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Straight proximal humeral nailing: Risk of iatrogenic tendon injuries with respect to different entry points in anatomical specimens

A.M. Schwarz[a,*], G.M. Hohenberger[b], S. Euler[c], A.H. Weiglein[d], R. Riedl[e], S. Kuchling[d,f], R. Krassnig[b], M. Plecko[a]

[a] AUVA-Trauma Hospital Graz, Graz, Austria
[b] Department of Orthopaedics and Trauma Surgery, Medical University of Graz, Graz, Austria
[c] Department of Trauma Surgery, Medical University of Innsbruck, Innsbruck, Austria
[d] Institute of Clinical Gross Anatomy, Medical University of Graz, Graz, Austria
[e] Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz, Graz, Austria
[f] Department of Trauma Surgery, State Hospital Wolfsberg, Wolfsberg, Austria

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ABSTRACT

Background: The purpose of the study was to evaluate the relationship of implant-related injuries to the adjacent anatomical structures in a newer generation straight proximal humeral nail (PHN) regarding different entry points. The proximity of the proximal lateral locking-screws of the MultiLoc proximal humeral nail (ML PHN) may cause iatrogenic tendon injuries to the lateral edge of the bicipital humeral groove (BG) as reference point for the tendon of the long head of biceps brachii (LBT) as well as the lateral insertion of the infraspinatus tendon (IST).

Materials and methods: The study comprised n = 40 upper extremities. Nail application was performed through a deltoid approach and supraspinatus tendon (SSP) split with a ML PHN. All tests were performed in three different entry points. First nail (N1) – standard position in line with the humeral shaft axis; second nail (N2) – a more lateral entry point; third alternative (N3) – medial position, centre of the humeral head. After nail placement, each specimen was screened for potential implant-related injuries or worded differently hit rates (HR) to the BG and the IST. The distances to the anatomical structures were measured and statistically interpreted.

Results: The observed iatrogenic IST injury rate was 17.5% (n = 7/40) for N1, 5% (n = 2/40) for N2 and 62.5% (n = 25/40) for N3, which was statistically significantly higher ($p < 0.001$). Regarding the BG, the evaluated HR was 7.5% (n = 3/40) for both N1 and N2. Only the nail placed in the head centre (N3) showed an iatrogenic injury rate of 20% (n = 8/40) ($p < 0.062$). No statistically significant association between humeral head size and the HR could be observed (head diameter: IST: $p = 0.323$, BG: $p = 0.621$; head circumference: IST: $p = 0.167$; BG: $p = 0.940$). For the IST and BG, all distances in nail positions N1 and N2 as well as N2 and N3 differ statistically significant ($p < 0.001$).

Conclusions: An entry point for nail placement in line or slightly laterally to the humeral shaft axis – but still at the cartilage – should be advocated.

Introduction

Proximal humeral fractures represent the third most common fracture type among people beyond 65 years of age [1,2] and 5% of all fractures [3]. Stable fractures can mainly be treated successfully conservatively [4,5], whereas in displaced and unstable fracture types, surgery may be recommended [6]. The optimal type of surgical treatment remains controversial [2,7–1–10]. Plate fixation, minimally invasive techniques, suture fixation technique, intramedullary nailing, hemi-arthroplasty and reversed shoulder arthroplasty are common or descript procedures [2,8,9,11–21]. However, no single technique has proved evidence-based superiority in the treatment of proximal humeral fractures [22]. Intramedullary stabilization of proximal or diaphyseal humerus fractures using a straight proximal humeral nail (PHN) represents a minimally invasive surgical procedure providing high primary stability, even in osteoporotic bones [23,24]. Early functional treatment is recommended to quickly regain mobility [12,17,18].

* Corresponding author at: AUVA-Trauma Hospital Graz, Göstinger Straße 24, 8020 Graz, Austria.
E-mail address: angelika.schwarz@auva.at (A.M. Schwarz).

