Poor relation between biomechanical and clinical studies for the proximal femoral locking compression plate

A systematic review

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Background and purpose — The proximal femur locking compression plate (PF-LCP) is a new concept in the treatment of hip fractures. When releasing new implants onto the market, biomechanical studies are conducted to evaluate performance of the implant. We investigated the relation between biomechanical and clinical studies on PF-LCP.

Methods — A systematic literature search of relevant biomechanical and clinical studies was conducted in PubMed on December 1, 2015. 7 biomechanical studies and 15 clinical studies were included.

Results — Even though the biomechanical studies showed equivalent or higher failure loads for femoral neck fracture, the clinical results were far worse, with a 37% complication rate. There were no biomechanical studies on pertrochanteric fractures. Biomechanical studies on subtrochanteric fractures showed that PF-LCP had a lower failure load than with proximal femoral nail, but higher than with angled blade plate. 4 clinical studies had complication rates less than 8% and 9 studies had complication rates between 15% and 53%.

Interpretation — There was no clear relation between biomechanical and clinical studies. Biomechanical studies are generally inherently different from clinical studies, as they examine the best possible theoretical use of the implant without considering the long-term outcome in a clinical setting. Properly designed clinical studies are mandatory when introducing new implants, and they cannot be replaced by biomechanical studies.

Efficacy and patient safety are key elements when new orthopedic implants are introduced on the market. This has been emphasized by Malchau in "On the stepwise introduction of new hip implant technology" (1995), consisting of 4 steps: the initial step with preclinical testing followed by 3 clinical steps including prospective randomized controlled trials, multicenter studies, and registry studies. Biomechanical studies are preclinical, and testing is aimed at reflecting the physiological situation with regard to efficacy of the mechanical fixation capability of the implant. They evaluate equivalency or improvement between the new implant and already established implants (Basso et al. 2012). Schemitsch et al. (2010) stressed the importance of biomechanical studies and suggested that studies could be ranked in the evidence hierarchy between expert opinion and clinical trials. However, biomechanical studies cannot reflect the clinical setting exactly. Malchau et al. (2011) referred to it as the "[..] inherent 'gap' between nonhuman supporting data and the unknowns of both efficacy and long-term safety in large human usage over many years [..]".

The "inherent gap" is especially interesting in the case of the locking compression plate (LCP) for the proximal femur (PF-LCP) (Figure 1), as biomechanical and clinical studies may not agree. An early prospective multicenter study on various fractures treated with LCP reported an 86% success rate (Sommer et al. 2003). The LCPs were supposed to be superior to the conventional fixation method in osteoporotic bone through better mechanical fixation of the implant to the bone (Wagner et al. 2004). The PF-LCP was then introduced for the treatment of proximal femoral fractures in 2007, with great expectations (Schmidt 2008)—as the first 3 biomechanical studies all showed PF-LCP to be stiffer and to have superior failure load compared to other implants (Aminian et al. 2007, Crist et al. 2009, Floyd et al. 2009). However, the first 2 clinical case-series showed complication rates of 29% and 70% (Wieser and Babst 2010, Glassner and Tejwani 2011).

This review explores the relation between the biomechanical and clinical studies for PF-LCP used in primary proxi-

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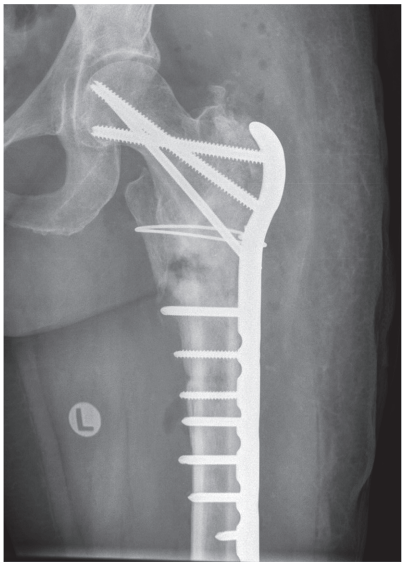

Figure 1. Locking compression plate used for treatment of a proximal femoral fracture.

mal femoral fractures, using a systematic approach for study retrieval. We chose PF-LCP for this review because it was introduced recently, with modern standards in both biomechanical and clinical trials.

