Title: Stem introducer designs and surgical technique play a significant role in achieving the optimal implant-cement interface.

Authors:

Bernard H van Duren (DPhil, FRCS) https://orcid.org/0000-0003-1877-8227

1) Nottingham Elective Orthopaedic Services, Nottingham University Hospitals NHS Trust, Nottingham, UK

3) Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK

Kevin Ilo (FRCS) https://orcid.org/0000-0002-2620-551X

2) Nottingham Elective Orthopaedic Services, Nottingham University Hospitals NHS Trust, Nottingham, UK

Sophie Walker

1) Nottingham Elective Orthopaedic Services, Nottingham University Hospitals NHS Trust, Nottingham, UK

Mark Higgins (FRCS)

1) Nottingham Elective Orthopaedic Services, Nottingham University Hospitals NHS Trust, Nottingham, UK

Benjamin V Bloch (FRCS) https://orcid.org/0000-0002-2305-7478

1) Nottingham Elective Orthopaedic Services, Nottingham University Hospitals NHS Trust, Nottingham, UK
2) University of Nottingham, School of Medicine Nottingham, UK

Andrew R Manktelow (FRCS)

1) Nottingham Elective Orthopaedic Services, Nottingham University Hospitals NHS Trust, Nottingham, UK

Hemant G Pandit (DPhil, FRCS) https://orcid.org/0000-0001-7392-8561

3) Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK

Conflict of Interests:

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Abstract:

Periprosthetic fracture is a major contributor to reoperation with polished taper-slip (PTS) cemented stems which is the most used fixation technique in many countries. A clear cause for this has yet to be established. A significant variation exists between PTS stem designs, associated fractured rates amongst them, and in the design of introducers employed to insert these femoral stems. Achieving a conforming implant-cement interface (ICI) is crucial to ensure optimal function of PTS implants. Movement of the stem within the setting cement during surgery should be uniplanar and should not be associated with any inadvertent or unplanned deviations from the intended position. This is in-part controlled by the stem introducer design which potentially can contribute to excess movement and ICI compromise.

We compared four stem introducer designs used with two commonly used PTS stems. The stems were mounted using a silicone rubber compound to simulate setting cement at different time points (early=soft, late=hard). The stem tips were left clear, and an inertial measurement unit attached to measure acceleration, angular velocity, and rotation. Participating surgeons (n=16) were asked to maintain stem position for ten seconds before releasing the introducer.

Simulation of soft cement conditions showed a mean root mean square (RMS) value ranging from 0.10g to 0.30g for acceleration, 12.75°/s to 67.94°/s for angular velocity, and 2.02° to 6.03° for rotation with significant differences noted between different stem introducers. Simulation of later insertion during the curing process (hard) showed a similar pattern, with a lower overall range of movement.

Our results showed that introducer design had a significant impact on stem movement within the setting cement. Furthermore, its removal earlier in the setting reaction resulted in increased movement. These findings highlight the importance of instrument design and correct technique in achieving the optimal ICI.

Introduction:

Polished taper-slip (PTS) cemented stems are the most used stem fixation technique in the UK and are also commonly used worldwide (1–3). PTS femoral stems offer a safe, simple, versatile, and reproducible reconstruction with an established track record in clinical outcomes and patient satisfaction(4). Following initial reports showing that there was likely to be an increased fracture risk with PTS stems(5,6) further studies have shown periprosthetic fracture to be a major contributor to reoperation with PTS stems(7–9). A clear cause for this increased fracture risk observed in PTS stems has yet to be established. Large cohort and registry studies have reported an association with patient factors such as gender and age(7,8). Other studies have suggested that taper design, cement viscosity, stem materials, and friction, among others, may contribute to an increased risk of periprosthetic fracture with PTS stems(10–15). It is recognised that the fracture risks with the same stem design vary significantly amongst surgeons, and therefore there are likely to be other modifiable factors which contribute to this complication.

PTS stems rely on a tapered interference fit to secure the stem within a cement mantle creating large contact area for the transfer of forces(16). The "load-transfer" (load transfer from stem to bone via cement mantle) generates stresses in the materials and at their interfaces with the likelihood of mechanical failure depending on the stress levels relative to the material strengths(17). Achieving the optimal conforming implant/cement interface is crucial to ensure optimal function of PTS implants. From the relationship $pressure = \frac{force}{area}$ we know that the contact pressure at the implant-cement interface is inversely proportional to the contact area. It follows that achieving a conforming implant-cement interface (ICI) is crucial to ensure optimal function of PTS implants. A non-conforming cement mantle and reduction in contact area is potentially introduced at the time of stem insertion before the cement has cured. Movement of the stem within the curing cement can result in a cement mantle which potentially does not match the implant taper (see *figure 1*). Movement of the stem within the setting cement is in-part controlled by the stem introducer design which can lead to excess movement and ICI compromise. We hypothesised that, in part, that excess movement during stem insertion is influenced by the design of the stem inserter.