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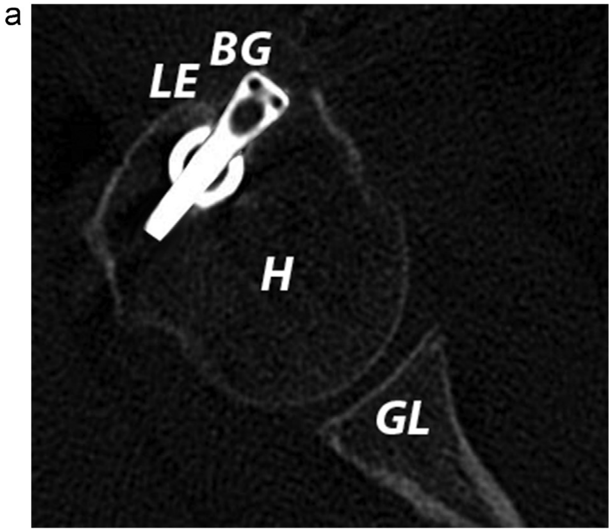

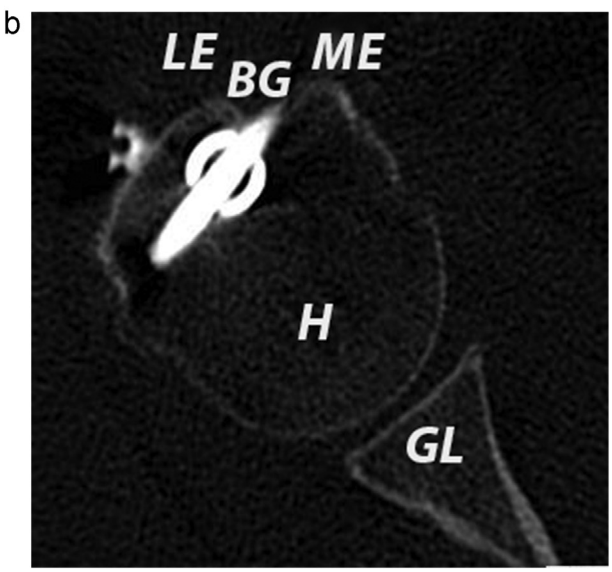

Fig. 1. (a) and (b). Axial CT scan of a MultiLoc screw lying in the bicipital humeral groove in two layers – as a clinical case for a biceps tendon implant-related injury. {CT: Siemens; Somatom Definition AS, 128 slices} (BG, bicipital humeral groove; H, humerus, GL, glenoid; LE, lateral edge of the bicipital humeral groove; ME, medial edge of the bicipital humeral groove).

The MultiLoc PHN (ML PHN) {Synthes GmbH, Solothurn, Switzerland} is a newer generation straight PHN and is developed for the treatment of simple and complex, unstable and dislocated proximal humeral fractures. Moreover, the nail may be applied in cases of diaphyseal fractures and proximal fractures extending distally towards the shaft.

Various proximal locking options additionally increase stability and can be adapted to the fracture type [23,24]. An exact subchondral proximal nail-end implantation into the densest proximal humerus zone significantly increases the stability in straight proximal humeral nailing. This additional supporting point decreases secondary varus displacement and consequently revision rates [25]. Anatomic reduction without distraction and stable fixation of the tuberosity's is essential for a successful clinical and functional outcome [2,11,15]. Furthermore, using the screw-in-screw options, the construct can be reinforced with additional locking-screws within the proximal primary locking-screws, anchoring in areas of better bone quality [24,26]. The main drawbacks of proximal humeral nailing include secondary dislocation of the fracture, screw loosening and migration or chronic implant-related shoulder pain. Rare complications seem to be humeral head necrosis and infections [12,18]. A higher risk of iatrogenic greater tuberosity fractures due to an entry point which has been chosen too far lateral has been described [8,17].

In addition, a potential violation of the rotator cuff as well as the tendon of the long head of biceps brachii (LBT) by the proximal anterior and posterior lateral locking-screws has sometimes been a concern in clinical cases [see Fig. 1a and b].

Thus, the purpose of the present study was to evaluate the relationship between these proximal lateral locking-screws and the adjacent lateral edge of the bicipital humeral groove (BG) as well as the lateral insertion of the infraspinatus tendon (IST) with regard to potential implant-related injuries to these structures. Our hypothesis was that medializing the entry point increases the likelihood of injuring and accordingly fixing one or both of these anatomical structures.

