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Acoustical determination of primary stability of femoral short stem during uncemented hip implantation

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A R T I C L E I N F O

Keywords:
Total hip arthroplasty
Operation monitoring
Vibro-acoustic analysis
Primary stability

A B S T R A C T

Background: Preparing the medullary space of the femur aims to create an ideal form-fitting of cementless implants to provide sufficient initial stability, which is crucial for osseous integration, ensuring good long-term results. Hammering the implant into the proximal femur creates a press-fit anchoring of the endoprosthesis in the medullary space. Implanting the optimal size of the shaft for best fitting should avoid damage to the bone. Modified acoustic signals in connection with implantation are being detected by surgeons and might be related to the primary stability of the implant.
Methods: This study aims to explore the relationship between frequency sound patterns and the change in stem stability. For this purpose, $n = 32$ Metha® short stems were implanted in a clinical setting by the same surgeon. During implantation, the sounds were recorded. To define a change in the acoustic system response during the operation, the individual blows of the implantation sequence were correlated with one another.
Findings: An algorithm was able to subdivide through sound analysis two groups of hammer blows (area 1 and area 2) since the characteristics of these groups showed significant differences within the frequency range of 100 Hz to 24 kHz. The edge between both groups, detected by the algorithm, was validated with expert surgeons' classifications of the same data.
Interpretation: In conclusion, monitoring, the hammer blows sound might allow quantification of the primary stability of the implant. Sound analysis including patient parameters and a classification algorithm could provide a precise characterization of implant stability.

1. Introduction

Total hip arthroplasty (THA) is one of the most common surgical procedures worldwide which can be attributed to its success rate (EPRD, 2022; Feng et al., 2020; Rolfson et al., 2021; Statistisches Bundesamt (Destatis), 2021). Preparation of the femur and fitting of the implant depends on the personal experience of the surgeon and objectifiable data for intraoperative monitoring of shaft implantation are missing. Improvement of anchorage of the implant is important to provide the best possible primary stability which is relevant for osseous integration and long-term results (Fonseca Ulloa et al., 2020; Jahnke et al., 2018; Rothstock, 2011; Thomsen et al., 2008). Hammering the implant bears the risk of femoral fracture which might harm the durability of the endoprosthesis (Fonseca Ulloa et al., 2020; Schmidbauer et al., 1993). The present techniques, which encompass radiological intraoperative monitoring and the expertise of the surgeon, when coupled with a proficient planning of the operation, demonstrate a significant success rate, and significantly contribute to the longevity of the prosthesis (Della Valle et al., 2005; Huo et al., 2021). Nevertheless, the lack of in situ monitoring and visibility for primary stability and femoral fractures also demonstrated a significant decrease in the long-term success of the operation in the past. This was enhanced by an inadequate planning or lack of experience by the surgeon (Jahnke et al., 2023). Variable sounds during implantation of femoral shaft implants can be recognized and seem to be correlated with the primary fixation of the implant. Previous studies examined the operation sound related to different situations of

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implantation (Goossens et al., 2017; Goossens et al., 2021; Morohashi et al., 2017; Rosenstein et al., 1989a; Sakai et al., 2020; Whitwell et al., 2013). Currently, there is no suitable method to quantify and classify these subjective sound variabilities to study the relation between acoustic changes and the primary stability of the implant. Analysis of the sound signals during implantation might be helpful to improve the anchorage of the implant and reduce the risk of intraoperative fracture which should be beneficial for the clinical outcome (Eggli et al., 1998; Pastrav et al., 2009). Reliable data would enable the surgeon to refine the implantation methodology of various implant models and consequently reduce the risk of intraoperative complications. Therefore, this study recorded sound signals during the implantation of uncemented hip endoprostheses generating a data pool to correlate the sound emissions and the initial stability of the implant (Rowlands et al., 2008).

Subsequently, the development of an algorithm and an instrument according to the principle of acoustics could highlight the blows forces' outcome and facilitate the operation (Schmidbauer et al., 1993). Although first steps in this direction are being shown by some studies, (Fonseca Ulloa et al., 2020; Jahnke et al., 2018; Rosenstein et al., 1989b; Schmidbauer et al., 1993) this examination presents another way to interpret these sound signals and contributes to the development of an algorithm with a new classification method using a broad spectrum of frequencies. This study aims to establish a clear link between the sound of hammer blows during implantation and the resulting stability changes in the endoprosthesis.