The primary aim of this study was to establish the potential for introducing unwanted movement when using/removing the cement introducer in relation to the design of the mechanism used to connect to the stem. The secondary aim was to estimate the impact of removing the introducer early or later in the cement setting process.

Methods:

We compared four stem introducer designs, available to surgeons in our department ("on the shelf"), used with two commonly used PTS stems (see *figure 2*):

- CPT-T: Used with the CPT stem (Zimmer Biomet, Warsaw, Indiana, USA). This introducer makes use of a threaded attachment to the stem which is tightened and loosened by a thumbwheel. It also uses an additional locking/release mechanism securing the thumb wheel which needs to be released prior to releasing the thumbwheel.
- CPT-NT: This is the same introducer as the one above using a further attachment allowing for the CPT stem to be introduced without using the threaded thumbwheel mechanism.
- C-Stem-C: Used with the C-Stem (Depuy Synthes, Raynham, Massachusetts, USA). This introducer incorporates a scissor mechanism to secure and subsequently release the stem. One arm of the mechanism inserts into the recess of the stem shoulder and the other behind the collar of the taper.
- C-Stem-S: This introducer is a straight cylindrical shaft with a flat edge which keys into a recess of the C-Stem.

The stems were mounted in 50mm long Perspex cylinders using a silicone rubber compound (BBDINO, Sipolysun Technology Co., Shenzhen, China) (*see Figure 2*). The stem tips were left clear to allow for an inertial measurement unit (WT9011DCL 9-axis, WitMotion, Shenzhen, China) to be attached. The inertial measurement unit (IMU) module integrates high-precision gyroscopes, accelerometers, and geomagnetic field sensors to measure real-time motion. Each stem design was mounted in a 30mm (soft) and 20mm (hard) inner diameter cylinders to give different stiffness fixations for each stem. The two different stiffness mountings were intended to simulate setting cement conditions at different time points (softer/ less stiff early on and harder/stiffer later in the curing reaction). The construct was then secured to a sturdy table using a multi angle vice. Participating surgeons were asked to maintain stem position for ten seconds to establish a baseline before releasing the introducer from the mounted stem. Each surgeon was asked to perform this using all four devices. Prior to recording measurements surgeons were given the opportunity to practice with the different introducers till they felt confident to proceed. Acceleration, angular velocity, and rotation were measured and recorded using the WitMotion mobile application (version 5.0.4, WitMotion, Shenzhen, China).

Acceleration, angular velocity, and angle of rotation were recorded in three axes (X, Y, Z). For these parameters the range of motion (Max – Min) for each axis was calculated. The range of motion was used as it represents the maximum deformation possible due to plastic deformation in setting cement. As a measure representative of the movement occurring during the removal of a stem introducer the root mean square (RMS) of the range across the axes for each parameter was calculated. Descriptive statistics used means, median values, ranges, and 95% confidence intervals where appropriate. To compare the RMS ranges an unpaired Wilcoxon Test was used (non-normal distribution was assumed) with a 95% confidence interval assumed to be significant. RStudio (version 2022.02.2+485) was used to perform the analyses.

Results:

Sixteen surgeons, all of whom had arthroplasty experience, participated in the study. Of these 7 were consultant arthroplasty surgeons, 5 fellowship level surgeons, and 4 training level surgeons.

In the early setting /soft simulation (30mm mount) the mean root mean square (RMS) values (for CPT-T, CPT-NT, C-Stem-C, C-Stem-S respectively) were 0.3g, 0.17g, 0.14g, 0.10g for acceleration, 67.94°/s, 25.39°/s, 22.99°/s, 12.75°/s for angular velocity, and 6.03°, 3.02°, 2.93°, 2.02° for rotation (*Table 1*). The results for the late setting cement simulation (20mm mount) showed a similar pattern, with the Introducer CPT-T having the greatest RMS acceleration, angular velocity and angle of rotation and the C-Stem-S the least (*Figure 3*). The measured values for the hard simulation were less than those measured for the soft simulation across all parameters. The two more complex/involved designs for each stem showed more movement than their simpler counter parts with RMS range values of 0.22g/43.55°/s/3.39° vs 0.08g/10.96°/s,1.58° (CPT-T vs CPT-NT) and 0.12g/16.4°/s /2.71° vs 0.06g/9.43°/s /1.56° (C-Stem-C vs C-Stem-S).