Materials and methods

Material

The study sample included n = 20 left and n = 20 right upper extremities (overall n = 40) of human adult body donors. The whole specimens have been embalmed using Thiel's method, which renders the tissue into stable lifelike consistency and flexibility [27–29]. Exclusion criteria involved severe obvious signs of deformities or trauma as well as visual evidences of prior surgeries. The study comprised n = 21 female and n = 19 male cadaveric upper extremities with a median age of n = 82 (ranged 51–96 years).

Approach and definition of nail positions

A deltoid-split approach was simulated between the anterior and central part of the deltoid muscle. Then, the humeral head was approached through a supraspinatus tendon (SSP) split.

Three different entry points – all located on the transversal axis - were defined as follows and fixed using the standard 2.5 mm guiding rod [see Figs. 2 and 3]:

- The first nail (N1) was positioned at the recommended standard position. This entry point is defined by the proximal extension of the humeral shaft axis to the apex of the humeral head.
- The second nail (N2) was placed 5 mm medial to the anatomical neck (cartilage rim) of the humerus, representing a more lateral entry point.
- As a third alternative, the nail (N3) was placed medial to the standard entry point to the centre of the humeral head. The distance between N3 and N1 was the same as between N1 and N2.

Testing methods

All tests were completed with the ML PHN, a straight proximal humeral nail. The three proximal lateral locking-screws are the MultiLoc screws and are required in fracture situations [see Figs. 4 and 5].

Each application was performed using an 8 mm short intramedullary nail. First, the 2.5 mm guide rod was inserted at the position of N1. A 10 mm hollow drill bit was passed over the guide

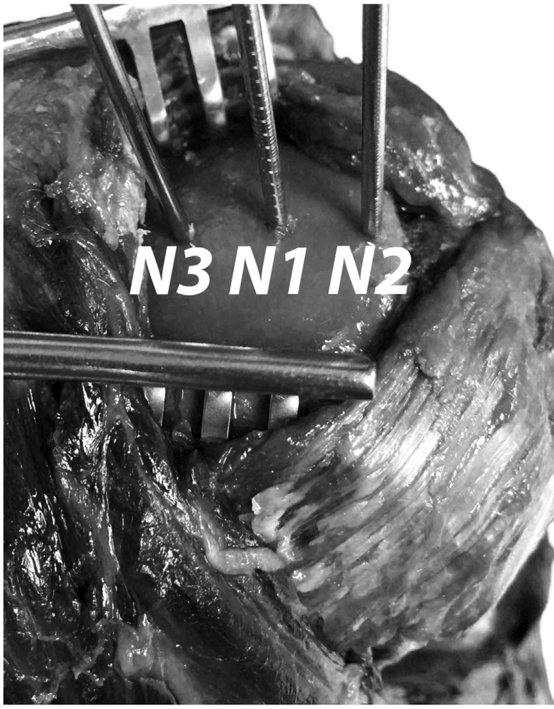

Fig. 2. The three different entry point positions, defined by the standard 2.5 mm guiding rod for each nail. (N1, nail position 1 - standard position; N2, nail position 2 – lateral position; N3, nail position 3 – medial or central position).

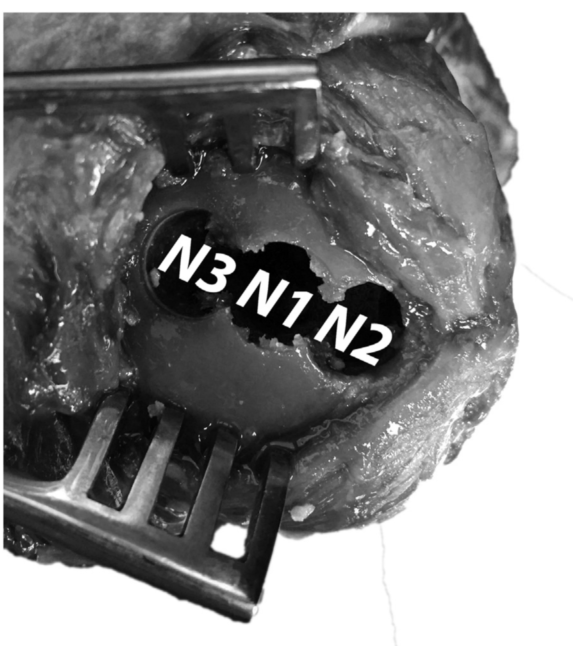

Fig. 3. The three different nail positions after opening the humeral medullary cavity in each entry position in a view from above. (N1, nail position 1 - standard position; N2, nail position 2 – lateral position; N3, nail position 3 – medial or central position).

