Optical performance and drilling forces of an orthopaedic DRS drill with a stagnant optical probe

An article on a Biomedical Engineering Master thesis about orthopaedic DRS drilling at the Delft University of Technology

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In spinal surgery, the misplacement of spinal screws is a common problem that causes (severe) pain, bleedings or even paralysis [1] [2] [3]. In order to improve the navigational support of spine surgeons, this research focuses on the development of an optical sensing diffuse reflectance spectroscopy (DRS) orthopaedic drill that identifies bone tissue boundaries, based on fat fraction. The developed drill concept introduces a stagnant optical fiber-equipped probe into a cannulated orthopaedic drill. To verify the clinical applicability of the developed system, the accuracy of the optical tissue boundary detection has been analysed under different tissue penetration speeds, as well as the axial drilling force increases due to the introduction of a stagnant probe into a cannulated drill. The maximum feed rate at which the drill consistently detects the tissue boundary before breaching it, is 0,5mm/s. The force increase due to the introduction of a stagnant probe is a factor 2,96 on average and varies widely between different feed rates and probe diameters (a factor 1,15–5,75). The established feed rate speed limit of 0,5mm/s is lower than drilling feed rates of up to 5mm/s, observed in the operation room. Increasing the sampling frequency –especially decreasing the inactive period between the measurements– is required. The feed force increase of approximately a factor 3 can be regarded as a challenge for surgeons, who indicated that they preferred feed forces to be kept low.

1. Introduction

Spine surgeries are common surgical procedures, used to relieve some of the most pressing physical health issues today. Low back pain for instance, has been the worldwide leading cause of disability for the past 30 years according to the Institute for Health Metrics and Evaluation (IHME) [4]. Between 1990 and 2015, years lived with disability (YLDs) caused by low back pain increased by 54%, and this growth is not expected to halt soon [5]. Recent publications in academical and mainstream media however, argue that overall, there is insufficient evidence that spine surgery improves patient outcomes overall [6] [7].

Researchers suggest to better this in two ways [7]:

1. Reduce the amount of spine surgeries by applying a stricter selection of patients, including only those who are likely to benefit from the procedure.
2. Reduce the risk of medical complications within the field of spine surgery.

This research focuses on the latter. Surgical screw misplacements are common as navigating in the spine is difficult due to the small vertebral dimensions and a lack of anatomical landmarks [3]. Furthermore, it inherits high risks due to the relatively close proximity of the spinal cord and vertebral artery [8]. A 2018 study by Woo and DiCuccio showed that in 31 studies on pedicle screws, misplacement rates varied from 2% to 50% [2].

This can be improved if surgical equipment offers better support to surgeons to minimize these medical complications. In spine surgery, a sensing surgical drill provides an opportunity to mitigate screw misplacement rates. This would prevent pain, damage to vital structures and –in severe cases– paralysis and arterial bleedings [1].

For this research a diffuse reflectance spectroscopy (DRS) drill has been developed, that uses a stagnant optical fiber-equipped probe, around which a cannulated orthopaedic drill rotates. To verify the clinical applicability of this DRS-drill concept, its optical accuracy and mechanical performance is of interest.

2. Methods

This research features an optical and a mechanical experiment.

Optical experiment

The optical tissue boundary identification accuracy is studied at varying feed rates. The tissue identification is based on a DRS-derived fat fraction (%). Cancellous bone (red and yellow marrow) feature fat fractions of 40% up to 80%, while cortical bone, also referred to as 'bone mineral', mainly consists of hydroxyapatites and mineral salts [9] [10]. This difference in bone fat fraction can be distinguished by using DRS [11] [12].

The solid, cortical outer layer of bone is as thin as 0,90mm on average in some regions in the cervical pedicles –which are the narrow vertebral passage ways through which spinal screws are placed [13] [14]. It is decided that for safe screw placement, the DRS drill should stop before entering the cortical bone. The cortical bone then provides a (small) buffer for the subsequently placed orthopaedic screws.

The model used for optical fat fraction measurements is first described by Farrell *et al.* is used to dertermine the absorption and reduced scattering coefficients $\mu_a(\lambda)$ and $\mu_s'(\lambda)$ [15]. The amount of fat and water in the tissue can then be derived by comparing the measured reflectance spectrum with known wavelength dependent reflection of fat and water following a procedure as previously described by the group [11]. The fat fraction (ff) is expressed as (1):

$$Fat\ fraction = \frac{Fat}{Fat + water}$$

The optical threshold value that indicates reaching the cortical bone is determined as (2):

$$Ff = avg.ff\ cancellous - (avg.ff\ cancellous - avg.ff\ cortical)^{-2}$$

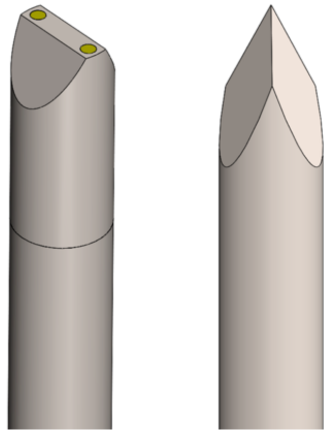

Figure 1. The DRS probe tip (left) and a K-wire trocar tip (right)

