

RESEARCH ARTICLE

Feasibility Analysis of a Novel Method for the Estimation of Local Bone Mechanical Properties: A Preliminary Investigation of Different Pressure Rod Designs on Synthetic Cancellous Bone Models

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Abstract

Background: Whilst traumatology around elderly population becomes more and more popular nowadays, the knowledge of local bone quality prior to osteosynthesis is of paramount importance. Assessment of the local bone mechanical properties provides essential information related to implant stability and can support treatment strategies in a timely manner. In the acute setting, dual-energy X-ray absorptiometry and quantitative computer tomography cannot be used routinely, and up till now no known intraoperative methods have been established.

Methods: A novel technique was developed to determine the local bone strength. A feasibility and sensitivity analysis were performed on synthetic cancellous bone models of various densities [including osteoporotic ranges (0.12 - 0.48g/cm³)] by testing the permeability of different rod probe designs.

Results: The Intraoperative Osseomechanical Strength Measurement (IOSM) method revealed high sensitivity for the evaluation of local density on synthetic bone material. Among the indenter designs tested, the one with 40° sharp apex and 5 mm diameter reflected accurately the density changes of the synthetic bones. It was also associated with less invasiveness posing no risk for the primary implant stability of the osteosynthesis that may follow.

Conclusion: The IOSM method using the indicated indenter design on synthetic cancellous models appears to be a minimal invasive technique with high accuracy in identifying different bone densities. Further studies on human bone material are now focused on the evaluation of the IOSM sensitivity compared to the gold standards (Dual-energy X-ray absorptiometry and quantitative computer tomography).

Level of evidence: V

Keywords: Bone mineral density, Implant failure, Intraoperative evaluation, Local bone strength, Osteoporotic fracture, Osteosynthesis

Introduction

Due to the demographic development of industrial countries and the consecutive increase in osteoporotic fractures, geriatric traumatology

becomes critically important (1). The prevalence of hip fractures has risen by approximately 70% and this increase may rise even more at a level of 150% by 2050

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in patients over 80 years of age (2).

Osteoporosis represents a worldwide health problem. The World Health Organization (WHO) considers osteoporosis one of the most important widespread diseases. Osteoporotic fractures of the hip are associated with a high comorbidity and mortality. They may also have a significant and detrimental effect on the patient's quality of life (3, 4). An adequate anatomic reduction followed by a stable fixation of the fracture that allows early mobilization of the geriatric patient constitutes decisive factors for a successful treatment of this challenging injury. Primary stability of the fixed implant strongly depends on the local bone quality (5, 6). Thus, even after an initially anatomical reduction and stabilization of a fracture, osteoporosis can independently induce secondary loss of correction and implant failure (7, 8).

Intraoperative evaluation of the local bone quality is of paramount importance and becomes an essential tool for each individual osteosynthesis. It provides valuable information to the surgeons directly assisting the treatment planning. In case of diminished mechanical bone quality, cement augmentation of osteosynthesis implants can increase the primary stability. It evens incongruences of cancellous bone and creates maximal contact surface at the implant-bone interface (9, 10). Subsequently, definitive decisions regarding which fixation-strategy is appropriate are often needed to be made on-site at the intraoperative stage. However, as this is commonly based on the surgeon's subjective experience, its accuracy is limited. Currently, no objective, reproducible and comprehensive method for assessing the mechanical bone quality during surgery exists. On the other hand, in the acute setting bone density measurements based on dual-energy X-ray absorptiometry (DXA) or quantitative computer tomography (QCT) cannot be used routinely due to technical barriers (11). In contrast to the above, osteodensitometry imaging techniques, an intraoperative mechanical evaluation of the regional intrinsic bone strength and quality immediately prior to osteosynthesis may offer surgeons more reliable information relevant to the implant anchorage (12).

