) where * stands for the type of loading (e.g., M:AL–;AT), Increased cyclic loading (ICL) with specifications.

Sample size: total sample size for each type of loading {group size}.

Boundary condition (BC) of sample: fixed boundary condition (FBC), rotational degree of freedom (RDF), translational degree of freedom (TDF), rotational and translational degree of freedom (RTDF), each with index regarding support/loading.

Type of implant: dynamic compression plate (DCP), locking compression plate (LCP) with index to helical shape, compression screw (CS), locking screw (LS).

Type of bone: cadaver bone (CB), artificial bone (AB) (brand + type), bone substitute (BS) (shape + material).

Type of fracture: AO-Classification, non-classified with regard to the number of bone parts and segment of fracture, size of fracture gap.

All results were analyzed using descriptive statistics and were listed in a table with specifics to each article. In general, extracted information was converted to SI units for enhanced comparability between studies. In addition, stated AO-Classification of fracture types of older publications were

updated to the latest standard of classification from 2018 [16] and fractures without stated AO-Classification were classified if distinct to description and visualization. Both kinds of adjustment got asterisked (*) in the results.

Since the research question of this systematic literature review focuses on implant systems in form of plate-screw-systems, data regarding biomechanical testing of intramedullary nails were not synthesized.

Results

In general, the setup configuration, the load protocols and the load specifications of the ISTs showed high variation among the 22 reviewed publications. Of these twenty-two, 4 publications performed ‘static only’ tests, 16 publications focused on ‘cyclic only’ tests and 2 publications performed ‘static & cyclic’ tests. In addition, a total of 54 biomechanical load scenarios were identified and analyzed.

The main type of loading was compression realized either in form of AL– (21/54) or IL– (14/54), followed by AT (14/54). Only one load scenario covered a mixed loading in form of M:AT;AL– (Figure 2).

The boundary conditions regarding the support and loading of the sample were well described in most publications. Only 3 load scenarios did not specify the BC of the loading. The most common support was the FBC (45/54). The most common BC for loading the sample was a RTDF (22/54), followed by FBC (16/54) and RDF (15/54) as seen in Figure 3.

Within the 54 load scenarios, a physiological based boundary condition (PB-BC) was declared and references in terms of the support 12 times, and in terms of the loading 6 times (Figure 3). The studies of Bergmann et al. [17, 18] and Westerhoff et al. [19] are common references for describing the plausibility for PB-BCs.

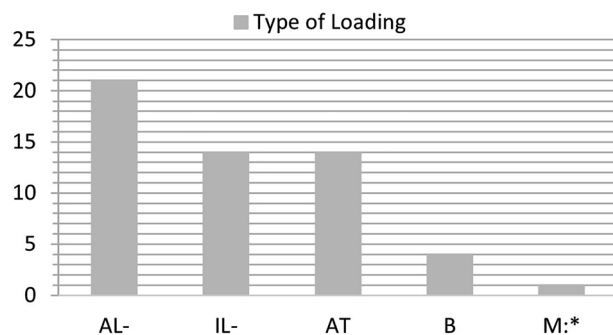


Figure 2: Quantity of types of loading identified in reviewed literature regarding axial compression (AL–), inclined loading compression (IL–), axial torsion (AT), bending (B) and mixed loading (M:*).

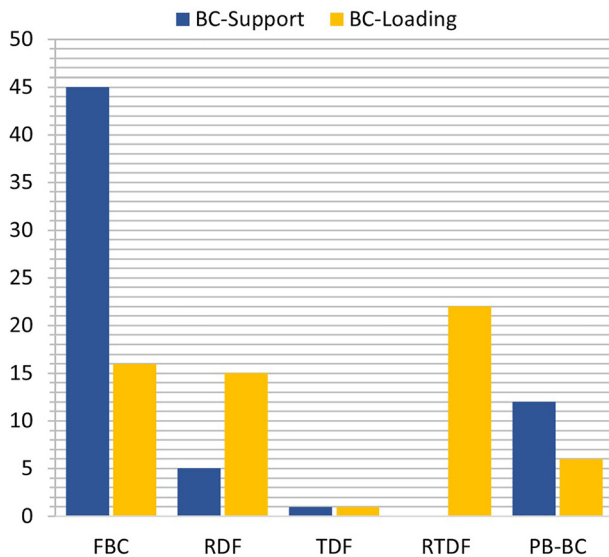


Figure 3: Quantity of different types of boundary conditions (BC) in ISTs in respect of the support (blue) and the loading (yellow) in the reviewed literature regarding a fixed boundary condition (FBC), rotational degree of freedom (RDF), translational degree of freedom (TDF), rotational-translational degree of freedom (RTDF) and the declarations of physiological based boundary conditions (PB-BC).