Mechanical experiment

The mechanical experiment examines the axial force increase –required to penetrate bone– due to the usage of a stagnant probe. Instead of coupling rotating optical fibers that are integrated in a drill bit to the DRS console, this experiment uses a stagnant 1,35mmØ optical probe introduced into the channel of a 2,7mmØ cannulated orthopaedic drill. Quantifying this required force increase is of clinical importance, as interviewed surgeons indicated that they preferred to apply low axial feed forces during surgery [16].

Because the used optical probe drill tip design is not suited for the penetration of hard materials such as bone, K-wires are used for the mechanical test; the tips are shown in *Fig. 1*. K-wires are steel pins, used in orthopaedic surgery. If this concept will be further developed, the DRS probe design needs to be optimized for bone penetration.

Bone phantom

The DRS measurements are taken in an optical bone phantom. The phantom consists of a layer of a 13% fat gelatin solution mixed with intralipid, resembling cancellous bone, and an agar solution with barium sulphate (added for optical scattering purposes), resembling cortical bone. The axial drilling force measurements are performed on a Sawbones® 15 PCF cellular foam block as a cancellous bone phantom with a Sawbones® fiber filled epoxy layer as a cancellous bone phantom. A phantom is used since it is not allowed to perform experiments on animal material in the used lab in Delft. As a benchmark, the drilling experiments are performed on a block of young Dutch cheese with a fat fraction of 31%.

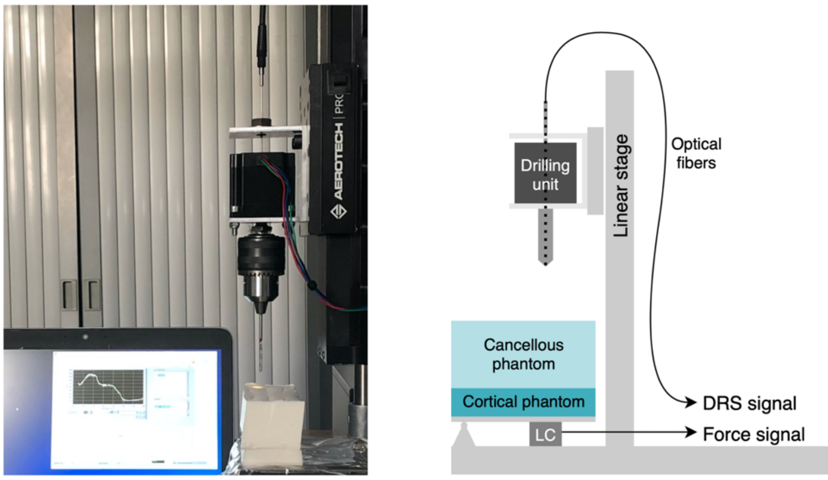

Figure 2. A picture and a schematic view of the experimental setup

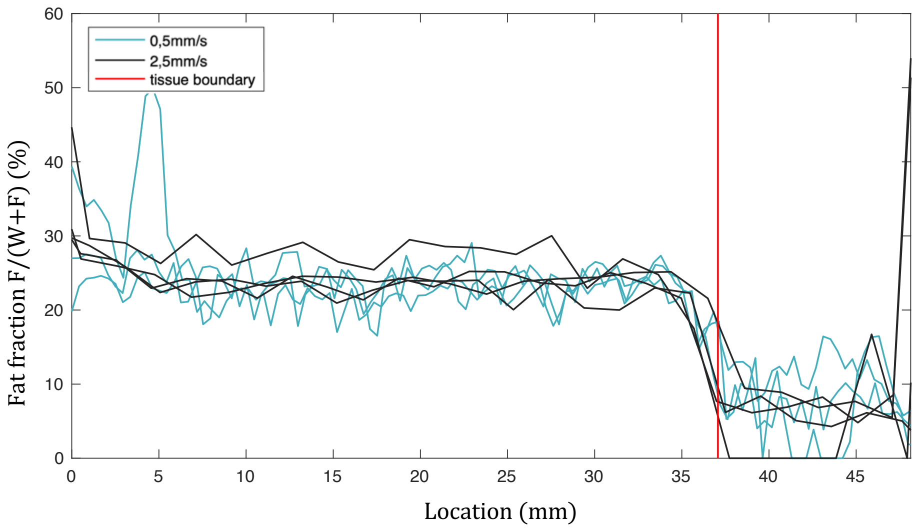

Figure 3. Fat fractions versus location at feed rates of 0,5mm/s and 2,5mm/s

In *Fig. 2*, a picture and a schematic view of the experimental setup is shown. (LC on the schematic view stands for Load Cell)