The current biomechanical study is a preliminary investigation on synthetic cancellous bone models of different densities that aims to reproducibly conduct a feasibility and efficacy analysis of a novel device that is based on the use of a penetrating pressure rod probe to determine local bone mechanical properties. The main goal here, is to compare different indenter designs and identify the one with the highest sensitivity and on the same time, the lowest invasiveness that could secure primary implant stability.

Materials and Methods

In this Intraoperative Osseomechanical Strength Measurement (IOSM) study, synthetic cancellous bone models in terms of foam blocks (*Sawbones, Malmö, Sweden*) with an open-pore structure (130 mm x 180 mm x 40 mm), different densities and pressure resistance values were used [Table 1]. Their density range was wide, covering also osteoporotic values (0.12 - 0.48g/cm³).

Four different rod probe profiles were used to test their

Designation	Density [pcf]	Density [g/cm ³]	Pressure resistance [MPa]	Pressure module [MPa]
#7.5	7.5	0.12	0.28	18.6
#15	15.0	0.24	0.67	53.0
#30	30.0	0.48	3.20	270.0

permeability and compare their sensitivity in all foam blocks included. The indenter designs were divided into two groups, one with 5 mm and another with 10 mm diameter. In each diameter-group two different types of tip profile were used: a round tip (r) and a 40°-pointed sharp apex (s) [Figure 1].

The synthetic bone blocks were fixed on the workbench via a clamp device. In all cases the indenter was penetrated into the foam block in a depth of 60 mm. The magnitude of material resistance against the feed motion of the rotating indenter into the artificial bone material, was evaluated by determining the changes in torsional loads (torque). The resulting resistance curve was then compared with the density and hardness values of each foam type for all indenter designs tested.

The experimental setup consisted of a drive unit, a measuring device, a drilling spindle unit, an analog-to-digital converter and a software data analysis (*Microsoft Visual Basic*) [Figures 2 and 3a-b]. The drive unit and measuring device contained following components (in order of force-flow):

- Cordless screwdriver IXO (*Bosch, Gerlingen-Schillerhöhe, Germany*) – torque: 4.5 Nm; empty run speed: 215 rpm
- Metal bellows coupling MK2 (*R+W Drive Unit Elements, Klingenberg, Germany*) with a magnet for speed measurements
- Torque transducer type 8645 (*Burster GmbH & Co KG, sensors & precision measurement, Gernsbach, Germany*)
- Metal bellows coupling MK2 (*R+W Drive Unit Elements, Klingenberg, Germany*)
- Spindle drive guided through a drilling sleeve that

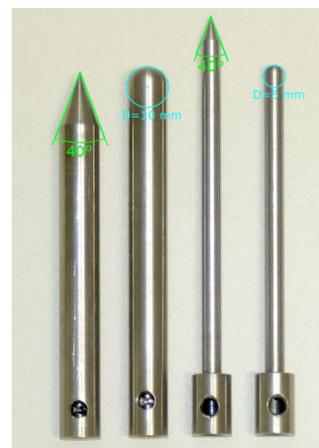


Figure 1. Indenter configurations.

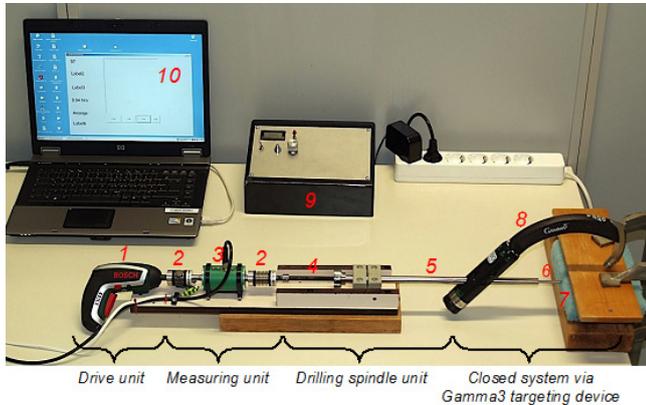


Figure 2. The IOM experimental setup. 1) cordless screwdriver, 2) two metal bellows coupling, 3) torque transducer, 4) threaded spindle, 5) drilling sleeve and 6) indenter, 7) foam block, 8) Gamma3 targeting device, 9) analog-to-digital converter, 10) data analysis.