2. Materials and methods

2.1. In vitro measurement

For proofing the concept and validating of the measurement sensor before in vivo implementation femoral shaft implants were inserted in $n = 15$ synthetic femora (Sawbone type #3403, small size, Malmö, Sweden). Then a cementless short stem endoprosthesis (Aida©, Implancast GmbH, Buxtehude, Germany) was chosen for the preliminary study. The synthetic femora were prepared and opened by an experienced orthopaedic surgeon using a similar intraoperative procedure and using the original instrument according to the manufacturer's instructions. Three different study collaborators implanted the prosthesis each $n = 5$ in synthetic femora to produce different sound characteristics in this setup. The prosthesis was implanted until it was completely seated and the unfiltered room sound was recorded at the same time. For this purpose, a directional microphone (Rode, 107 Carnarvon St, Silverwater, NSW, Australia) with a frequency range of 100 Hz – 24 kHz was used. The sound signals occurring during the experiments were finally recorded with a digital recording system (Digital Voice Recorder, ZIKO, China) and saved in WAV format. The difference in the recorded sound at the beginning and at the end of the implantation was clear and indicated a broad change in the frequencies during the implantation in the synthetic bone. Therefore, the proof of concept was successful and Ethical approval for the in vivo study was granted by the Ethical Committee of the Justus-Liebig-University Giessen (file number: 160/19).

2.2. Demographic data

In the department of orthopaedics and orthopaedic surgery at the UKGM Giessen cementless hip endoprosthesis type Metha® short stem (B.Braun SE, Melsungen, Germany) are being implanted via an anterolateral approach. Based on the inclusion and exclusion criteria (Table 1) $n = 32$ patients between the age of 20–70 years were included in this study. All included patients had x-ray examinations before and directly after the implantation procedure. Quantitative bone densitometry (qCT) of the femoral head was also performed to characterize the bone density parameters. These are routine controls examination after a THA procedure.

Table 1
inclusion and exclusion criteria for the study.

Inclusion criteria	Exclusion criteria
only one experienced surgeon	Previously operated femur
indication for a cementless hip endoprosthesis	Previously fractures of the femur
implantation via anterolateral access	Contraindications for the minimal invasive operation
No contraindications for an x-ray examination (pregnancy or younger than 18 y.o.)	Femoral head donation for allogeneic and autologous bone grafting
hip stem type Metha®	
signed letter of acceptance from the patient	

2.3. In vivo measurement

Based on the preliminary in vitro experiments, the recordings within the operation room were made with the same directional microphone during the implantation process of the Metha® implant until the surgeon declared the correct seated position of the prosthesis. To ensure the sterilization protocol, the position of the directional microphone was attached to a height-adjustable tripod and placed at the same level as the femora axis where the stem was implanted. The tripod was placed in the non-sterile operation area with one meter between the microphone and the operation zone. The tripod height was also adjusted to accommodate the operation table and the patient's position within it. The distance between the operation table and the patient was always chosen to be the same and during the recording period (average 40 s) the operating personnel were asked to be silent. (Fig. 1).

2.4. Data processing

The recorded data signals in WAV format are then marked by an expert with AUDACITY (Audacity 2.3.2, audacity.org). The individual hammer blows, interference noises or artefacts were manually classified and designated with different markers (S = hammer blow, A = artifact/ interference noises). During the implantations, a patient monitor was used for monitoring the vital sign of the patients and the monitoring sound could not be suspended. As a result, the frequency band from 3 kHz to 3.3 kHz is not included in the analysis. Further signal processing was carried out with MATLAB (R2018b, MathWorks Inc., Natick, Massachusetts). A discrete Fourier transformation (DFT) was calculated for each marked hammer blow and an energy standardized power spectrum was computed considering the frequency response of the composite system. To define a change in the acoustic system response during the operation the individual blows of the implantation sequence were