The analysis of the load scenarios and their respective specifications lead to the identification of 5 approaches applied to ISTs: (a) the use of separate samples for static and cyclic loadings, (b) a stiffness and maxima determination via static loading, (c) a stiffness and maxima determination via cyclic loading with 2–5 cycles, (d) sequential test protocols with non-destructive loadings followed by cyclic loading and (e) sequential test protocols with cyclic loadings followed by load-to-failure loadings (Figure 4).

Only one of the twenty-two publications investigated the biomechanical performance of a helical shaped bone plate against a straight bone plate under different load conditions. The results showed significant differences in

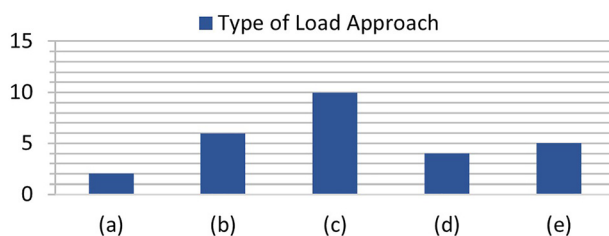


Figure 4: Quantity of different load protocols identified in literature review: (a) Separate samples for static and cyclic loading, (b) stiffness and maxima determination via static loading, (c) stiffness and maxima determination via cyclic loading, (d) sequential test protocols with non-destructive loadings followed by cyclic loading, (e) sequential test protocols with cyclic loadings followed by load-to-failure loadings.

axial compression, bending and torsional tests between the helical and straight groups with favoring results for the helical shaped plate in axial compression and torsional loading [20].

Detailed results of all synthesized literature are listed in Tables 1 and 2.

Discussions

The scope of the presented systematic literature review was to synthesize the included publications with the objective to answer the three stated research questions regarding the biomechanical testing of osteosynthetic systems for proximal humeral shaft fractures.

The comprehensive results show a wide range of different test methods, especially in terms of the applied boundary condition of the support and loading, the load approach and the type of loading in general. Due to this heterogeneity in IST, specific results between studies are mostly incomparable to one another.

Physiological based boundary conditions were only referenced in 7 publications [21–27], resulting in 12 declarations for PB-BC of the support and 6 declarations for PB-BC of the loading. To proof plausibility of the chosen PB-BC, common references were the studies of Bergmann et al. [17, 18] and Westerhoff et al. [19]. These referenced studies measured *in vivo* the resulting loads inside the glenohumeral joint under typical daily activities via an instrumented implant. The peak of the load is stated to be under 20° abduction and adduction. To mimic this scenario of an inclined loading (IL-), the test sample is mounted in inclined position as a FBC in $\pm 20^\circ$ relative to the vertical axis of the test machine in studies with PB-BCs. The IL-was performed in 8 of the 22 publications. Within that group, 3 publications applied the test load via an RDF and 5 via an RTDF. Anatomically, the glenohumeral joint is a ball-and-socket joint with no transversal degree of freedom. The use of an RDTF is therefore questionable.

For enhanced replicability, 20 of 22 publications created the fracture based on AO-Classifications. A specific description of the osteotomy with information about the fracture type, gap and used tools was done in most publications. Cadaveric as well as artificial bones (Sawbones®/Synbone®) were commonly used for biomechanical testing. However, the use of cadaver bones requires the determination of the bone mineral density beforehand, to avoid the use of pathologic bones. Beside that time consuming process, each donor's individual bone characteristic may lead inevitably to an inconsistency within a sample group. On the other hand, artificial bones replicate the mechanical

Table 1: Summary of findings (part 1 of 2) with labeled data in regard to the load scenario: static (S) or cyclic (C) loading; the type of loading: axial loading tension (AL+), axial loading compression (AL-), axial torque (AT), inclined loading tension (IL+), inclined loading compression (IL-), bending (B), mixed (M^{a,b}); the sample size: total sample size for each type of loading (group size); the boundary condition: fixed boundary condition (FBC), rotational degree of freedom (RDF), translational degree of freedom (TDF), rotational and translational degree of freedom (RTDF), each with index regarding support/loading; the type of implant: dynamic compression plate (DCP), locking compression plate (LCP) with index to helical shape, compression screw (CS), locking screw (LS); type of bone: cadaver bone (CB), artificial bone (AB) (brand + type), bone substitute (BS).