had equal diameter as the manufactured lag screw guide sleeve of the Gamma3 Trochanteric Nail System (Stryker, Duisburg, Germany)

- Targeting System of the Gamma3 Trochanteric System (Stryker, Duisburg, Germany), which was fixed with drilling sleeve of the spindle unit and the clamped foam block
- Indenter with a different apex design in each case, compliant with the coupled spindle.

The driven spindle was guided through a matching drilling sleeve, which was assembled and blocked in place on the targeting device of the Gamma3 Trochanteric System, equally as during the intraoperative placement of the lag screw guide sleeve in a trochanteric femoral fracture treated with a gamma nail. The Gamma3 targeting device was also

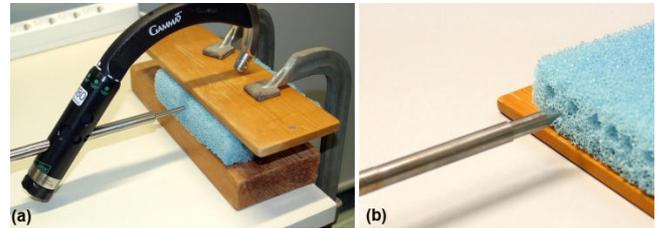


Figure 3. (a) Closed system between foam block and drilling spindle unit with a 5 mm round indenter led by the Gamma3 targeting device. (b) Penetrations on a foam block using the indenter with 10 mm diameter and an 40° apex.

coupled with the fixed construction of foam block and clamp device, so that a stable and closed system between guide sleeve and the bone model could be assured.

The electrical signals and rotation speed measurements received from the torque load transducer were provided directly from the analog-to-digital converter to the evaluation software. Each combination of indenter design and foam block type was repeated ten times. The values measured: time $[(t)]$ measured in seconds, sec], penetration depth $[(s)]$ measured in millimeters, mm] and torque $[(M)]$ measured in newton metre, Nm], where then stored directly in an ASCII file.

The statistical analysis of the selected values was performed using the software IBM SPSS V. 19. Linear regression was used for the evaluation of the resistance courses and calculation of the maximum torque (M_{max}) and slope (m) of a straight-line equation as described below. The Mann-Whitney test ($P < 0.05$) was used to compare the absolute values of M_{max} and m among different foams and different indenter design [Table 2]. Finally,

Table 2. Comparison of the absolute values of Maximum torsion moment M_{max} and slope m among different foams and different indenter designs (Mann-Whitney test, $P < 0.05$)

Indenter	M_{max}			m		
	#7.5	#15	P	#7.5	#15	P
5r	0.1194	0.1935	<0.001	0.0003	0.0017	<0.001
5s	0.1080	0.2247	<0.001	0.0004	0.0021	<0.001
10r	0.2567	0.4546	<0.001	0.0024	0.0053	<0.001
10s	0.2501	0.5423	0.001	0.0026	0.0078	0.001
	#7.5	#30	P	#7.5	#30	P
5r	0.1194	0.3332	<0.001	0.0003	0.0034	<0.001
5s	0.1080	0.3919	<0.001	0.0004	0.0046	<0.001
10r	0.2567	0.8198	0.001	0.0024	0.0108	0.001
10s	0.2501	0.9511	0.001	0.0026	0.0131	0.001
	#15	#30	P	#15	#30	P
5r	0.1935	0.3332	<0.001	0.0017	0.0034	<0.001
5s	0.2247	0.3919	<0.001	0.0021	0.0046	<0.001
10r	0.4546	0.8198	0.001	0.0053	0.0108	0.001
10s	0.5423	0.9511	0.001	0.0078	0.0131	0.001