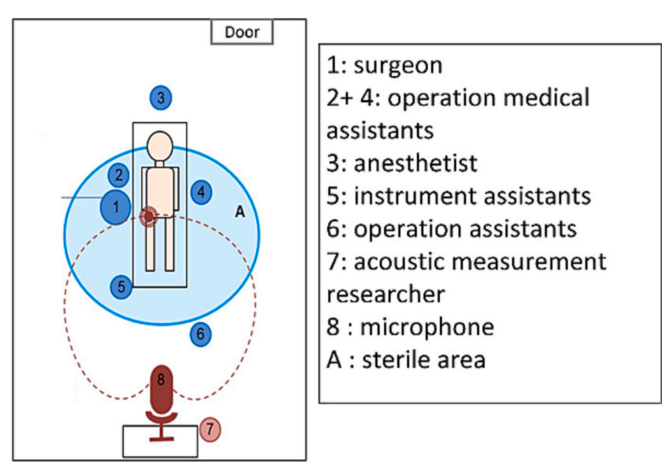

Fig. 1. Sketch of the operation room and positioning of the directional microphone.

correlated with one another. This results in a (Blows X Blows) Pearson correlation matrix, where Blows is the number of strokes by each implantation process. The correlations of the impulse responses were tested for significance. The correlation coefficients are plotted against each other in a heat map, maintaining the time sequence to visually analyze the correlation coefficients with an increasing number of implantations blows regardless of the implantation process (Fig. 2).

To detect the edges in the correlation matrix outliers were previously removed from the matrix and the correlation of two blows around roh = 0.1 dropped in comparison to the neighboring implantation blows. Then, a dominant edge can be seen where the further blows differ from the following ones (Fig. 2). Using a gradient across the correlation matrix it was possible to identify the blows that show the greatest change over the entire implantation. This algorithm guarantees to separate the insertion into two groups: one before the edge (Area 1) and one after (Area 2). Within these areas, the average of all the spectrums of the hammer blows was calculated.

For comparability with the work of Gossens et al., the band power feature (BPF) as well as the Pearson correlation coefficients (PCC) were determined and implemented in MATLAB (Goossens et al., 2021). The time series over the course of implantation were also smoothed with a moving average filter over five blows.

The following frequency bands were used for the BPF comparison:

- $f_1 = 200$ Hz
- $f_2 = 3000$ Hz
- $f_3 = 20.000$ Hz
-

$$BPF = \frac{PSD_{f1-f2}}{PSD_{f1-f3}} * 100\%$$

For the PCC comparison, the following frequency bands have been correlated from blow to blow:

- PCC_1 ($f_1 = 0.2$ kHz, $f_2 = 0.8$ kHz)
- PCC_2 ($f_1 = 0.2$ kHz, $f_2 = 1.5$ kHz)
- PCC_3 ($f_1 = 0.2$ kHz, $f_2 = 2.0$ kHz)

To compare the method of Gossens et al. with the results of this study better the blow-to-blow correlation for a non-band-limited blow was used additionally.

- PCC_M (f1 = 20 Hz, f2 = 48 kHz)

Additionally, to Gossens' features PCC_M is shown in black (Fig. 3) and the PCC_M corresponds to the black line for clarity since the graph of the correlations can be interpreted based on the color scale (Fig. 2).

Gossens et al. examined the convergence of properties to determine possible endpoints acoustically. For this purpose, the coefficient of variation (COV) of all four properties of the last three implantation steps is determined. The following three criteria are checked before the current considered blow is marked as convergent:

1. The coefficient of variation of the last three blows is ≤ 5%.
2. The current blow lies within the coefficient of variation or within the interval of the standard deviation of the mean value of the last three blows.
3. The correlation of the blow interval is at least 0.6 for PCC.

The blows are marked with colored triangles where there is convergence according to Gossens (Fig. 3. Black: The BPF converges; Blue: The BPF and at least 2 PCCs converge; Green: All properties converge).

2.5. Statistics

The primary outcome parameters were the central tendencies between the averaged amplitude strengths of the impulses from areas 1 and 2 by the described algorithm and expert. Since the length of the blows differed the algorithm resembled the spectra of area1 and area 2 for all subjects. The test statistic used was the Friedman test to compare column effects in a two-way layout, as there was no normal distribution of the amplitudes of the individual frequencies ($\alpha = 0.05$) (Hollander, 2014). The column effect measures the main difference between area 1 and area 2 and the rows represent the frequency of the resembled spectra.