Reference	Loading scenario	Type of loading	Sample size	Specifications of loading	Boundary condition of sample: support/loading	Type of implant	Type of bone	Type of fracture
Acklin et al. [21]	C	IL-	12(4)	1st cycle: 20–100 N; ICL: 0.05 N/cycle; 2 Hz	FBC/RDF in 30° adduction	a) Gliding plate (prototype) b) PHILOS (synthes) c) Gliding plate (a) with cement	CB	3P proximal (AO-11B1.1*) gap: 1 mm
Ahmad et al. [28]	S	AL-	12(3)	100 N steps until failure	FBC/FBC	DCP & LCP	AB	2P middle diaphyseal gap: 10 mm (AO-12A3 ^a)
		AT	12(3)	5 Nm	FBC/FBC		Sawbones 3rd gen.	2P middle diaphyseal gap: 10 mm (AO-12A3 ^a)
	C	AL-	12(3)	5–250 N, 5 N/s, 1,000 cycles	FBC/FBC			
		AT	12(3)	0–5 Nm	FBC/FBC			
Aksakal et al. [20]	S	AL-	28(7)	0.083 mm/s	FBC/FBC	a) DCP	CB(sheep)	2P middle diaphyseal gap: 1.5 mm
		AT	28(7)	0.017 rad/s	FBC/FBC	b) DCP helical 90°		
	B		28(7)	0.083 mm/s	3-Point-bending			
Al-Jahwari et al. [29]	S	AT	24(8)	0.0017 rad/s (linear), 0.524 rad/s (failure)	FBC/FBC	DCP 10-hole (zimmer)	AB	2P middle diaphyseal gap: 20 mm (AO-12A3*)
							Sawbones #3304 CB & AB	2P middle diaphyseal gap: 5 mm
Becker et al. [30]	C	AT	12(12)	±10 Nm, 0.3 Hz, 1,000 cycles	FBC/FBC	LCP 10-hole (synthes)	Synbone & Sawbones	(AO-12A3*) 3P proximal
			36(6)					
Dankl et al. [31]	C	AL-	24(12)	1st cycle: –10–50 N, ICL: 0.05 N/cycles, 5 mm/s, 10,000 cycles	FBC/RDF	PHILOS (synthes)	CB	V-gap ≤10 mm (AO-11B1.1*) 2P proximal neck V-gap: 5–10 mm (AO-11A2.2*) 2P proximal neck V-gap ≤8 mm (AO-11A2.2*) 2P proximal neck V-gap ≤10 mm (AO-11A2.2*)
Di Tullio et al. [32]	S	AL-	15(5)	0.083 mm/s	FBC/RDF	T-shaped anatomic LCP (Johnson&Johnson)	AB (3012BESP)	
Hessmann et al. [33]	C	AL- AT	24(6)	10–120 N, 0.1 Hz, sinus, 4 cycles 0.4–2.5 Nm, 4 cycles	FBC/RDF FBC/RDF	AO T-plate (synthes)	CB	
Katthagen et al. [22]	C	AL- IL- AT	32(8)	Stiffness tests: 0.1 mm/s, 200 N, 3 cycles Stiffness test: ±3.5 Nm, 0.0017 rad/s, 3 cycles Cyclic tests: 50–250 N, 1 Hz, sinus, 5,000 cycles	FBC/RTDF in 0°, ±20° ab-/adduction RDF/RDF	PHILOS (synthes)	CB	
		AL- IL-			FBC/RTDF in 0°, ±20° ab-/adduction			(AO-11A2.1*)

Table 1: (continued)

Reference	Loading scenario	Type of loading	Sample size	Specifications of loading	Boundary condition of sample: support/loading	Type of implant	Type of bone	Type of fracture
Katthagen et al. [23]	C	AL- IL-AT	14(7)	Stiffness tests: 0.1 mm/s, 200 N, 3 cycles Stiffness test: ± 3.5 Nm, 0.0017 rad/s, 3 cycles Cyclic tests: 50–250 N, 1 Hz, sinus, 5,000 cycles	FBC/RTDF in 0°, $\pm 20^\circ$ ab-/adduction RDF/RDF	a) PEEK plate (arthrex) b) PHILOS (synthes)	CB	2P proximal neck gap: 10 mm (AO-11A2.1*)
Kim et al. [24]	C	AL-	24(6)	500 N, 1 Hz, 5,000 cycles & 0.083 mm/s load-to-failure after cyclic loading	FBC/RDF	PHILOS (synthes)	AB (1,028)	2P proximal neck V-gap ≤ 10 mm (AO-11A2.2*)
Röderer et al. [34]	C	IL-	12(6)	1st cycle: 15–50 N, ICL: 0.035 N/cycle, 0.25 Hz, sinus	FBC/RDF in adduction	PHILOS (synthes)	CB	V-gap: ≤ 10 mm (AO-11A2.2*)

characteristics of real bones adequately, ensure consistency within the test sample group, but idealize reality.