3. Results

Optical experiment

In *Fig. 3*, the fat fraction functions are shown of the drilling experiments with feed rates of 0,5mm/s and 2,5mm/s. The optical threshold value for indicating a tissue boundary is 17,5%. Increasing the drilling feed rate under a constant sampling frequency creates larger distances between the optical measurements. At a feed rate of 0,5mm/s, the DRS-drill detects the phantom tissue boundary before breaching it. At feed rates of 1mm/s to 2,5mm/s, the drill optically identifies the tissue boundary at a range of locations from 2,1mm before to 3,2mm after the boundary, as shown in *Fig. 4.*

The DRS fat fraction identifications show a consistent overestimation: the approximate 13% fat lipid phantom is indicated at an average of 24,5%, the 0% fat agar phantom is indicated at 9,6% on average, and the average DRS derived fat fraction of the 31% fat young cheese block is 50,5%. The spectral fit program, which is developed for real tissue identification, is not optimized for the used artificial bone phantom [16]. The overestimation observed in these experiments does not occur in studies using the same devices on real bone [11] [12]. Because this overestimation is consistent, it did not affect the tissue boundary identification abilities of the drill.

In 5 of the 25 DRS drilling cycles, the through DRS derived fat fractions showed large deviations from the actual (0%) phantom fat fraction of the agar layer up to 84% fat. Individual spectra of such measurements show a discrepancy between the measured signal and the (lower) fit function at

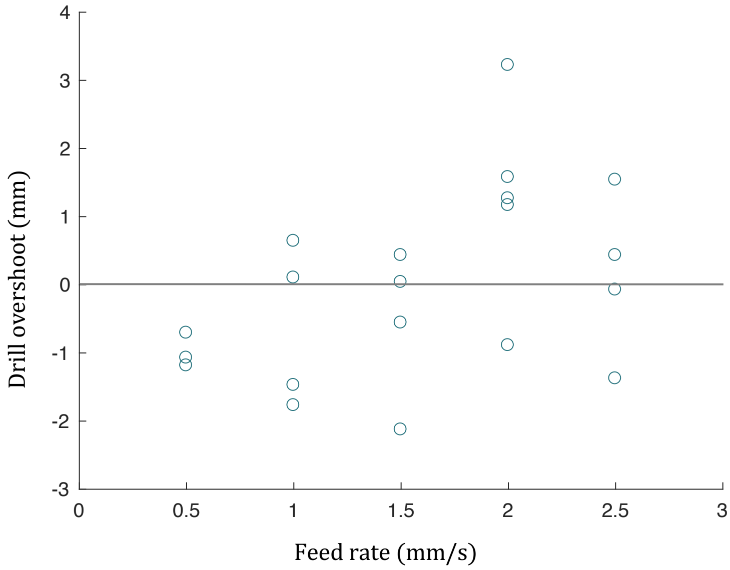

Figure 4. Scatterplot of the feed rate and overshoot of the DRS drilling setup

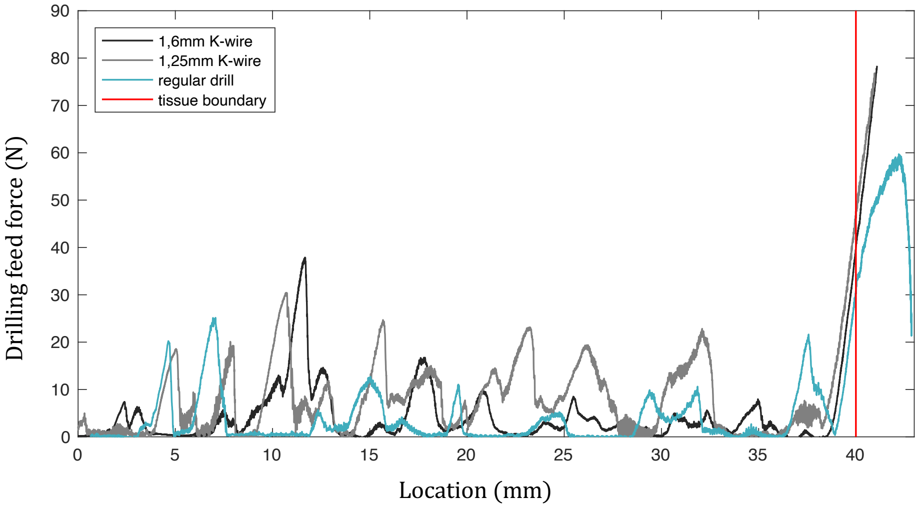

Figure 5. Axial drilling forces of three drill types in Sawbones® phantom at 2mm/s