The secondary outcome parameter was the mean absolute deviation (MAD) of the algorithms compared to a medical expert examination. The expert judgment was based on the audio recordings and the implantation history. For each implantation procedure, the expert and the algorithm chose a blow where the implant could reach a press-fit situation. The convergence according to Gossens et al. (Goossens et al., 2021) does not define only one precise blow but a converging range of strokes. Therefore, the beginning of the first convergence interval with the highest score was defined as the estimated press-fit blow of the implantation.

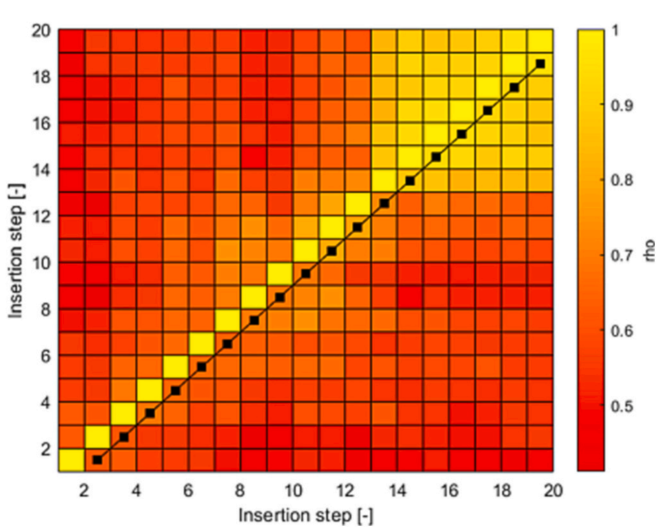

Fig. 2. Correlation matrix from subject 10.

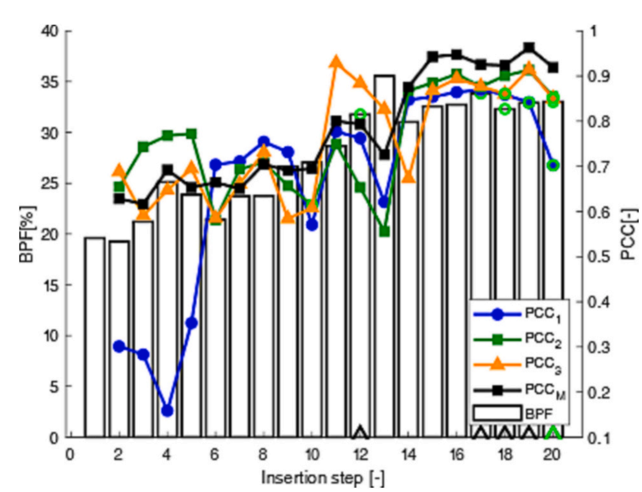

Fig. 3. BPF and PCC from subject 10 after Gossens et al. (2021).

3. Results

3.1. In vivo measurement

For the edge detected by the algorithm as well as by the expert a significant column effect could be determined between area 1 and area 2 (Algorithm: Friedman-Test: Chi-Quadrat (1) = 1031.06, $p \leq 0.001$, $n =$ 29 & Expert: Friedman-Test: Chi-Quadrat (1) = 1034.28, $p \leq 0.001$, $n =$ 29). The mean rank was 30.1 versus 28.1 (algorithm $\sigma = 16.9$) and 30.7 versus 28.3 (expert $\sigma = 16.9$).

There are differences between area 1 and area 2 in the mean power of the amplitudes over the entire frequency range (Fig. 4). The low-frequency band up to approximately 2500 Hz is more dominant in area 2 and in area 1 more energy is visible in the high-frequency band. Prominent bands where the energy in area 2 decreases in high frequencies are at ~2900 Hz, ~ 4400 Hz and ~ 8700 Hz. In the 400 Hz range surrounding the already mentioned bands, the area 2 exhibits an amplitude increase of 8%, 20%, and 22%.

The MAD compared to the localization by the expert is 2 ± 5 blows for the algorithm presented in this study and 7 ± 6 blows for the implementation (Goossens et al., 2021).