The synthesis regarding static and cyclic load protocols among the included literature resulted in five different types of load approaches. The approach of sequential loadings, type (d) and type (e), were identified in 9 out of 54 biomechanical load scenarios, as seen in Figure 4. Both approaches analyze the results of each test sequence separately, regardless of the factor that the second sequence is applied on a pre-loaded sample. The biomechanical interpretation of the second sequence is therefore limited, due to the pre-loaded state of the sample. However, a sequential approach of one sample is reasonable if the change of a certain parameter is meant to be analyzed over time in comparison to the system's initial performance. For example, the bending stiffness of an implant system is meant to be analyzed during an overall cyclic test via subsequential static tests.

Within the identified 45 cyclic load scenarios, the load limits were defined in either of the following three types: (1) based on physiological loadings from literature, (2) system-specific loads based on previous static tests of the same osteosynthetic system or (3) as an increased cyclic loading starting from a relatively small load. In terms of type two, system specific loads lead to an incomparability between studies since the performance of the osteosynthetic systems is tested under different load boundaries. And in terms of type three, an increased cyclic loading tests the system in a wider load range than may physiologically relevant. Once the physiological range is reached, the osteosynthetic system is already in a pre-loaded state and might have already experienced a change in performance. Hence, type one is the most plausible type to define load limits.

Conducting the systematic literature review, only one study by Aksakal et al. was identified testing helically deformed DCPs regarding potential advantages in performance over conventional straight DCPs under compressional, torsional and 3-point-bending loading [20]. This study states significant differences between the helical and straight sample group under compression and 3-point-bending load. Unfortunately, a continuous mix-up in labeling the sample groups was identified during the screening process. Due to this mistake, the results of this study are unclear.

Conclusions

The conducted systematic literature review in the field of IST of osteosynthetic locking plates for proximal humeral shaft fractures displayed a high variance in test methods and

Table 2: Summary of findings (part 2 of 2) with labeled data in regard to the load scenario: static (S) or cyclic (C) loading; the type of loading: axial loading tension (AL+), axial loading compression (AL-), axial torque (AT), inclined loading tension (IL+), inclined loading compression (IL-), bending (B), mixed (M+); the sample size: total sample size for each type of loading (group size); the boundary condition: fixed boundary condition (FBC), rotational degree of freedom (RDF), translational degree of freedom (TDF), rotational and translational degree of freedom (RTDF), each with index regarding support/loading; the type of implant: dynamic compression plate (DCP), locking compression plate (LCP) with index to helical shape, compression screw (CS), locking screw (LS); type of bone: cadaver bone (CB), artificial bone (AB) (brand + type), bone substitute (BS).