A similar pattern with the CPT-T having the highest mean acceleration, angular velocity, and angle of rotation was also noted across the individual axes (*Table 1*). The largest angular velocities and angles of rotation occurred in the X-axis corresponding to rotational movement about the length axis of the stem (*Figure 3*). The accelerations were greatest in the Y-axis when compared to the other axes which corresponded to anterior-posterior movement followed by the Z-axis and the X-axis respectively.

Unpaired Wilcoxon tests comparing the RMS ranges for acceleration, angular velocity, and angles of rotation between inserters for both soft and hard simulations are represented in *Table 2*. The RMS range of movement for the CPT-T was significantly different (*$p < 0.02$ – table 2*) to the other inserter designs for both soft and hard simulations (with exception of CPT-T vs C-Stem-C angles of rotation for the hard simulation). The increased movement with the more complex inserter for each stem type was significant for all measures with the CPT and only noted to be significant in the soft simulation for the C-Stem inserters. Although all absolute values for the hard simulation trended to lower movement when compared to the soft simulation and this was significant for (CPT-T acceleration [$p=0.025$], angular velocity [$p=0.013$], and angle of rotation [$p=0.002$], CPT-NT acceleration [$p=0.015$] and angle of rotation [$p=0.038$], C-Stem-C angular velocity [$p=0.025$], C-Stem-S acceleration [$p=0.047$]) (*Table 3*).

Discussion:

Achieving an optimal implant-cement interface is crucial to ensuring optimal function of polished taper-slip implants. Movement of the stem within the setting cement can lead to a sub-optimal ICI. This movement during the cement curing process when inserting the stem is in-part controlled by the stem introducer design which can subsequently also lead to excess movement when it is detached from the stem. The aim of this paper was to compare the amount of movement that occurred with the use of four stem introducer designs supplied with two commonly used PTS stem designs.

Our findings showed that the amount of stem movement was significantly influenced by the design of the stem introducer. The threaded CPT introducer was associated with the largest amount of movement when compared to all the other inserters. This difference was significant ($p<0.05$). When comparing the two introducers supplied with each stem design the more complex of the two designs (CPT-T for CPT and C-Stem-C for C-Stem) resulted in a greater amount of movement than the simpler designs. The amount of movement was also greater in the simulation representing softer cement earlier in the curing process.

Of note was that there was a large variation in the amount of stem movement between individual surgeons with large standard deviation (*Table 1 & Figure 3*). This suggests that familiarity with a stem introducer design would minimise potential movement. However, this variation was also increased for the more complex designs (CPT-T & C-Stem-C) which suggests that additional mechanism to secure the stem to the introducer introduces a risk of increased stem movement on removal. The CPT-T stem mechanism requires a both locking mechanism and a threaded attachment to be released and unscrewed sequentially. Achieving this release is difficult to perform with one hand (the other hand recommended to stabilise the stem by holding at the taper). This difficulty is reflected in the resulting mean angular velocity being significantly more than that of the other introducers; likely as result of the torque required to mobilise the thumbwheel mechanism. Specifically, this Angular velocity is significantly greater ($p<0.05$) than that seen with the use of the CPT-NT inserter which makes use on additional component converting it to a two-pin inserter (it should be noted that although a smooth pin was used on the introducer this did on a number of occasions catch the threaded hole in the stem on release). The C-Stem-C inserter makes use of a scissor mechanism to hold the stem rotationally stable requiring a lever to be depressed to release the stem which was noted to lead to additional stem movement. The C-Stem-S inserter performed best as it fitted cleanly into place with the straight edge allowing for version control and could be simply withdrawn (leaving other hand free to stabilise the stem). Although the more complex introducer designs have a more secure hold on the stem, they introduce a greater risk of stem movement when they are removed. To the contrary there is an increased risk of dropping a stem with the non-mechanised designs. The length, bulk, and weight of the introducer may also play a role from an ergonomic perspective in that they are more challenging to control. The use of release mechanisms necessitates an increased length and working space to minimise risk of catching on soft tissues with the trade-off being reduced control.