Table 3. Comparison of the absolute values of Maximum torsion moment M_{max} and slope m among different indenter designs and different foam types (Wilcoxon test, $P < 0.05$)

Foam type	M_{max}			m		
	5s	5r	P	5s	5r	P
#7.5	0.1080	0.1194		0.0004	0.0003	
#15	0.2247	0.1935		0.0021	0.0017	
#30	0.3919	0.3332	0.038	0.0046	0.0034	0.011
	10r	5r	P	10r	5r	P
#7.5	0.2567	0.1194	0.005	0.0024	0.0003	0.005
#15	0.4546	0.1935	0.012	0.0053	0.0017	0.012
#30	0.8198	0.3332	0.018	0.0108	0.0034	0.018
	10s	5r	P	10s	5r	P
#7.5	0.2501	0.1194	0.012	0.0026	0.0003	0.012
#15	0.5423	0.1935	0.012	0.0078	0.0017	0.012
#30	0.9511	0.3332	0.018	0.0131	0.0034	0.018
	10r	5s	P	10r	5s	p
#7.5	0.2567	0.1080	0.005	0.0024	0.0004	0.005
#15.0	0.4546	0.2247	0.012	0.0053	0.0021	0.012
#30.0	0.8198	0.3919	0.018	0.0108	0.0046	0.018
	10s	5s	P	10s	5s	P
#7.5	0.2501	0.1080	0.012	0.0026	0.0004	0.012
#15	0.5423	0.2247	0.012	0.0078	0.0021	0.012
#30	0.9511	0.3919	0.018	0.0131	0.0046	0.018
	10s	10r	P	10s	10r	P
#7.5	0.2501	0.2567		0.0026	0.0024	
#15	0.5423	0.4546	0.012	0.0078	0.0053	0.012
#30	0.9511	0.8198	0.043	0.0131	0.0108	

the Wilcoxon test ($P < 0.05$) was performed to compare the absolute values of M_{max} and m among different indenter designs and different foam types [Table 3].

Results

The average torsion moment following the 10 trials for each individual foam type are summarized in Figure 4. In all combinations of foam block densities and indenter designs tested, the torque values measured, showed a linear progression [Table 4; Figures 5; 6].

The rising resistance courses (positive slope) of torsion moments detected in all cases here, were linearly associated with increasing values of (1) the foam density that was independent of indenter design, (2) the penetration depth into the foam block and (3) the diameter (5 mm or 10 mm) of the indenter designs as a result of the material displacement effect [Figure 4]. The influence of the indenter tip profile (40° pointed apex versus rounded apex) became clearer mainly when using thicker indenter designs (diameter 10 mm) on foam blocks with higher densities (foam #15 and #30), due