Retrieval of studies

The searches were performed similarly to systematic reviews regarding the methods paragraph of the the PRISMA statement (Moher et al. 2010). Search strings were created in collaboration with a scientific librarian with expertise in systematic review.

The search string for biomechanical studies was as follows: ((biomechanical testing) OR (biomechanical research) OR (cadaver study) OR (biomechanical investigation) OR (in vitro) OR (biomechanical study) OR (biomechanical analysis) OR (biomechanical phenomena) OR (mechanical testing) OR (comparative analysis)) AND ((femoral neck fracture*) OR (fracture of the femoral neck) OR (hip fracture) OR (trochanteric fracture) OR (proximal femoral fracture) OR (intertrochanteric fracture) OR (subtrochanteric fracture)) AND (locking plate OR proximal femoral locking plate OR pflp OR LCP OR locking compression plate OR lc-dcp OR limited contact dynamic compression plate OR locking screw plate* OR (locked nail plate) OR pflcp OR pf-lcp OR proximal femur locking compression plate OR femur compression bone plate OR femoral neck locking plate OR FNLP).

The search string for clinical studies was as follows: clinical study OR comparison OR (case control) AND ((femoral neck fractures) OR (fracture of the femoral neck) OR (hip fracture) OR (trochanteric fracture) OR (proximal femoral fracture) OR (intertrochanteric fracture) OR (subtrochanteric fracture) OR (pertrochanteric fracture)) AND (locking plate OR proximal femoral locking plate OR pflp OR LCP OR locking compression plate OR lc-dcp OR limited contact dynamic compression plate OR locking screw plate* OR (locked nail plate) OR pflcp OR pf-lcp OR proximal femur locking compression plate OR femur compression bone plate)

The searches were conducted in PubMed on December 1, 2015. PF-LCP was introduced in 2007, and therefore 2007 was used as a time limit and all study designs were included. Language was limited to English or German, and animal studies were excluded. The following implants were excluded: implants resembling the PF-LCP, such as the Targon FN (Parker 2011), distal femur LCP used proximally, or LCP used in periprosthetic fracture management. Revision of earlier operations and pathologic fracture (other than osteoporosis) management were also excluded.

The searches yielded 124 biomechanical and 148 clinical studies. 2 reviewers screened the studies by title, then by abstract, and finally by reading the full text. The final list with included studies was compared and disagreement was solved through discussion between the 2 reviewers. To ensure literature saturation, reference lists of included studies or relevant reviews identified through the search were scanned, and 2 further clinical studies were found. 7 biomechanical studies (Table 1) and 15 clinical studies (Table 2) met the inclusion and exclusion criteria.

One reviewer extracted data from the studies, and discussion of relevant data was done by all authors. A second reviewer cross-checked all the data in Tables 1 and 2.

Femoral neck fractures were defined as fractures classified as Arbeitsgemeinschaft für Osteosynthesefragen (AO) subgroup 31-B (Müller et al. 1990), and by Pauwels (1935). Pertrochanteric fractures were defined as fractures classified as AO subgroup 31-A1 and 31-A2 (Müller et al. 1990), and by Jensen (1980a) and Kyle (1979). Subtrochanteric fractures were defined as fractures classified as AO subgroup 31-A3 and 32 (Müller et al. 1990), and by Seinsheimer (1978) and Zickel (1976). Complications were defined as revision surgery due to hardware failure, fracture collapse, nonunion, malunion, cut-out, or deep infection. Biomechanical studies included axial stiffness, torsional stiffness, and failure load. Stiffness is defined as force divided by displacement i.e. axial stiffness is the force (in Newtons) needed to bend the implant (in millimeters). Failure load is defined as the force needed to make the implant fail as defined by the individual paper.