It could be argued that the stem introducer should only be detached once the cement has cured. However, this is often not possible as the handle of the introducer can often be impeded by soft tissue or an overhanging trochanter increasing the risk of varus insertion or suboptimal version. Also, once the stem is in position removing the introducer facilitates clearing of excess cement and a clearer appreciation of stem version. Of note is that many surgeons in our institute will use the stem introducer for insertion up to approximately half the depth of the stem before removing it and inserting the stem the rest of the way by hand; or with the assistance of another instrument (e.g. a

Trethowan bone lever or heavy forceps) to maximise positional control and minimise excess movement.

Excessive stem movement potentially leads to incongruent regions between implant and cement mantle creating cement defects and/or unequal cement mantles. In addition to incongruence between implant and cement mantle, excess movement during implantation correlates with a reduced control of implant positioning and ability to achieve the optimal cement mantle. The effects of cement mantle thickness, implant positioning, and cement porosity have been extensively discussed in the literature(18). However, to our knowledge the effect of an incongruent implant-cement interface in PTS stems has not been described before. In theory incongruence between stem and mantle leads to reduced contact surface resulting in an increased contact pressure. In turn this leads to an increase in stresses on the cement mantle. A feature of the PTS stems is its controlled early subsidence into the cement mantle(19,20). With the taper-slip design this incongruence can be in part compensated for by subsidence of the implant which restores contact area at the interface likely attenuating some of the stress peaks. However, this does come with the trade-off of plastic deformation of the cement mantle in the initial contact areas with increased creep and stress relaxation. Higher stress levels will result in increased creep(21,22). The elastic properties (Young's modulus) of bone cement have been shown to be significantly altered by stress level with a stiffening effect(22,23). Creep and stress relaxation play a contributory role in cement mantle fatigue failure(24,25). Fatigue fractures of the cement mantle have been demonstrated in retrieval studies, radio-graphic analysis, and in vitro studies (26–28). The majority of cement mantle studies to date have focused on cement mantle failure as a mechanism of loosening, and primarily in composite beam type stems. The controlled subsidence in PTS stems counteracts loosening with the stem "reseating" itself within the cement mantle. However, once the cement mantle has failed it follows that a greater demand is placed on the surrounding bone, potentially increasing the risk of periprosthetic fracture. An increased incidence of periprosthetic fracture has been observed in PTS stems in comparison to composite beam stems(7,8). The mechanism discussed here is based on first principles and not experimentally proven, and to our knowledge, has not previously been described in the literature. Though discussing this potential mechanism here it is not possible to conclude from this work whether this translates in to increases in periprosthetic fracture rates. It is unlikely to be the sole mechanism contributing to periprosthetic fracture but rather one of several contributing factors and in part subject to a modifiable risk factor related to our findings highlighting the potential influence of stem introducer design on stem movement during detachment.

It is important to recognise the limitations with this study. It was not possible to blind the participating surgeons to the introducers used. The use of a silicone compound moulded in different sized cylinders to simulate softer and stiffer timepoints is an approximation rather than an exact representation of how a stem will behave during insertion. As such the absolute values are unlikely to be the same. Our experimental setup did not consider the role of the assistant who may be a further factor introducing relative movement of the cement in their role of supporting the leg. Additionally, the impact of soft tissues is not taken into account, which potentially would increase the movement with added impediments to operating release mechanisms in a restricted environment. Although, the participating surgeons were given opportunity to familiarise themselves with the mechanisms and use of the introducers prior to undertaking measured tests it remains that they may have been more familiar with one or maybe two of the instruments in their day-to-day practice, and less so with the others.

In this study, movement was quantified using measures of axial and angular acceleration, and rotation about each axis. The extent to which this movement translates into the postulated implant-cement interface is not known. Future work to establish whether there a correlation between movement (and timing during the curing process) is necessary. Furthermore, the hypothesis that incongruence between the implant and cement mantle at the implant-cement interface results in an increased risk of cement failure or fracture remains theoretical and will need to be further investigated as a potential contributor to periprosthetic fracture.

Although this study highlights the potential of introducing incongruities at the cement-implant interface when using stem introducers (some more so than others), it did not measure actual mismatch between implant and cement. Future studies using targeted experimental setups to explore this concept as well as the effect of forces within the cement mantle would help understanding to what extent the implant cement interface plays a role in implant performance.