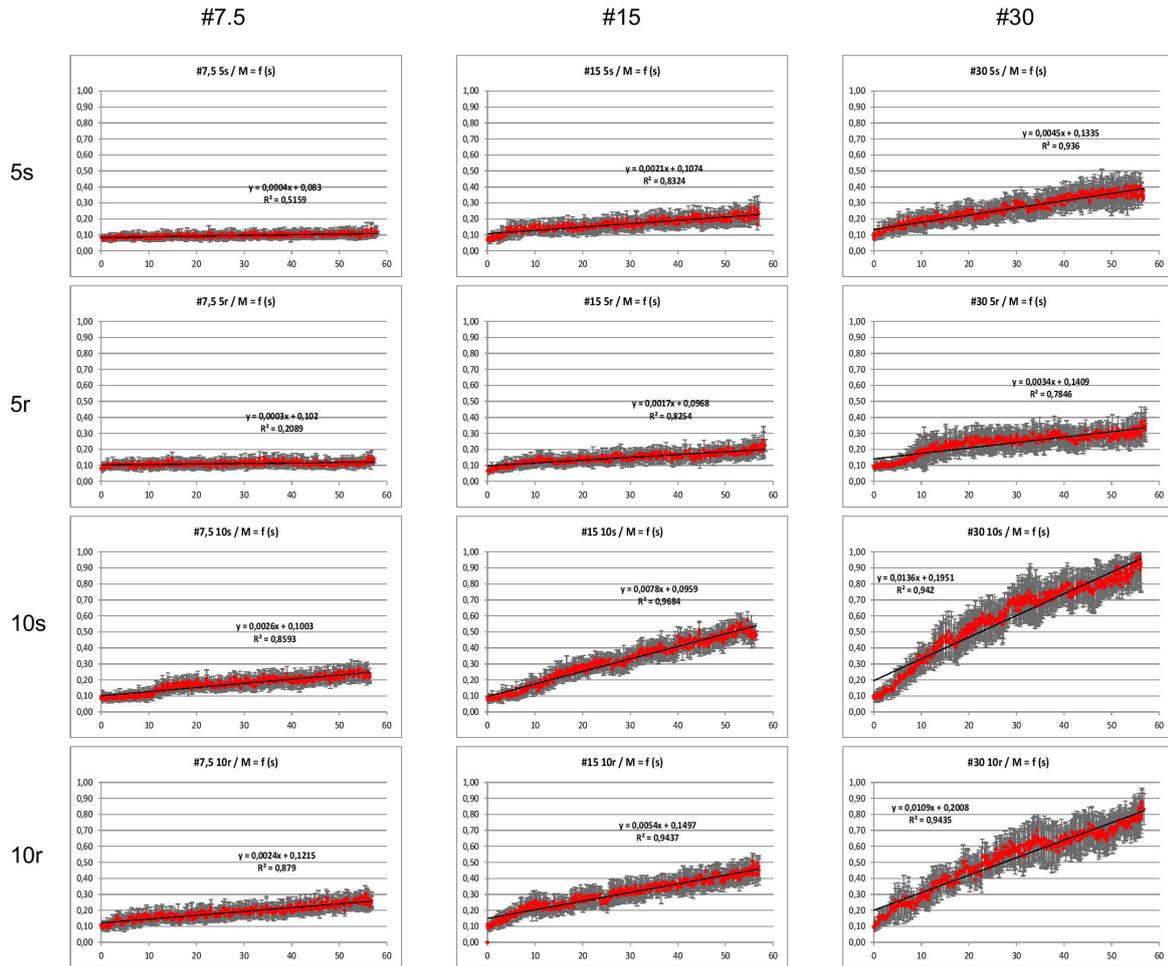
to the higher penetration resistance. The indenter with rounded apex showed generally a flatter slope of torque increase and a lower maximum torque value (M_{max}) compared to the other design group with pointed tip profiles [Table 2].

The influence of the indenter design and foam density on the M_{max} and slope increase in the torsion resistance is shown graphically in figures 5 and 6.

The statistical analysis, as depicted in tables 2 and 3, showed (with only few exceptions) significant differences in M_{max} and torque increase among the various foam types and indenter configurations tested.

Discussion

In all test configurations of different foam types and indenter designs, the resulted resistance moments detected, were increasing linearly when the indenter penetration depth was progressing. Both tested parameters, foam density and indenter design (diameter and tip profile) could significantly influence the values of slope m and maximum torque M_{max} seen on the torsion



x (horizontal axis) indicates the penetration depth s (in mm) of the rotating indenter.
 y (vertical axis) indicates the torsion moment M (in Nm) of the penetrating indenter.

Figure 4. Course of the torsion moment M for an indenter penetration depth s in relation to different foam densities (#7.5, #15, #30) and indenter designs [5mm or 10mm diameter with round (r) or sharp (s) apex].