Review of studies

Femoral neck fracture

2 biomechanical studies were included here (Table 1), and both showed that PF-LCP had higher axial stiffness. However, 1 study showed that the dynamic hip screw (DHS) had the highest

Table 1 Biomechanical studies with locking plates for proximal femoral fractures (PF-LCP)

Author Year, country	Bone type	Implant type	Fracture type	Axial stiffness, mean, N/mm	Torsional stiffness, Nm/degree	Failure load, mean, kN
Femoral neck						
Nowotarski et al. 2012, USA	Synthetic	FNLP DHS CS	Pauwels' 3	3,211 2,779 2,207	18.7 Nm mm^{-1} 4.5 Nm mm^{-1} 4.1 Nm mm^{-1}	1.94 2.32 1.74
Aminian et al. 2007, USA	Synthetic	PF-LCP DHS DCS CS	Pauwels' 3	618 (SD 164) 245 (SD 51) 320 (SD 46) 166 (SD 50)	–	2.43 (SD 0.62) 1.19 (SD 0.21) 2.16 (SD 0.44) 0.86 (SD 0.37)
Subtrochanteric						
Wang et al. 2014, China	Cadaveric, frozen	PF-LCP PFN DHS DCS	Seinsheimer 1, 3, 4	No difference between implants	DCS most stiff	1.90 (SD 0.37) 2.81 (SD 0.32) 2.37 (SD 0.65) 1.57 (SD 0.40)
Latifi et al. 2012, Malaysia	Synthetic	PF-LCP DCS ABP	Seinsheimer 4 (2-cm gap)	131 (SD 11) 110 (SD 12) 71 (SD 16)	–	1.60 (SD 0) 1.17 (SD 0.05) 1.10 (SD 0)
Forward et al. 2012, USA	Cadaveric, frozen	PF-LCP PFN ABP	Seinsheimer 4 (2-cm gap)	102 142 82	–	1.09 (CI 1.01–1.16) 1.73 (CI 1.69–1.77) 1.07 (CI 0.93–1.21)
Floyd et al. 2009, USA	Synthetic	PF-LCP old PF-LCP new ABP	Seinsheimer 3–4 (2-cm gap)	120 (CI 99–141) 151 (CI 125–176) 112 (CI 91–135)	–	0.60 (CI 0.49–0.70) 0.75 (CI 0.63–0.88) 0.56 (CI 0.45–0.67)
Crist et al. 2009, USA	Synthetic	PF-LCP PF-LCP+KS ABP LBP	30° osteotomy similar to 31A3, 32B1-3, C1-3	48 (SD 12.6) 92 (SD 17.4) 44 (SD 3.7) 30 (SD 8.9)	1.76 (SD 0.12) 1.89 (SD 0.39) 2.42 (SD 0.08) 1.60 (SD 0.11)	Failure by 1,000 N reported in mm, PF-LCP + KS is superior

ABP: Angled blade plate; CI: 95% confidence interval; CS: Cannulated screw; DCS: Dynamic condylar screw; DHS: Dynamic hip screw; FNLP: Femoral neck locking plate; KS: Kickstand screw; LBP: Locking broad plate; PFN: proximal femoral nail.

failure load (Nowotarski et al. 2012) whereas the PF-LCP had the highest failure load in the other study (Aminian et al. 2007). Only 1 clinical study (Table 2) included femoral neck fracture and found a complication rate of 37% (Berkes et al. 2012).