In summary our results showed that introducer design had a significant impact on stem movement within the setting cement. This highlights to surgeons that they should be aware of the potential compromise this may introduce at their implant cement interface and choose instrumentation and make use of techniques to mitigate this.

Figures:

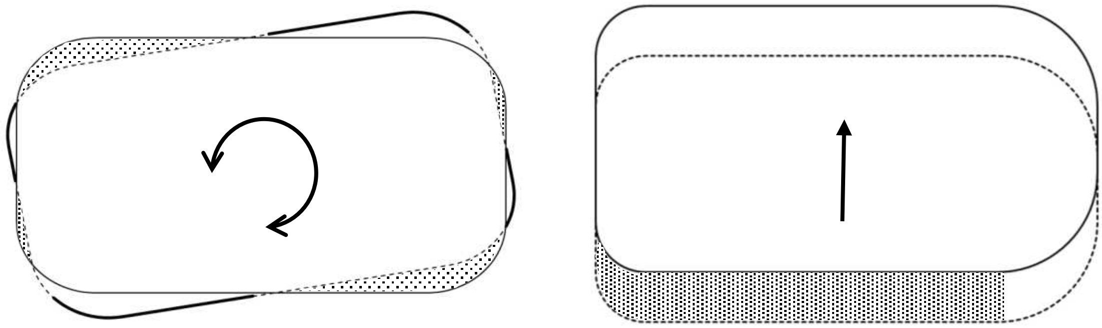


Figure 1: *Illustration to show how stem movement in setting cement potentially results in a reduced contact surface area with rotational (left) and translational (right) movement. The shaded areas represent the gap between stem and cement mantle resulting from movement.*

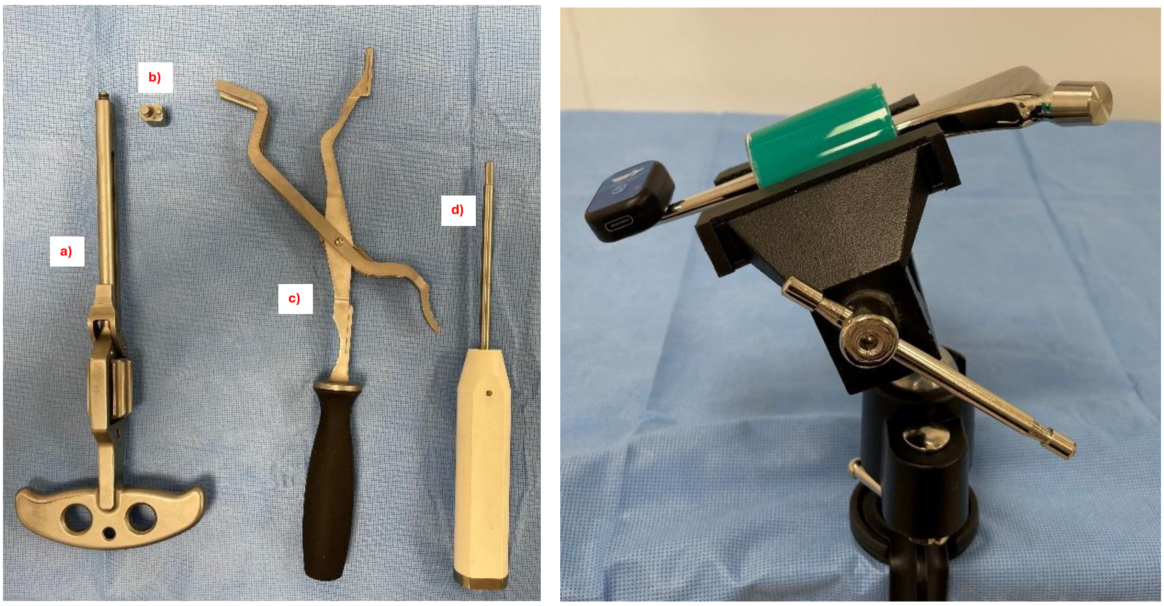
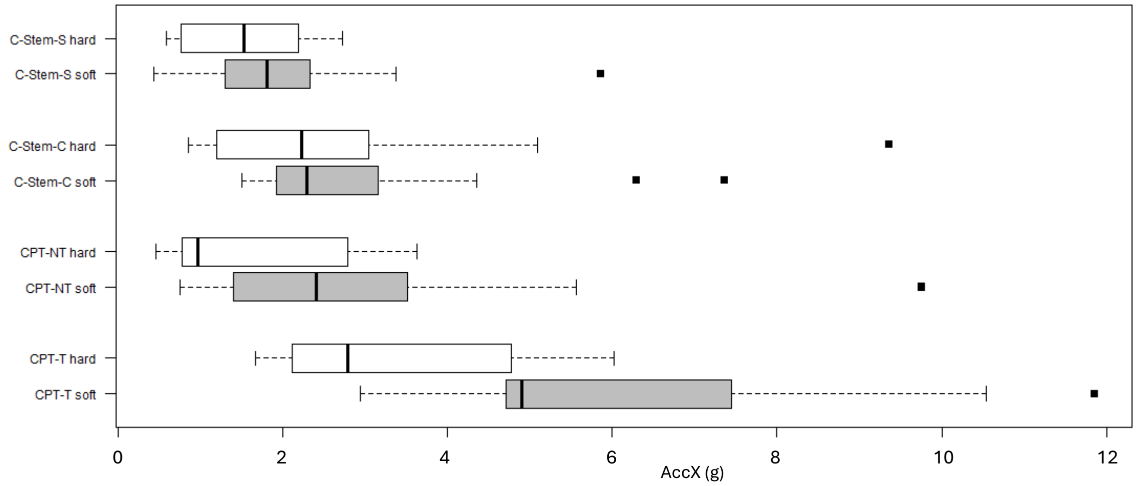