Table 4. Maximum torsion moment M_{max} [Nm] and slope values m as calculated via linear regression $M = m s + n$ (M = torque in Nm, m =slope, s = depth 57 mm) for each combination of foam type and indenter design

Foam type	#7.5		#15		#30	
Indenter	M_{max}	m	M_{max}	m	M_{max}	m
5s	0.1058	0.0004	0.2271	0.0021	0.3900	0.0045
5r	0.1191	0.0003	0.1937	0.0017	0.3347	0.0034
10s	0.2485	0.0026	0.5405	0.0078	0.9703	0.0136
10r	0.2583	0.0024	0.4575	0.0054	0.8221	0.0109

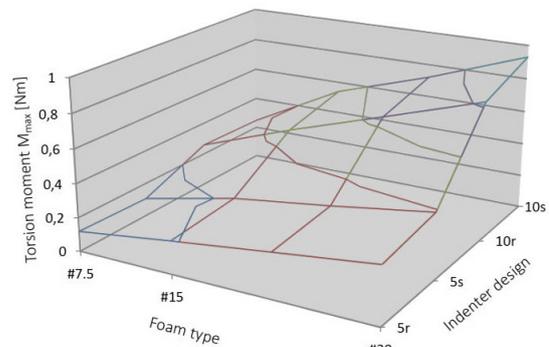


Figure 5. Graphical representation of the impact of foam type and indenter design on the maximum torsion moment M_{max} .

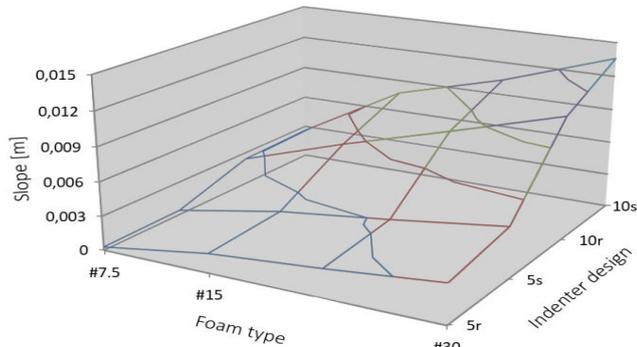


Figure 6. Graphical representation of the impact of foam type and indenter design on the slope m .

moment courses [Figure 4]. Increasing foam hardness led to almost linear increase in M_{max} and m , independent of the indenter design used. Doubling the indenter diameter from 5 to 10 mm affected the M_{max} and m in a different manner: M_{max} uniformly increased approximately 2.3 times, while m grew from 3 to 8 based on the density of the foam used. Regarding the influence of the indenter tip design on the resistance curve, the rounded profile showed a flatter linear slope m and a lower maximum torque M_{max} compared to the 40°-pointed apex. This finding indicates that a wedge-shaped indenter tip produces greater material displacement resistance than a rounded one, and therefore offers higher measurement sensitivity.

In the acute management of fractures, although the mechanical resistance capability of the bone can be determined using DXA or QCT, these osteodensitometry measurement techniques are not always available, either preoperatively or intraoperatively, and may not be applicable in some cases (11). Furthermore, the presence of implants near the examination field can cause artifacts and affect the accuracy of measurements. Moreover, DXA and QCT provide only general and indirect information of bone strength. Hence, bone mineral density scores (BMD) account for only 60% of the variance (13). The architecture and dimension as well as the degree of mineralization and remodeling of cancellous bone seem to have an important impact on local resistance capability of the bone. They provide useful information that is directly associated with the mechanical stability of a fixation system used to treat a fracture. However, the evaluation of these bone quality properties is missing when using the osteodensitometry imaging techniques, DXA and QCT (12).

Intraoperative evaluation of mechanical bone strength is very important and clinically relevant, but until now it depends mostly on experience and subjective interpretation. Different techniques have been described in the field of dentistry and oral implantology. However, they reveal high variations in terms of invasiveness and objectivity (14). Other methods that are based on the principle of a rotating propeller tip design, recently described for intraoperative use, showed limited predictability for implant migration in clinical settings (15). The management of osteoporotic fractures, especially

of proximal femur, would considerably benefit from any objective assessment of the cancellous bone quality prior to fixation that could support on site decision-making regarding the appropriate treatment strategy (9, 10).