Pertrochanteric fracture

No biomechanical studies were found here. 1 clinical study included only pertrochanteric fractures and 7 studies included both pertrochanteric fractures and subtrochanteric fractures (Table 2). The outcome varied markedly; 5 studies found complication rates of 25–53% (Wieser and Babst 2010, Floyd et al. 2013, Mardani-Kivi et al. 2013, Wirtz et al. 2013, Johnson et al. 2014). 1 study showed a combined low complication rate of 6% for pertrochanteric and subtrochanteric fractures (Chalise et al. 2012). The largest study, with 98 pertrochanteric fractures, reported a 2% reoperation rate, but it was not clearly defined as being prospective or retrospective (Zha et al. 2011). Finally, 1 study did not give any clear overall complication rate (Zhong et al. 2014).

Subtrochanteric fracture

5 biomechanical studies were included here. 2 used cadaveric bone and 3 used synthetic bone (Table 1). In the 2 studies that used cadaveric bone (Forward et al. 2012, Wang et al. 2014) PF-LCP had lower failure load than proximal femoral nail (PFN) and DHS. In the 3 studies that used synthetic bone (Crist et al. 2009, Floyd et al. 2009, Latifi et al. 2012), a PFN was not used for comparison and PF-LCP had higher failure load than an angled blade plate (ABP) in all 3 studies.

5 retrospective studies included only subtrochanteric fractures, and the complication rates varied from 3% to 43% (Table 2). 1 study was quasi-randomized, with a complication rate of 25% as compared to 35% in the DHS group (Dhamangaonkar et al. 2013). As stated above, both pertrochanteric and subtrochanteric fractures were often merged in a single study, and 3 of these studies (Wieser and Babst 2010, Zha et al. 2011, Johnson et al. 2014) had between complication rates of between 0% and 39% for subtrochanteric fractures.

Discussion

Even though the biomechanical studies showed equivalent or higher failure loads for femoral neck fracture, the results from the only clinical study (Berkes et al. 2012) were far worse—with a complication rate of 37%. This may not seem as high a complication rate as in meta-analysis results (Rogmark and Johnell 2006), but the patients of Berkes et al. (2012) were selected and compared to a historical cohort with a 9% complication rate.

Table 2 Clinical studies with locking plates for proximal femoral fractures. Complications in percentage of number (n) at follow-up

Author Year, Country	Design	Device (manufacturer)	Mean age, years	Mean follow-up, months	Fracture classification	Fracture n	Complication, n (%)
Femoral neck							
Berkes et al. 2012, USA	Retrospective	PLFLP (Synthes)	72 (35–89)	Min. 12	31B1	3	0 (37, overall)
					31B2	4	0
					31B3	11	7
Pertrochanteric							
Mardani-Kivi et al. 2013, Iran	Retrospective	LCP (?) (DHS comparison)	71 (SD 10)	Range 9–31	Stable/unstable	44	11 (25) (DHS 7%)
Subtrochanteric							
Saini et al. 2013, India	Retrospective	PF-LCP (Sharma Surgicals)	45 (17–75)	9 (7–16)	Seinsheimer 3	19	0 (3, overall)
					Seinsheimer 4	10	1
					Seinsheimer 5	3	0
					?	3	
Hu et al. 2012, China	Retrospective	PF-LCP (?)	76 (43–85)	16 (6–28)	Seinsheimer 3–5	48	3 (7)
Gunadham et al. 2014, Thailand	Retrospective	PF-LCP (Synthes)	42 (SD 23)	11 (SD 6)	32A1-3	8	2 (23, overall)
					32B1-3	14	3
					32C1-2	4	1
Azboy et al. 2014, Turkey	Retrospective	LPFP (Tipmed) (ABP comparison)	49 (17–72)	24 (18–30)	31A3	20	3 (15) (ABP 21%)
Streubel et al. 2013, USA	Retrospective	PF-LCP (Synthes Paoli)	56 (SD 22)	20 (SD 17)	31A3	41	12 (43)
Dhamangaonkar et al. 2013, India	Quasi-randomized	PFLP (Universal Orthosystems) (DHS comparison)	55 (32–78)	18	Unstable intertrochanteric	20	5 (25) (DHS 35%)
Mixed							
Zhong et al. 2014, China	Retrospective	PFLCP (Libeier) (DHS comparison)	70 (SD 2)	18 (SD 1)	31A1	13	? (No diff.)
			67 (SD 2)	20 (SD 1)	31A2-3	14	? (No diff.)
			52 (SD 3)	18 (SD 1)	32A-C	14	? (PFLCP better)
Wirtz et al. 2013, Switzerland	Retrospective	PF-LCP (Synthes)	59 (19–96)	34 (24–48)	31A1-2	14	10 (53)
					31A3	5	
Johnson et al. 2014, England	Retrospective	PF-LCP (Synthes)	76 (20–100)	24	Jensen 2,4,5	9	3 (33)
					Seinsheimer 1–5	23	9 (39)
Zha et al. 2011, China	Prospective?	PFLCP (Trauson or Kanghui)	74 (SD 12)	12	Jensen 1–2	22	0
			75 (SD 10)		Jensen 3–5	76	2 (2, Jensen 1–5)
			74 (SD 14)		Zickel	12	0 (0)
Floyd et al. 2013, USA	Case-series	PF-LCP (Synthes)	47 (23–80)	13 (0–23)	31A1-2	3	6 (46)
					31A3	8	
					32B2, C1	2	
Chalise et al. 2012, Nepal	Retrospective	PFLCP (?)	57 (23–88)	12	Kyle 2–4	19	2 (6)
					Seinsheimer 2–5	14	
Wieser et al. 2010, Switzerland	Case-series	PF-LCP (Synthes)	?	?	31A2-3	2	1 (50)
					Seinsheimer 2, 3, 5	6	2 (33)