Table 2 shows the range at which the Gossens algorithm (Goossens et al., 2021) converges in addition to the rated and detected blows for a given maximum number of strokes (column 3, in Table 2). Implantations 16, 21, 22 and 31 each show large deviations from the expert rating.

Table 2
Results from the algorithm in comparison with Gossens et al. (Goossens et al., 2021) and the expert rating.

ID	Fonseca & Schreynemackers et al.	Expert	Nbr. hits till final seating	Gossens et al.(Goossens et al., 2021)
1	6	6	21	5–8
2	6	7	17	9–12
3	8	8	26	21–24
4	20	20	33	12–15 23–26
5	5	5	43	11–14
6	7	7	22	13–16
7	8	8	25	16–19
8	6	14	25	11–14
9	8	8	22	7–8
10	13	13	20	17–20
11	6	6	21	13–16
12	6	10	31	12–15
13	3	3	17	13–16
15	17	17	28	5–8
16	12	19	37	12–15
17	8	8	43	14–17
18	5	5	27	13–16
19	6	6	19	13–16
20	14	13	33	14–17
21	4	4	20	23–26
22	2	6	25	18–21
23	6	10	26	10–13
25	10	10	30	18–21
27	22	22	40	17–20
28	8	14	38	10–13
29	11	11	44	13–16
30	40	31	50	20–23
31	11	37	50	6–9
32	9	9	42	8–11

4. Discussion

Bone site preparation is important to ensure substantial primary stability being relevant for the durability of the hip stem which had already been demonstrated in similar studies. Damaging the femur intraoperatively e.g., by too forceful hammering the implant or the broach might have an enormous negative effect on the implantation site and the longevity of the implant (Fonseca Ulloa et al., 2020; Schmidbauer et al., 1993). This study shows a possible algorithm and measurement concept, that could signalize to the surgeon the moment in which the prosthesis changes from loose to fit. Therefore, this application could prevent the surgeon to make unnecessary hammer blows avoiding possible damage to the patient. In the first version, the algorithm can significantly identify two different areas of interest and a very specific edge in the sound correlations where the stability change could take place. This edge detection was independently confirmed in 25 of 30 cases by an expert surgeon and showed that the algorithm could detect the acoustic moment with a mean accuracy of 2 blows and with a standard deviation of 5 blows. Therefore, this algorithm showed a better correlation with the subjective judgment of an expert surgeon than the implemented algorithm of Gossens et al. (Goossens et al., 2021) (mean accuracy 7 ± 6 blows). Otherwise, Gossens methodology employed a recursive mechanism to analyze the acoustic data, which may potentially facilitate its prompt implementation in a real-time in vivo setting. Nonetheless, the frequency band selected by Gossens et al. (limited to a frequency range of 2 kHz) may also be a contributing factor to the larger discrepancies observed between Gossens et al. and the experts. This study demonstrates that an additional frequency range, such as 2900 Hz, 4400 Hz, and 8700 Hz, contains values that provide information for identifying the implant's stability. Moreover, Gossens et al. focus on interpreting and recognizing the last four blows. This mechanism enhances the speed of the algorithm, but it also makes it susceptible to outliers and artefacts. by patient 31 could be shown that both algorithms have a different appreciation from the edge detection as the expert. This shows the factual limitations of this kind of algorithm since it could be influenced by acoustic artefacts or other sources. Nevertheless, both algorithms clearly showed that an acoustic monitoring system could be good assistance for surgeons since the edge recognition rate of both algorithms appeared relatively high. However, there are differences between these edges and the number of blows till final seating. Although the experience of the operator recognizes the acoustic change of tone the prosthesis will be hitten further until final seating, because of other visual and haptic parameters. Therefore, both algorithms must deeply understand the process after the edge recognition to allow a possible detection of the exact final seating point. This understanding could be achieved with the integration data of a force sensor in the hammer or with training and recognition of the same patterns in the implantation's acoustics after the edge. Otherwise, there are instances where the skilled surgeon may administer additional blows beyond the required amount, either to ensure certainty or due to inadequate monitoring of the optimal

