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Automated surgical screwdriver: automated screw placement

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Abstract: The use of power screwdrivers and drills for tapping and screw insertion in surgery is becoming more common. It has been established from clinical observations that the use of a small air drill for inserting self-tapping screws provides improved coaxial alignment and precision, and that the drill should be stopped before the screw head is completely seated on the plate, presumably to reduce the risk of over-tightening. The risk of overrun and over-tightening during tapping and screw insertion is increased with the use of power tools. Prevention of over-tightening is dependent upon when the surgeon detects the onset of tightening, both visually and from the feel of the rapid increase in torque. If detection is too late, then over-tightening or stripping can occur. This study is concerned with using a mechatronic screwdriver to control the tapping depth and to prevent the over-tightening of screws. The effects of various parameters upon the torque profile during tapping and screw insertion have been investigated in synthetic bone and sheep tibia. An automated system is proposed for preventing over-tightening of pre-tapped and self-tapping screws when attaching a surgical plate to a sheep tibia *in vitro*. The system was used to attach a plate to a sheep tibia using self-tapping screws. The mean torque of the screws inserted using the automated system was 35 per cent of the stripping torque.

Keywords: surgical screwdriver, automated screw placement, mechatronic screw insertion

1 INTRODUCTION

Screw insertion and tapping in orthopaedic surgery are traditionally performed entirely by hand. More recently power screwdrivers have been used for tapping and screw insertion for increased speed and accuracy of the process. The clinical observations reported by Baumgart *et al.* [1] concluded that use of a small air drill for inserting self-tapping screws (STSs) provides improved coaxial alignment and precision. It also stated in the clinical observations that the drill should be stopped before the screw head is completely seated on the plate. This is presumably to guard against over-tightening and stripping of the screw–bone interface. When using a power screwdriver for the insertion of STSs and self-drilling screws, there is an added increased risk of

over-tightening because the screw advances unexpectedly and very rapidly once the thread has started to form. If the power screwdriver is not shut down in time, then over-tightening or stripping of the screw may occur.

Gotzen *et al.* [2] advocated tightening screws to 84 per cent of their maximum torque value. Another study by McGuire *et al.* [3] reported that experienced surgeons stripped the bone thread on screws inserted in the laboratory when attempting to achieve the same level of torque. A more recent study by Lawson *et al.* [4] found that over-tightening of a screw in both cortices of bone resulted in approximately 40 per cent loss of pull-out strength. It was found that screws in a single cortex, if tightened to over 65 per cent of the maximum torque, suffered a measurable loss in strength. From this study it may be assumed that screws tightened to less than 65 per cent of the maximum torque would not be considered to be over-tightened.

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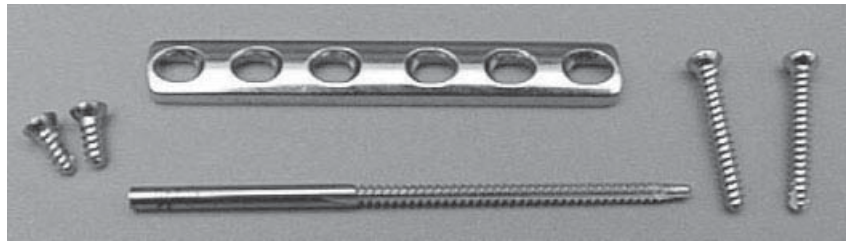


Fig. 1 Small fragment set with PTSs and STSs

Use of a power screwdriver or drill increases the risk of overrun during tapping and over-tightening during screw insertion. With a normal power screwdriver, prevention of over-tightening is entirely reliant upon the surgeon's judgement, which is based upon visual and tactile information. A mechatronic screwdriver can record torque and insertion depth to produce a torque profile (TP). This can be used to enhance the surgeon's judgement and to implement automated mechanisms that offer a fail-safe method of screw insertion to prevent overrun or over-tightening.

1.1 Aims

The aim of this research is to demonstrate the advantages of an automated or mechatronic power screwdriver for screw insertion in orthopaedic surgery.

1.2 Objectives

The objectives for this investigation are twofold:

- (a) to investigate how various parameters affect the torque profile during tapping and screw insertion;
- (b) to test the implementation of automated fail-safe systems.

2 EXPERIMENTAL METHOD

The most likely scenario for over-tightening of screws is during the insertion of a small screw into thin or diseased bone. In order to test this, this study used small screws inserted into brittle synthetic bone (solid polyurethane foam) that meets ASTM F1839-97 [5] and sheep tibia. A foam with a density of 0.64 g/cm^3 (40 lb/ft^3) was used to represent diseased bone. The screws, tap, and plate used were taken from a small fragment fracture repair set with

pre-tapped screws (PTSs) and STSs, i.e. screws of 3.5 mm diameter supplied by DePuy (Fig. 1). The screws meet ASTM F543-98 [6].

2.1 Experimental rig

A mechatronic rig similar to that described in ASTM F117-95 [7] was designed for the study. The only difference was that, in order to represent a surgical application better, the experimental rig designed for this study facilitated a rotational speed of 50 r/min compared with the recommended 3 r/min in ASTM F117-95. The rig consisted of a mechanical rig with sensors connected to a personal computer (PC) used for controlling the rotational speed and data logging.