Remarkably, there was no biomechanical study of pertrochanteric fracture. For the subtrochanteric fractures, PF-LCP had lower failure load than PFN, but higher than ABP. The reoperation rate for pertrochanteric and subtrochanteric fractures should be below 8% if compared to randomized controlled trials and large registry studies that use DHS or PFN (Parker and Handoll 2010, Matre et al. 2013a, 2013b, 2013c). However, only 4 studies on PF-LCP had complication rates below 8% and 9 studies had rates above this, having reoperation rates of between 15% and 53%.

We did not find any clear relation between the biomechanical studies and clinical studies. We can suggest several explanations for the disparities between biomechanical studies and clinical studies.

Biomechanical principle of internal fixation by LCP

The biomechanical principle of LCP combines compression techniques by using conventional holes, and bridging techniques by using threaded locking holes (Wagner 2003). This may allow an inherently rigid stabilization that should facilitate biological fixation through secondary bone healing due to callus formation (Miller and Goswami 2007). However, the rigid mechanical construction may be jeopardized by the quality of osteoporotic bone that cannot withstand the continuous stress, which subsequently results in microfracture—development of gaps between implant and bone with increasing micromotion. This may result in implant loosening and subsequently nonunion or failure of the implant (Wazen et al. 2013). In addition, historically, fractures in weight-bearing long bone have been found to be best treated by methods where compression and axial motion are tolerated (Parker and Handoll 2010). Thus, the LCP principle may be wrong in the treatment of standard proximal femoral fractures.

Clinical handling of the implant

Increasing options for application may mean technical challenges and increase the need for tutoring and training; otherwise, a long learning curve will increase the risk of failure (Bjorgul et al. 2011). Approximately 15 procedures are needed before a surgeon reaches a plateau for PFN (Altintas et al. 2014) and we suspect that the PF-LCP is technically more demanding. Moreover, proximal femoral fractures require acute surgery within 24 hours, which is often performed unsupervised by less experienced surgeons, which may increase the risk of complications with PF-LCP. In addition, we believe that introduction of more treatment options will increase the risk of failure overall.