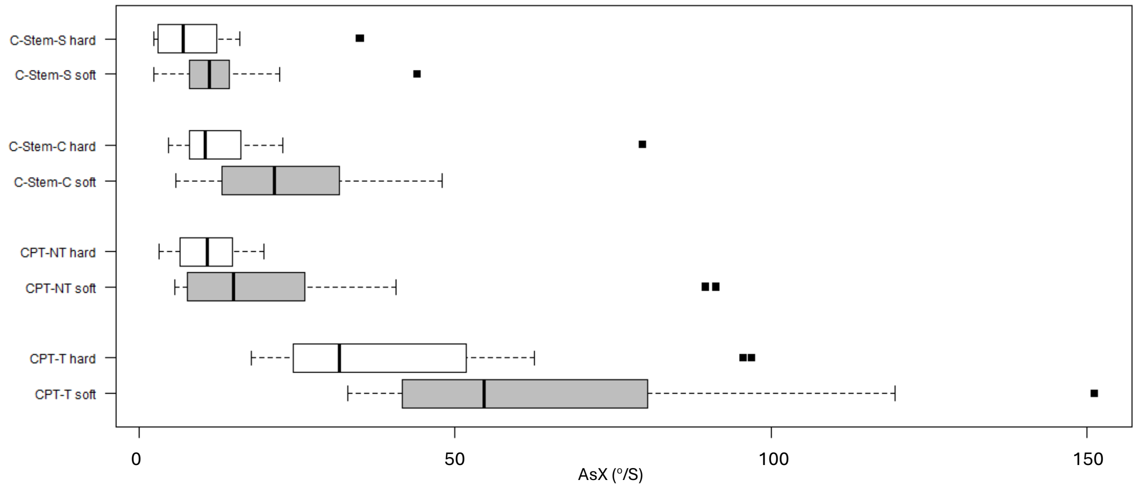
Figure 2: *Images showing the experimental setup used. 1) the four introducers tested (from left to right a: CPT-T, b: CPT-NT (add on component), c: C-Stem-C, and d: C-Stem-S) 2) The experimental setup showing a CPT stem in 30mm mount and IMU placed at the tip of the stem.*

a)