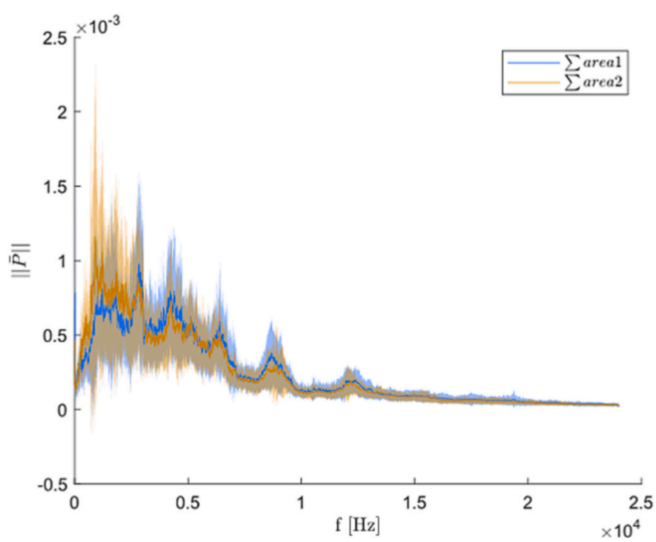

Fig. 4. Averaged power spectrum over all subjects. The transparent area in the color of the graphs of the areas is the one standard deviation.

position of the prosthesis. For this purpose, the utilization of an algorithm and acoustics monitoring could eliminate these unnecessary subsequent blows, thereby reducing the likelihood of intraoperative fractures and implant misplacement.

Hence the method of this study is based on the signals postoperatively and it was able to clarify a difference in the accuracy, but limitations related to the real-time application must be considered.

The algorithm and the new methodology have various limitations. The classification of the stability sound was not proven with another system and the long-term component must be evaluated at least in the first two years, where most of the aseptic loosening occurs. However, a qualitatively better difference between our algorithm and the state of the art could only be observed after the use of our system as a predictor for stability sounds. The study only shows the data after the operation, and all operation show good results for all 30 patients. Therefore, the classification and understanding of the data occur when the surgeon has no complications, and the patients have a good postoperative sitting of the prosthesis. That might affect the analysis or the recognition of the edges. Another limitation is the use of only one prosthesis type, then the acoustic sound is related to the prosthesis material and sound. This study attempts to reduce the influence of individual parameters (patient, prosthesis material, and others) by normalizing each acoustics signal with the energy of each acoustic blow. However, it could only be confirmed that the influence of these parameters has been reduced through the monitoring system if this study were expanded to include other prosthesis types. The same limitation applies to the surgeon influence and the operation room influence on the sound, since in this study the surgeon and operating room remained the same. Therefore, further in vitro and in vivo studies are necessary to improve the measurement concept. The use of simulation and finite element analysis for a better understanding of the mechanical relation between the different materials and the sound generated in the operation room should also improve the outcome of the algorithm, and eradicate various residuals components, that are already been studied in different studies (Bhawe et al., 2022; Chethan et al., 2022). A machine learning approach being able to gather information from different implantations with a broad range of outcomes could allow a real-time decision for edge detection or in other words a support to stop implantation at the right moment. Otherwise, the acoustic operation data can be expanded to other endoprosthesis models since this algorithm must not be limited to only one implant system. An acoustic register for different prostheses and a well-validated machine learning system might be useful to introduce an algorithm to reduce the likelihood of failure providing the ideal fitting of the implant and the best possible outcome for the patient (Ishaque et al., 2020; Jahnke et al., 2018; Jakubowitz and Seeger, 2015; Morlock et al., 2006).

5. Conclusion

The acoustic signals in the operation room during an endoprosthesis implantation contain important information on the stability of the prosthesis in the bone. Detecting and classifying this signal could improve the quality and outcome of such operations. This study proves and validates a new method for the recognition of the acoustic data during joint replacement. It also, shows a link between the changes in the acoustics during the operation, as well as between the beginning and ending hammer blows throughout implantation. Concluding that the algorithm created for this task might offer possible features for acoustic-based assistance surgery in the future. The incorporation of additional studies and registers containing information on acoustic signals with the aim of implementing a universal self-learning system could enhance the quality and endurance of the prosthesis.

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Ethical approval

Positive ethical vote of the Ethics committee of the Justus-Liebig-University in Giessen (file number: 160/19).

Declaration of Competing Interest

None declared.

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