wire to open the humeral medullary cavity. Then the ML PHN was inserted into the medullary cavity, using the aiming device provided by the manufacturer. To control to implant insertion depth a 2.5 mm Kirschner-wire (KW) was placed through the “0” marked hole into the aiming arm. In each specimen, the proximal end of the nail was subchondral in line with the humeral cortical head surface. In order to ensure fixation and rotation control

Fig. 4. Depiction of a short MultiLoc proximal humeral nail (ML PHN) from the anterior view with all locking-screw options. The oblique proximal lateral locking-screws are marked (ML PHN screws). (ALS, anterior proximal lateral locking-screw; PLS, posterior proximal lateral locking-screw; ML PHN, MultiLoc PHN).

Fig. 5. Axial view with the three mandatory proximal lateral locking-screws. External are the anterior (ALS) and the posterior (PLS) proximal lateral locking-screws, which both can damage the LBT and the IST, respectively. (ALS, anterior proximal locking-screw; PLS, posterior proximal locking-screw; ML PHN, MultiLoc PHN).

during measurements, a 2.5 mm KW was drilled through the middle lateral proximal locking sleeve parallel to the humeral head-neck axis. A trocar assembly, consisting of a 10 mm protection sleeve, a 3.8 mm drill sleeve and a 3.8 mm trocar were inserted through the anterior and posterior hole of the aiming arm. Afterwards a 3.8 mm three-fluted drill bit was placed into the trocar and drilled into the cortex.

The procedure was accomplished in equivalent descript method in all nail positions or worded differently, each specimen was used for all three starting point placements. In total n = 120 nail applications were performed in n = 40 upper extremities.

Measured anthropological definition of humeral head circumference and diameter is defined as follows:

- Circumference measured at cartilage-bone border around the humeral head [30].
- Transverse head diameter measured between the most prominent points of the humeral circumference [30].

Following the implantation of the constructs, the specimens were screened for potential iatrogenic damages to the BG and the IST or worded differently hit rates (HR). Subsequently, the distances from the midpoint of the resulting hole to the lateral edge of the BG (AD) were measured using a digital calliper rule {Emil Lux GmbH & Co. KG, Germany; art. No. 572587}. During the next step, the distances between the midpoint of the drill hole and the lateral insertion of the IST (PD) were evaluated. These distances were named `laterally bony bridge` as an expression for a safe zone regarding iatrogenic tendon violation via the oblique proximal lateral locking-screws. For clinical impression, screw implantation with and without tendon injuries is pictured in Figs. 6–8 in each nail position.

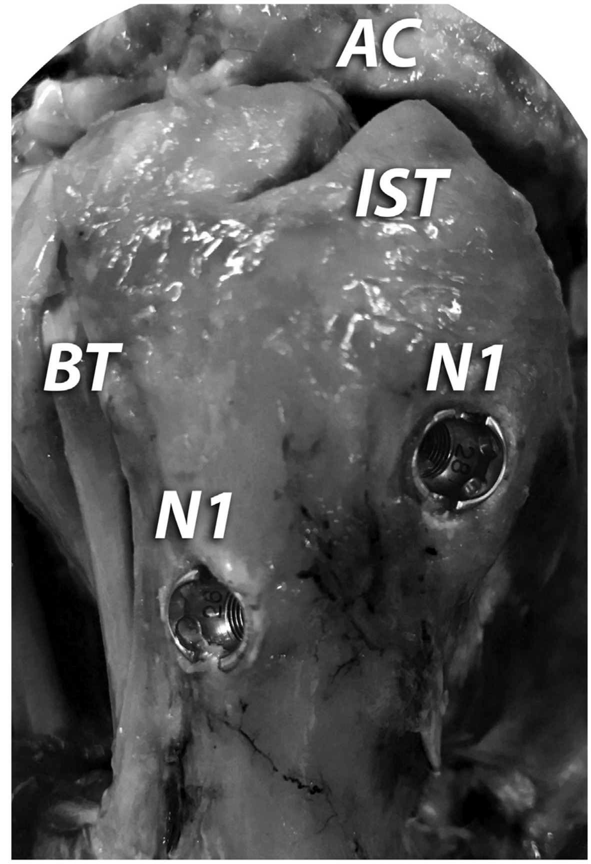

Fig. 6. N1 position from lateral with the two proximal lateral locking-screws and no tendon damage. (AC, acromion; BT, long head brachial biceps tendon; IST, lateral insertion of the infraspinatus tendon; N1, nail position 1 - standard position).