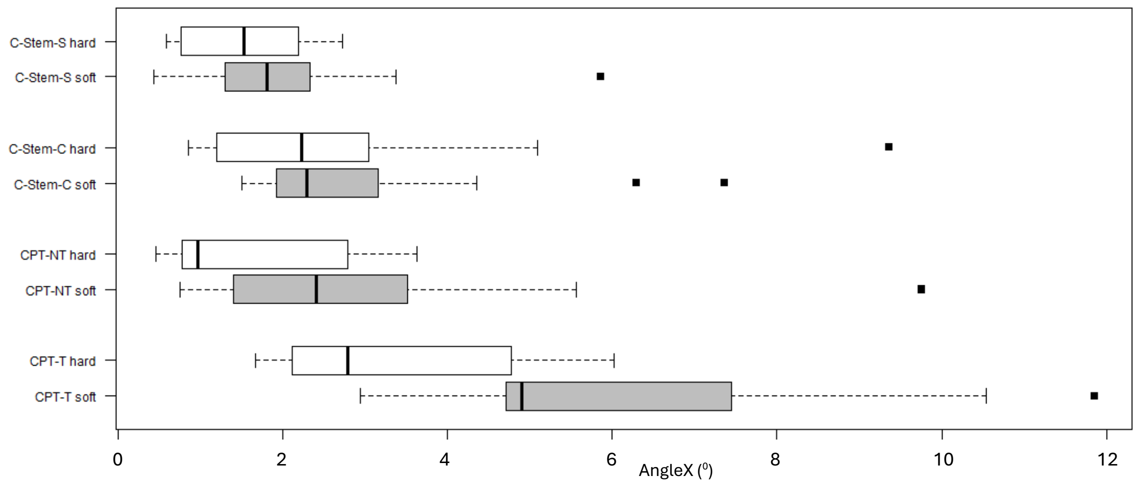
C-Stem-S hard
C-Stem-S soft
C-Stem-C hard
C-Stem-C soft
CPT-NT hard
CPT-NT soft
CPT-T hard
CPT-T soft
0
2
4
6
8
10
12
AccX (g)

b)



C-Stem-S hard
C-Stem-S soft
C-Stem-C hard
C-Stem-C soft
CPT-NT hard
CPT-NT soft
CPT-T hard
CPT-T soft
0
50
100
150
AsX (°/S)

c)



C-Stem-S hard
C-Stem-S soft
C-Stem-C hard
C-Stem-C soft
CPT-NT hard
CPT-NT soft
CPT-T hard
CPT-T soft
0
2
4
6
8
10
12
AngleX (°)

Figure 3: *Boxplots of RMS ranges for the four different introducers tested against a) acceleration [g] b) angular velocity [°/S] and c) angle of rotation [°] for all inserter types and both hard (shaded) and soft (unshaded) simulations.*

Tables:

	Soft				Hard			
	AccX(g)	**AccY(g)**	**AccZ(g)**	**RMS AccXYZ(g)**	**AccX(g)**	**AccY(g)**	**AccZ(g)**	**RMS AccXYZ(g)**
CPT-T	0.11 (0.05)	0.23 (0.13)	0.21 (0.13)	0.34 (0.16)	0.06 (0.03)	0.16 (0.10)	0.12 (0.11)	0.22 (0.14)
CPT-NT	0.07 (0.09)	0.11 (0.09)	0.09 (0.10)	0.17 (0.15)	0.03 (0.18)	0.06 (0.05)	0.04 (0.04)	0.08 (0.06)
C-Stem-C	0.05 (0.04)	0.10 (0.05)	0.08 (0.04)	0.14 (0.07)	0.046 (0.04)	0.09 (0.12)	0.06 (0.08)	0.12 (0.15)
C-Stem-S	0.03 (0.02)	0.07 (0.05)	0.06 (0.05)	0.10 (0.06)	0.03 (0.02)	0.04 (0.02)	0.03 (0.02)	0.06 (0.03)
	AsX(°/s)	**AsY(°/s)**	**AsZ(°/s)**	**RMS AsXYZ(°/s)**	**AsX(°/s)**	**AsY(°/s)**	**AsZ(°/s)**	**RMS AsXYZ(°/s)**
CPT-T	58.59 (30.99)	19.68 (12.13)	23.05 (19.81)	67.94 (34.93)	40.78 (26.04)	9.81 (5.40)	9.24 (4.24)	43.55 (25.87)
CPT-NT	20.08 (21.29)	11.02 (15.57)	9.37 (11.82)	25.39 (28.29)	10.21 (4.86)	2.60 (2.02)	2.65 (1.49)	10.96 (5.26)
C-Stem-C	15.78 (9.59)	10.37 (7.85)	10.76 (7.52)	22.99 (12.22)	15.03 (18.81)	4.14 (3.38)	3.83 (2.22)	16.40 (18.92)
C-Stem-S	8.34 (5.01)	6.62 (7.36)	5.45(5.86)	12.75 (9.64)	8.34 (8.56)	2.96 (2.05)	2.32 (1.32)	9.43 (8.58)
	AngleX(°)	**AngleY(°)**	**AngleZ(°)**	**RMS AngleXYZ(°)**	**AngleX(°)**	**AngleY(°)**	**AngleZ(°)**	**RMS AngleXYZ(°)**
CPT-T	4.61 (2.60)	2.38 (1.10)	2.72 (0.9)	6.03 (2.58)	3.04 (1.53)	1.02 (0.26)	0.98 (0.37)	3.39 (1.48)
CPT-NT	2.42 (2.11)	1.13 (1.13)	1.11 (0.86)	3.02 (2.38)	1.47 (1.14)	0.32 (0.18)	0.40 (0.27)	1.58 (1.14)
C-Stem-C	1.96 (1.01)	1.45 (1.5)	1.36 (0.59)	2.93 (1.70)	1.69 (1.37)	1.60 (1.91)	1.02 (0.69)	2.71 (2.25)
C-Stem-S	1.27 (0.84)	1.19 (0.69)	0.83 (0.90)	2.02 (1.26)	0.98 (0.67)	0.86 (0.68)	0.55 (0.35)	1.56 (0.72)