Design of biomechanical studies

Biomechanical studies examine the response of a construct when force is applied; the results are then expressed in terms of force (Burstein and Frankel 1971). All studies try to take time into account by loading the implant dynamically to test alteration in the system over time. The amount of cycles resembles patient movement within the first couple of months after surgery. This contrasts with the longer duration of bone healing: up to 3–9 months. Some studies use only a few cycles and some use up to 90,000, which makes the studies incomparable (Crist et al. 2009, Forward et al. 2012). In addition, the biomechanical studies do not take into account that human bones are continuously remodeling and that microcracks may appear (Hazenberg et al. 2009). Thus, biomechanical methodology is based on the implication that a construct will ultimately break with the continuous loading of force. The clinical studies, on the other hand, include the time aspect as they report a percentage of failure over time. Finally, the biomechanical models often include synthetic bone of a quality different to that of osteoporotic bone. Thus, this represents the gap between biomechanical and clinical studies.

The gap between preclinical and clinical testing of new implants

According to the proposed stepwise methodology (Malchau et al. 2011), ex vivo studies should be an absolute necessity for future studies in vivo, as the initial step is preclinical testing followed by prospective randomized studies, multicenter studies, and registry studies. However, a few admissions are necessary regarding the initial step of preclinical testing. "The inherent gap" means that results from biomechanical studies are only snapshots of a process compared to clinical studies, which show the actual patient outcome. Also, the transparency of biomechanical studies can be challenging for people educated in the health system—as the vocabulary is in terms of physics. Knowledge in medicine, including orthopedic surgery and traumatology, tends to be cyclical and to develop with exponential progression (Lutter 2000). Consequently, grasping, reading, and understanding biomechanical studies requires a critical eye. It requires collaboration between research fields to better understand the results of and improvements in translational research, but still there will be a gap. This highlights the importance of proper clinical studies, to be conducted before widespread use of a new implant.

External validity of the present study

LCP gained immediate popularity after promising early reports (Sommer et al. 2003). A historical parallel to the PF-LCP is the sliding hip screw (SHS). Using a similar search strategy for DHS resulted in 88 biomechanical studies and several hundred clinical studies. The earliest biomechanical and clinical articles were published in 1980 and 1978 (Jensen et al. 1978, Jensen 1980b). The DHS is still used, and clinical studies with failure rates of around 3% are still being published. A long-term evaluation, as in the case of the DHS, is rare nowadays. The pace is high when marketing modern orthopedic implants. Implants are presented to the orthopedic community after—or at the same time as—biomechanical testing, leaving surgeons to perform the clinical survey in parallel to everyday use of the actual implant. Performing clinical trials is time-consuming. In the worst case, by the time that results from clinical studies with a high level of evidence are presented, the implant studied may already have been replaced with a new one (Carr 2005). We need to make conclusions about the performance of newly introduced implants before introducing new ones.

The question of evidence hierarchy and the clinical significance of biomechanical testing

It has been proposed that preclinical science, including biomechanical studies, may be regarded as part of the evidential hierarchy (Schemitsch et al. 2010). The evidence hierarchy has no universally accepted definition, but it can be explained as a reflection of the relative, empirical authority of various types of medical research. The empirical basis of biomechanical research gives value to the proposed idea of them as part of the evidential hierarchy. In addition to the empirical basis, a relation to the scientific problem is necessary for the applied research if it is to be considered to be part of the evidential hierarchy in this context.

We found that biomechanical studies have limited value in predicting clinical outcome of the PF-LCP. The biomechanical studies are concerned with how the PF-LCP fails and the clinical studies are concerned with how much it fails. The biomechanical studies are of no more value than to suggest candidates for clinical testing, if they fulfill test requirements.

The work in perspective

The biomechanical studies could not predict the clinical outcome of the LCP used for proximal hip fractures. Put in perspective, such biomechanical studies are inherently different from the clinical studies, as they examine the best possible theoretical use of the LCP without knowledge of the long-term outcome in a clinical setting. There is no doubt that they may have value when evaluating a new implant for fatigue failure or some similar problem. Properly designed clinical studies are mandatory when introducing new implants, and they cannot be replaced by biomechanical studies

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