Statistical analysis

Statistical analysis was performed using SAS software {version 9.4, SAS Institute, Cary, NC}. For continuous parameters mean, standard deviation (SD), median, minimum and maximum plus for categorical parameters frequencies and relative frequencies are presented. In order to compare the HRs of the IST and the BG between the three different nail positions, a Cochran’s Q test was used. The post hoc analysis was performed using McNemar's tests. Only distances >0 (i.e. without hits) were included in the analysis to compare the measured distances between the anterior und posterior screw positions of each nail and the IST and BG. Comparisons were performed, using mixed models with nail position as repeated measurement and with dependent variables IST and BG distances. In these models, an unstructured covariance structure was used. In order to investigate the difference in humeral head diameter and circumference between the upper extremities with and without hits for IST and BG, respectively, independent t-tests were used. A p-value of <.05 is regarded as statistically significant. For the post hoc analyses, a Bonferroni correction was performed.

Results

The observed HR of the IST was 17.5% (n = 7/40) using the standard insertion variant (N1). Moreover, the IST HR of Nail 2 was 5% (n = 2/40). The nail position in the humeral head centre (N3) showed a HR of 62.5% (n = 25/40). A Cochran's Q test determined these iatrogenic injury rates regarding the three different positions

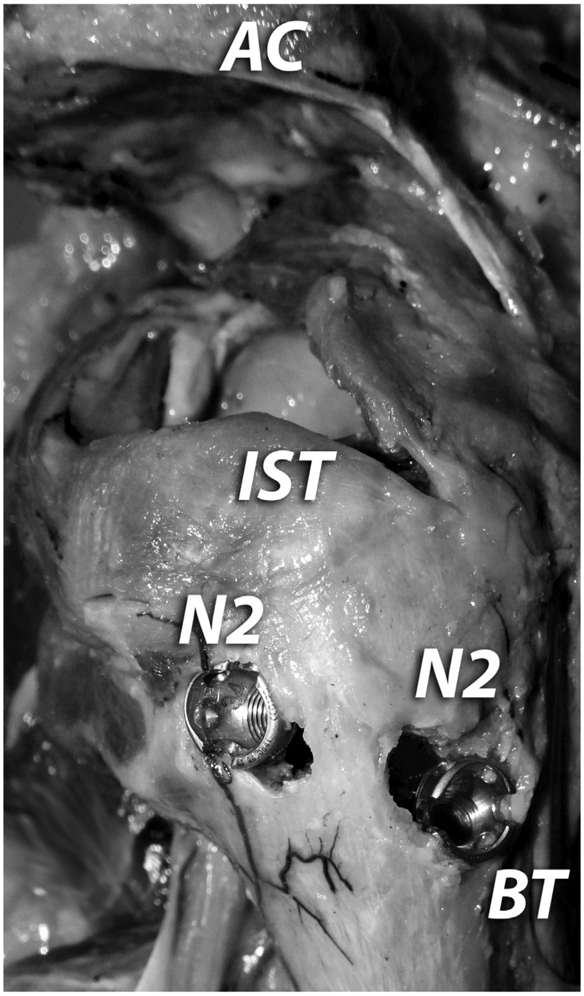

Fig. 7. N2 position from dorsolateral with the two proximal lateral locking-screws and no tendon damage. (AC, acromion; BT, long head brachial biceps tendon; IST, lateral insertion of the infraspinatus tendon; N2, nail position 2 – lateral position).