BMD threshold values of $\leq 0.68 \text{ g/cm}^2$ and approximately $\leq 0.25 \text{ g/cm}^3$ after volumetric BMD indicate a high fracture risk and are associated with an increased danger of implant failure (16-18). The predetermined porosity and hardness of the tested plastic foams in this biomechanical setting spanned a desired range of densities (0.12 to 0.48 g/cm^3) and simulated a spectrum close to reality that covered osteoporotic (risk group) and denser cancellous bone qualities.

Our method is based on the principle of material displacement resistance measured in the form of a torsion moment (torque) against the penetration of a rotary indenter. The testing of different indenter designs served several purposes. On one hand, the use of different diameters could determine the technical feasibility in regards to the required driving power and the extent of associated invasiveness that may endanger the stability of attending implant fixation. On the other hand, as it was unclear whether the apex form of the indenter had any influence on the sensitivity of measurements, two different indenter tip profiles were compared (rounded versus 40°-pointed apex).

From this study we can conclude that different mechanical qualities of the cancellous bone models, including osteoporotic density values, could be precisely verified using IOSM in torsion-moment route diagrams. This study showed that higher trabecular bone strength and mass (density) needed higher torque in order to be displaced by the penetrating indenter. In these cases, the torque showed steeper curve ascent with a positive linear correlation to the penetration depth of the indenter.

A potential limitation of this study is the discrepancy in the mechanical properties between synthetic cancellous bone models used in this study and the human bone that the surgeons encounter intraoperatively. However, as the foam block densities tested here corresponded to the osteoporosis BMD threshold values, they could represent not only healthy populations but also the high-risk patient group of interest. Furthermore, in order to achieve more reliable measurement analysis in this preliminary setting compared to the high variations seen in human bones, we utilized synthetic bone models for our experiments. This could offer a desirable high reproducibility and homogeneity for the comparison analysis of the different indenter designs.

The increased invasiveness associated with the large diameter (10 mm) indenters tested here might present a clinically relevant risk for the implant stability, due to the induced bone loss in the same area, where the lag screw of the gamma nail system will be introduced.

The final goal of the IOSM concept is to integrate this novel pressure rod system into surgical procedures and support surgeons intraoperatively make the right treatment decisions. Using this technique, the surgeons can recognize and prevent potential complications, such as cutting-out of a femoral neck screw and subsequently reduce the revision rates. Therefore, the setup of this preliminary study was designed to customize the IOSM

method and adapt it to the instruments of Gamma3 trochanteric nail system from *Stryker* that is commonly used for the treatment of proximal femoral fractures. Hence, while the sleeve of the drilling spindle unit is fixed on the Gamma3 targeting device, the indenter is oriented in the same projection as the femoral neck screw. In this way it can provide useful information about the local bone properties directly at the same area where the neck screw will be inserted. However, as the manufactured femoral neck screw (*Gamma3, Stryker*: diameter / length 10.5 mm / 70-130 mm) appears to have a similar diameter to the thicker pressure rod designs used in our investigation (10 mm), this indenter group could endanger the stability of the implant.

Among the indenter designs tested, the pressure probe with a 40°-pointed apex and a 5 mm diameter accurately reflected the density changes of the bone models. In addition, its small diameter is associated with low invasiveness and therefore no negative effect on implant stability can be expected.

The current preliminary biomechanical study plays a key role in the development of the IOSM concept, as it not only shows promising results with a high sensitivity and feasibility of the novel IOSM technique, but also constitutes the cornerstone for further upcoming studies on human materials.

Integration of the IOSM method into surgical instruments and standardized procedures (e.g., a drill) could facilitate intraoperative quantification of regional mechanical bone quality near osteosynthesis. This method might offer surgeons a more objective basis for decision-making during surgery to deal properly with critical bone

situations. Further studies using the indicated indenter on human bone are now focused on assessing the sensitivity of the IOSM method compared to the gold standard bone density measurements (*DXA* and *QCT*) (19).

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