Table1: *Table giving an overview of the results [mean (standard deviation)] measured for acceleration, angular velocity and rotation angles in X, Y, Z axes and RMS of the range across all axes for both soft and hard simulations.*

Soft →

		CPT-T			CPT-NT			C-Stem-C			C-Stem-S		
		p-value	95% CI		*p*-value	95% CI		*p*-value	95% CI		*p*-value	95% CI	
			lower	upper		lower	upper		lower	upper		lower	upper
CPT-T	**AccX(g)**				**0.001**	0.064	0.316	**<0.001**	0.082	0.312	**<0.001**	0.115	0.348
	AsX(°/s)				**<0.001**	25.712	60.221	**<0.001**	22.277	55.913	**<0.001**	32.924	65.691
	AngleX(°)				**0.001**	1.583	4.006	**<0.001**	1.770	3.613	**<0.001**	2.602	4.633
CPT-NT	**AccX(g)**	**<0.001**	0.059	0.167				0.759	-0.071	0.045	0.272	-0.026	0.076
	AsX(°/s)	**<0.001**	14.599	41.573				0.248	-14.073	5.634	0.318	-2.850	12.129
	AngleX(°)	**0.002**	0.923	3.033				0.770	-0.999	0.859	0.264	-0.324	1.611
C-Stem-C	**AccX(g)**	**0.005**	0.042	0.154	0.346	-0.041	0.016				0.110	-0.010	0.090
	AsX(°/s)	**<0.001**	13.693	40.172	0.662	-5.739	3.620				**0.010**	2.827	18.511
	AngleX(°)	0.125	-0.243	2.007	0.057	-1.943	0.062				**0.043**	0.067	1.461
C-Stem-S	**AccX(g)**	**<0.001**	0.064	0.189	0.662	-0.018	0.032	0.265	-0.008	0.053			
	AsX(°/s)	**<0.001**	17.560	44.084	0.135	-2.073	7.356	0.077	-0.324	8.143			
	AngleX(°)	**<0.001**	0.745	2.881	0.872	-0.874	0.683	0.094	-0.193	1.601			

Hard ←

Table 2: *Comparison chart overview of Wilcoxon rank sum tests comparing RMS ranges for inserter groups against each other. The values to the right of the dotted diagonal line represent the soft simulation and those to the left the hard simulation (e.g. the values highlighted by the red border represents the p-value and confidence interval for the Wilcoxon rank sum test comparing the AsX of the CPT-NT introducer to the C-Stem-C introducer using the soft simulation). ACC = acceleration, AsX = angular velocity, and AngleX = angle of rotation. P-values representing significance (p<0.05) have been highlighted in bold.*

	CPT-T			CPT-NT			C-Stem-C			C-Stem-S		
	p-value	95% CI		*p*-value	95% CI		*p*-value	95% CI		*p*-value	95% CI	
		lower	upper		lower	upper		lower	upper		lower	upper
AccX(g)	**0.025**	-0.265	-0.008	**0.015**	-0.088	-0.009	0.085	-0.103	0.002	**0.047**	-0.073	0.000
AsX(°/s)	**0.013**	-40.075	-3.913	0.144	-14.494	2.098	**0.025**	-17.797	-0.957	0.154	-7.862	1.213
AngleX(°)	**0.002**	-3.367	-0.881	**0.038**	-2.046	-0.090	0.400	-1.214	0.715	0.423	-0.914	0.374

Table 3: *Comparisons between hard and soft simulations using Wilcoxon rank sum tests. Significant p values highlighted in bold text (p<0.05).*

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