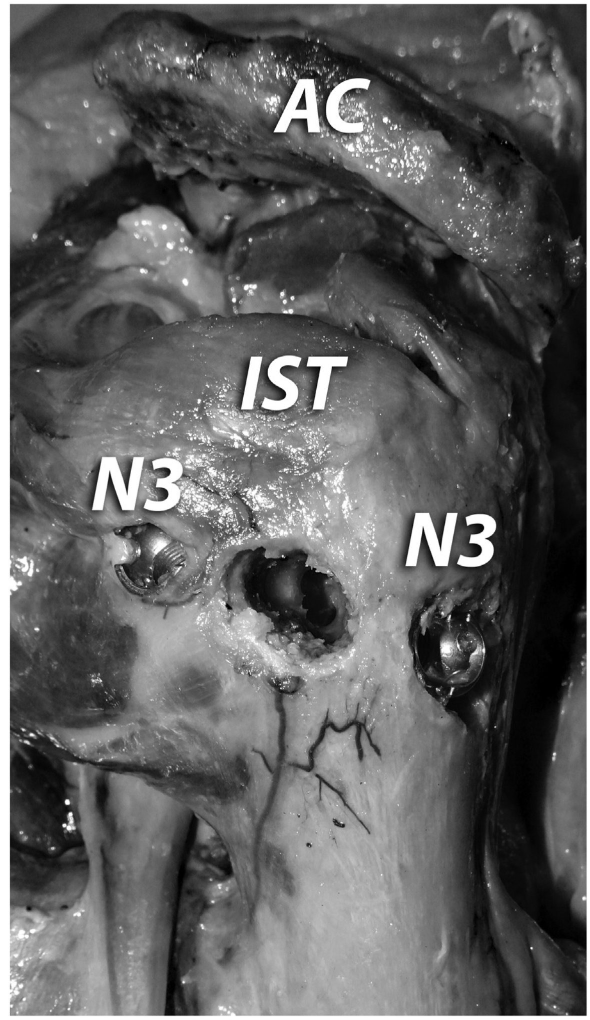

Fig. 8. N3 position from dorsal with the two proximal lateral locking-screws and an iatrogenic IST tendon damage. (AC, acromion; IST, lateral insertion of the infraspinatus tendon; N3, nail position 3 – medial or central position).

as statistically significant ($p < 0.001$). The post hoc analysis revealed statistically significant differences between nail position 1 and 3 as well as between nail position 2 and 3 ($p < 0.001$, for both) [see Table 1].

The HR of the BG showed a frequency of 7.5% (n = 3/40) for both, N1 and N2. The medial nail (N3) showed a HR of 20% (n = 8/40). There was a clear tendency but Cochran's Q test determined no statistically significant difference between the three individual nail positions ($p < 0.062$) [see Table 1].

Table 2 displays the measured distances >0 between the anterior und posterior screw positions of each nail and the BG, respectively the IST. For IST as well as for BG, the distances in nail positions N1 and N2, and N2 and N3 differ statistically significant ($p < 0.001$). Post hoc analysis showed statistically relevant differences between the three nail positions with respect to the distances to both structures as mentioned above.

The statistical analysis revealed a mean humeral head circumference of 159 mm (SD 107; range 143–182) and an average head diameter of 48 mm (SD 45; range 39–57). The *t*-test did neither reveal a significant relation between the implant-related tendon injuries of IST or BG and the humeral head diameter (IST: $p = 0.323$; BG: $p = 0.621$) nor between the HR and the humeral head circumference (IST: $p = 0.167$; BG: $p = 0.940$). For more details, see Table 3.

Table 1
Hitrate in each nail position.

	No hit		Hit	
	N	%	N	%
N1_ IST	33	82.5	7	17.5
N2_ IST	38	95.0	2	5.0
N3_ IST	15	37.5	25	62.5
N1_BG	37	92.5	3	7.5
N2_BG	37	92.5	3	7.5
N3_BG	32	80.0	8	20.0

Observed implant-related tendon injury for the respective nail positions.
(N1, nail position 1 - standard position; N2, nail position 2 – lateral position; N3, nail position 3 – medial or central position; IST, lateral insertion of the infraspinatus tendon; BG, lateral edge of the bicipital humeral groove).

Discussion

The purpose of this study was to prove the relationship of iatrogenic injuries to the LBT and the IST by the anterior and posterior proximal locking-screws in newer generation PHNs regarding different entry points. With straight proximal humeal nailing surgeons seek a far medial entry point to avoid injuries to the critical insertion zone of the SSP. Since a surgical SSP tendon

Table 2
Distances between the oblique locking-screws and the IST and BG.