1200nm. The measurements show an inverted scattering function as well. These drilling cycles have been excluded from the comparison of the feed rate and the drill overshoot in *Fig.4*. As the threshold value was either not reached, or reached at an overshoot of approximately 10mm in some cases, these inaccurate fat fraction determinations do compromise the ability of the DRS drill to optically identify tissue boundaries. Such values have (again) not been observed in DRS fat fraction determinations of real bone [11] [12]. If these measurements do occur in real bone however, the optical fitting should be improved in order to prevent the DRS drill from breaching the cortical bone.

Mechanical experiment

The mechanical experiment shows that increasing the feed rate increases the axial drilling forces. Introducing a stagnant probe into the drill increases the axial forces as well –especially in the epoxy mechanical cortical bone phantom, as none of the K-wire equipped drills can penetrate it. This can be seen in *Fig. 5*. When using a regular 2,7mmØ orthopaedic drill on the Sawbones® cancellous bone phantom, the overall measured peak force is 38,2N. Using the 2,7mmØ drill with a 1,6mmØ K-wire, gives a peak force of 57,6N. These peaks occurred at a feed rate of 4mm/s. The measured forces can be regarded as relatively high, but they do not exceed drilling force experiments performed on real bone [13].

Because the force measurements in the Sawbones® foam give severely skewed data, the force increase quantification is done using the measurements of drilling cycles in cheese. These measurements are normally distributed, and an ANCOVA analysis finds that both the feed rate and the drill type have a significant effect on the axial drilling force (*Sig. .000*). The introduction of a K-wire increases the required drilling forces by a factor 3 on average. However, the force increase varies widely among the different feed rates and drill types between 16% and 475%.

4. Conclusions

Optical experiment

The DRS drilling feed rate speed limit based on this experiment is 0,5mm/s.

The sampling frequency of the optical system needs to be increased for the DRS drill to make timely detect tissue boundaries at higher feed rates. To reach a feed rate of 5mm/s (a factor 10 faster), the sampling time needs to be reduced by a factor 10, from approximately 0,8s to 0,08s. As the sampling time used in this experiment consists of a 0,1s optical integration time and a 0,7s inactive period between two optical measurements, it is recommended to focus on reducing the inactive period. Nonetheless, when completely eliminating the inactive period, the resulting sampling time of 0,1s is still too long, so the optical integration time needs reduction as well.

Inaccurate fat fraction measurements are problematic for the phantom tissue boundary detection, but they are not expected to occur in human tissue. Apart from reducing the sampling time, suggestions for follow-up research include DRS-tissue identification while drilling at an angle, testing on cadaveric bone and eventually, clinical trials.

Mechanical experiment

None of K-wire equipped drills have been able to penetrate the epoxy cortical bone phantom. In the Sawbones® 15 PCF cellular foam mechanical cancellous bone phantom, the drill exerts forces up to 60N, to maintain constant feed rates. The peak forces can be regarded as relatively high compared to the 20N to 40N bone drilling forces found in literature [17] [18] [19] [20] [21]. However, they do not fall outside of the retrieved force ranges, as some studies show forces of up to 100N [22]. It can therefore be concluded that the peak forces can be regarded as representative for actual bone drilling.

The (skewed) distribution of the force measurements in the Sawbones® foam however, are not similar to the force distributions in real bone. Several studies show constant axial forces in bone drilling instead of the peaks shown in *Fig. 5*. [22] [23]. Introducing stagnant K-wires into the drill in a drilling experiment on cheese increased the drilling forces by approximately a factor 3, ranging from a factor 1,16 to 5,75. This can be regarded as problematic for surgeons, who indicated that they preferred feed forces to be kept low [16].

Testing stagnant probe equipped drills on (cadaveric) bone is required to verify whether the measured forces in the Sawbones® phantom occur in real bone as well. It is also of importance to verify whether the probe equipped drills cannot penetrate relatively thin cortical bone layers, similar to the thin cortical bone in cervical pedicles [13].

Disclosures

The instruments used in this study have been provided by the Delft University of Technology, the Erasmus University Medical Center, the Reinier de Graaf Hospital and Philips Research. The supervising professor of this thesis project (prof Dr. B.H.W. Hendriks) has financial interest in the matter, in the sense that he is an employee of Philips.

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