Reference	Loading scenario	Type of loading	Sample size	Specifications of loading	Boundary condition of sample: support/loading	Type of implant	Type of bone	Type of fracture
Sandmann et al. [35]	C	AL-	12{6}	1st cycle: -50 – 10 N, ICL: 0.05 N/cycles, 5 mm/s	RDF/FBC	a) PHILOS (synthes)	CB	3P proximal
		AT	12{6}	1st cycle: ± 0.5 Nm, ICL: ± 0.0025 Nm, 0.25 Hz	TDF/RDF	b) PHILOS + dynamic locking screws		
Seide et al. [36]	S	AL-	14{7}	0.083 mm/s	RDF/RDF	a) Tifix plate + LS (litos)	CB	2P proximal gap: 10 mm
	C	AL-	10{5}	10–80 N, 5 Hz, 1 m cycles	RDF/RDF	b) Tifix plate + CS		(AO-11A2.1*)
Shin et al. [25]	C	IL-	24{8}	500 N, 5 Hz, 1,000 cycles & 0.083 mm/s load-to-failure after cyclic loading	FBC/RDF in 20° adduction	ARIX (JEIL medical)	AB	2P proximal neck gap: 10 mm
Siffri et al. [37]	C	AT	12{6}, 10{5}	± 2 Nm, 5,000 cycles	FBC/FBC	a) LCP (synthes)	Synbone (LD 5030) CB & AB	(AO-11A2.1*) 2P proximal neck
		B	12{6}	0–7.5 Nm, 10,000 cycles	FBC/TDF	b) LC-Angled blade plate (synthes)	Sawbones 2nd gen. CB	(AO 11A2.1*) 2P proximal neck
Theopold et al. [38]	C	IL-	18{9}	10–250 N, 1 Hz, sinus, 5,000 cycles & 0.1 mm/s load-to-failure after cyclic loading	FBC/RTDF in 20° abduction FBC/RTDF	a) Winstaph (axomed)		gap: 10 mm (AO-11A2.1*)
		AL-		Nondestructive cyclic loading – torsion:	FBC/RDF	b) Winstaph + straight AO plate a) LCP proximal humerus (synthes)	AB	3P proximal neck
Tilton et al. [26]	C	AT	15{3}	Nondestructive cyclic loading – torsion:	FBC/RDF	b-e) Prototypes based on reversed engineering	Sawbones 4th gen.#10	gap: 10 mm (AO-11B1.1*)
		AL- IL-		± 3.5 Nm, 0.0017 rad/s, 4 cycles Nondestructive cyclic loading – compression:	FBC / RTDF in 0°, $\pm 20^\circ$ ab-adduction			
		AL-		50–200 N, 0.1 mm/s, 4 cycles Cyclic loading – compression:	FBC/RTDF			
				1st cycle: 0–50 N, ICL: 0.25 N/cycle, 1 Hz, sinus				
Yoon et al. [27]	S	AL-	16{8}	1.67 mm/s	FBC/RTDF in 20° abduction	a) 3.5 mm LCP b) 4.5 mm LCP	CB	2P proximal neck V-gap ≤ 10 mm (AO-11A2.2*)
Zettl et al. [39]	C	AL-	18{9}	200 cycles: 0–90 N, 0–180 N, 1 Hz 2,200 cycles: 0–450 N, 1 Hz & 1 N/s load-to-failure after cyclic loading	FBC/RDF	a) PHILOS (synthes) b) NCB plate (zimmer)	CB	2P proximal neck V-gap ≤ 10 mm (AO-11A2.2*)

Table 2: (continued)

Reference	Loading scenario	Type of loading	Sample size	Specifications of loading	Boundary condition of sample: support/loading	Type of implant	Type of bone	Type of fracture
Zhang et al. [40]	C	AL-	12{3}	100–500 N, 10 Hz	FBC/FBC	LCP PHILP (Jiangsu ideal medical science & technology co., ltd.)	AB	2P proximal neck
		AL-		100–500 N, 0.25 mm/s	FBC/FBC		Synbone (#5010)	(AO-11A2.2*)
		B		4.16 N/s, max. 7.5 Nm	3-Point-bending			
		AT		0.01 Nm/s, max. 3 Nm	FBC/FBC			
Zheng et al. [41]	C	AT	24{8}	±5 Nm, 0.05 Hz, 1,500 cycles	FBC/FBC	10-hole limited-contact plate (Tianjin ZhengTian medical instrument co., ltd.)	AB	2P distal diaphyseal
		M:AT;AL-		50–500 N, ±5 Nm, 0.05 Hz, 1,500 cycles	FBC/FBC		Sawbones	gap: 6.5 mm
		B		24–240 N, 0.5 Hz, 1,500 cycles	4-Point-bending		4th gen #3404	(AO-12A3C*)
		AT		0.0043 rad/s load-to-failure after cyclic loading	FBC/FBC			

procedures. The absence of a specific standard for IST in this field results in an incomparability of test results between studies, due to heterogeneous boundary conditions and load scenarios.

A physiological based approach seems to be the most plausible approach for IST, due to the available biomechanical *in vivo* data provided in literature. BCs for the support and loading, load scenarios and load specifications can therefore be uniformly defined, leading to an enhancement of comparability between studies and realistic analyses of the biomechanical performance and safety of the tested system. The most common loading type in literature was compression as type AL- and IL-. A plausible PB-BC for humeral IST is FBC/RDF (support/loading).

Only one study of an IST on helically deformed bone plates was identified in this systematic literature review, showing a significant difference between straight and helical DCPs under loading. However, no study was identified covering helical locking type plates. Further biomechanical analyses via ISTs of helically deformed bone plates are reasonable to investigate potential changes in performance and safety due to plastic deformation of the osteosynthetic system.

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