	N	Mean	SD	Median	Minimum	Maximum
N1_ IST	33	3.3	2.6	3.0	0.5	11.0
N2_ IST	38	5.0	3.2	4.3	0.5	12.0
N3_ IST	15	3.1	2.2	2.5	1.0	9.0
N1_BG	37	5.1	3.5	4.0	0.5	13.0
N2_BG	37	6.8	4.2	6.0	0.5	16.0
N3_BG	32	4.7	2.9	4.3	0.5	10.5

Distances between the anterior and posterior locking-screws of each nail and the defined adjacent structures. Negative values indicate a hit and are to be interpreted from medial to lateral.
(N1, nail position 1 - standard position; N2, nail position 2 – lateral position; N3, nail position 3 – medial or central position; IST, lateral insertion of the infraspinatus tendon; BG, lateral edge of the bicipital humeral groove, SD, standard deviation).

split is always visible and repaired by side to side sutures, an injury of the IST or LBT by locking screws is on contrary intraoperatively invisible. Chronic shoulder pain is a common described complication after proximal humeral nailing – although the precise ethology cannot be defined in each case. It is believed to be caused by the rotator cuff incision during nail insertion or damages in the critical insertion zone of the SSP [13,31].

Implant-related shoulder pain caused by proximal locking-screws in PHNs has to be given attention likewise. There is no information about it in the existing corpus of literature. These injuries may be underestimated and might play a bigger role than believed in chronic shoulder pain. As the angle of the oblique proximal locking-screws is fixed, it may cause a potential risk of injuring and accordingly fixing the IST or LBT. The results expose via choosing a more medial insertion point, the observed implant-related injury of the IST increased statistically significant (IST: $p < 0.001$). The evaluation of the BG HR showed a clear tendency and an increased iatrogenic injury rate in medial position similarly, but no statistically relevant superiority (BG: $p < 0.062$). Hence, the results prove that medializing the entry point increases the likelihood of injuring and accordingly fixing both of these anatomical structures, especially the IST.

Furthermore, the measured distances between the locking-screws of each nail and the BG, respectively the IST, showed statistically significant differences. Nail position 2 exhibited the longest distances from both anatomical structures and showed consequently the largest 'safe zone' or `laterally bony bridge` for the locking-screw implantation.

The optimal entry point is still under discussion because of the association with iatrogenic tendon injuries and the necessity of preservation of stable bone around the PHN. Euler et al. [32] categorized 38.5% of all humeral heads as 'critical types' for implant-related SSP damages with straight PHNs, due to their morphology. A minimal distance of 3 mm from the medial edge of the SSP insertion on the greater tuberosity was chosen. In another CT scan and gross anatomy comparative study, Euler et al. [33] described 42.5% of all specimens as 'critical types' for iatrogenic tendon damages. CT scans and gross anatomic measurements showed excellent reliability in all shoulders and similarly excellent agreements in the contralateral side in the CT scans as well as in the anatomical cases. They concluded a contralateral preoperative CT scan might assist to reduce the risk of iatrogenic tendon footprint damage and classify 'critical types' for iatrogenic SSP injuries.

Furthermore, more medial insertion points in PHNs showed a better clinical outcome with regard to chronic shoulder pain [13,31]. Lopiz et al. [8] observed a decreased complication rate including rotator cuff pain and dysfunction using newer generation straight nails compared to curvilinear nails with comparable union rates.

Hessmann et al. [17] as well as Lopiz et al. [8] mentioned an increased risk of iatrogenic greater tuberosity fractures as a result from lateral entry points for the ML PHN. This may be related to non-displaced underestimated fracture lines between the humeral head and the greater tuberosity. In our study sample, we never observed this complication.

Stedtfeld et al. [34] showed that it is necessary to have a "ring" of stable bone around the nail for proximal humeral fracture treatment with PHNs. If there is no "ring", a secondary avulsion or dislocation can be provoked. Therefore, they concluded that secondary dorsal dislocation from the humeral head could be prevented with a bony "ring" around the nail. In Harnoss et al.'s [35] virtual morphological comparisons of three different intramedullary nails a stable osteosynthesis was capable of using a minimum distance of 5 mm between the implant and the fracture line in most of the cases. They observed an increasing chance for a successful osteosynthesis with higher neck diameters of the humerus.

In contrary, the results of our anatomical study with the ML PHN did not show any statistical relationship between increasing humeral head size and the implant-related injuries of both structures. Nevertheless, it is worth mentioning, that in this collective was a tendency of lower iatrogenic injury rates in standard position (N1) with higher neck diameters to observe. In medial (N3) and lateral entry position (N2), we could not observe any association between humeral head size and HR regarding starting point. Although, a tendency for merely iatrogenic IST injuries regarding the humeral head circumference (IST: $p = 0.167$; BG: $p = 0.940$) versus implant-related damage rates to the humeral head diameter (IST: $p = 0.323$; BG: $p = 0.621$) was to observe.

A limitation of this study may be the use of cadaveric upper limbs without fractures as a discrepancy to an intraoperative non-anatomic situation. Another potential selection bias might be the fact, that all body-donors are of Caucasian origin and mainly from one region in Austria. Consequently, the findings might not be applicable to patients of other ethnic groups. Furthermore, in this

Table 3
Associations between the HR and the humeral head size.

			N	Mean	SD	Median	Minimum	Maximum
Head circumference (mm)	**Hits IST**	**no hit**	15	156.2	8.00	154.0	144.0	174.0
		Hit	25	160.6	11.90	159.0	143.0	182.0
Head diameter (mm)	**Hits IST**	**no hit**	15	47.0	4.1	47.0	41.0	57.0
		Hit	25	48.5	4.8	49.0	39.0	56.5
Head circumference	**Hits BG**	**no hit**	30	158.9	10.6	157.0	143.0	182.0
		Hit	10	159.2	115.0	155.5	144.0	179.0
Head diameter	**Hits BG**	**no hit**	30	47.7	4.5	47.5	39.0	55.0
		Hit	10	48.6	4.8	47.0	43.0	57.0

Descriptive statistics for humeral head circumference / diameter for upper extremities with and without implant-related tendon injury of IST / BG.
(IST, lateral insertion of the infraspinatus tendon; BG, lateral edge of the bicipital humeral groove, SD, standard deviation).

study design, the evaluated entry point effect was tested on a straight PHN on locking-screws. Consequently, another weakness as well as fact is that these results cannot be compared to curvilinear nails due to the different entry point situation.

As main strength of our findings is the substantial benefit to underscore, that this is the first study which focuses iatrogenic tendon injuries for IST and LBT damages in proximal straight humeral nailing. Further, our analysis was performed in a representative study collective with a large series of n = 120 nail applications in total. In this regard, we highlight that in all entry point positions the standardized nail placement was accomplished without any effect to the measurements or otherwise difficulties. A supplementary force is the study collective with the well-renowned Thiel's method, which renders lifelike tissue flexibility and consistency [27–29]. Accordingly, conclusions to clinical situations can be drawn due to this true-to-life conservation method.

Furthermore, we want emphasise that our research addresses a valid topic in newer generation proximal humeral nailing. Since straight PHNs have similar angulations of the locking bolds, our study design is suitable to address the main risk for iatrogenic tendon damages. The conclusions aim in order to avoid these complications and might guide continuatively to decreasing numbers of patients with chronic shoulder pain. Based on these findings – namely that medializing increases the risk of iatrogenic IST and/or LBT injuries – our data may represent a valid approach for further research in clinical trials, which continuatively might prove better functional outcomes regarding the entry point effect.

Conclusions

The risk to damage LBT or IST was low in standard position (N1) with an entry point in line with the humeral shaft axis and even lower in a more lateral position (N2). An entry point medial to the projection of the humeral shaft axis (medial position, N3) leads to a statistically relevant higher risk with regard to iatrogenic tendon injuries, especially for the IST – which affirms our hypotheses. No statistically significant association between humeral head size and implant-related tendon injury rate could be surveyed.

Keeping in mind that a stable bone collar between the nail and a fracture line at the anatomical neck or the greater tuberosity is leading to improved stability, an entry point for nail placement in line or slightly laterally to the humeral shaft axis – but still at the cartilage – should be advocated.

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Conflict of interest

Each author certifies that he or she has no commercial associations (employment, consultancies, stock ownership, honoraria, paid expert testimony, and patent applications/registrations) that might pose a conflict of interest in connection with the submitted article.

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