The mechanical structure was composed of a rigid outer shell that held the specimen and measured the applied torque. This contained a sliding inner unit, which housed the shaft for driving the screw (Fig. 2). The drive shaft was connected to an optical encoder that allowed rotational speed to be controlled via a feedback loop to the PC. The torque applied to the specimen was measured by mounting it on a turntable that was prevented from rotating by a cantilever. The cantilever was equipped with strain gauges arranged in a Wheatstone configuration that allowed the torque to be derived. The signal from the strain gauges was amplified and passed through a fourth-order Butterworth filter to reduce or eliminate noise. Data were captured using the PC at a frequency of 50 Hz allowing a TP to be displayed and recorded. All tests were conducted at a constant rotational speed of 50 r/min. A constant axial force of 2.0 gf was applied for all tapping and screw insertion tests except where stated. Torque profiles were recorded for various combinations of tapping and screw insertion into synthetic bone and sheep tibias (single and double wall).

All tapings and screw insertions were performed in pre-drilled pilot holes of 2.5 mm diameter. Ten tests were conducted for each set of conditions and the screws were always rotated until stripping

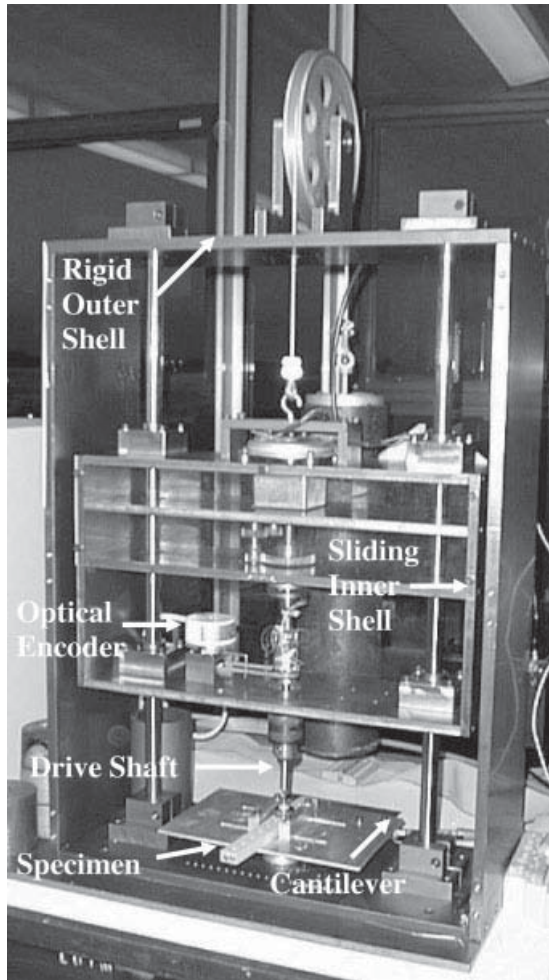


Fig. 2 Photograph of the rig

occurred. Pre-tapping was always conducted prior to inserting the PTS. The test protocols are described below under the headings of 'Synthetic bone' and 'Sheep bone'.

2.2 Synthetic bone

The effect of friction between the screw-head and mating surface was tested with both PTSs and STS in synthetic bone (solid polyurethane foam that meets ASTM F1839-97 [5]). This was done by placing a bearing or surgical plate between the screw head and the material surface during screw insertion (Fig. 3). Long (30 mm) screws were used for this test and a spacer was also included between the screw head and the foam to prevent the screw from entering deeper than eight rotations (10 mm). All pilot holes were spaced 20 mm apart. Ten STS-bearing combinations, ten STS-plate combinations, ten PTS-bearing combinations, and ten PTS-plate combinations were tested, making a total of 40 tests.

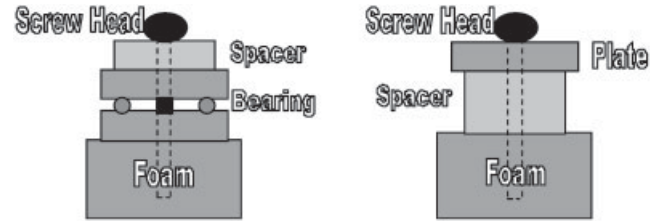


Fig. 3 Diagram of the screw inserted into the foam block with the bearing and with the plate

2.3 Sheep bone

All the tests on sheep bones were concerned with the use of a PTS or an STS for the attachment of a surgical plate. Ten bones were used for testing and a long and short PTS and STS were inserted into each, making a total of 40 tests. Tibia bones taken from butchered sheep, were defleshed and set into blocks of plaster of Paris. This allowed for accurate alignment during drilling, tapping, and screw insertion. All tests were conducted in the shaft section of the bone, where the outer cylindrical wall consists of cortical bone and the centre is filled with soft bone marrow. This allowed tapping and screw insertion to be conducted in either a single (first) or double (first and second) wall. Short (10 mm) and long (30 mm) screws were used for single- and double-wall tests respectively. It was found that a higher axial force of 6 gf was required to insert the short STS. This was thought to be due to the small size of the single cutting flute.

3 RESULTS

The insertional cycle for a screw can be divided into two phases:

- insertional phase (phase I);
- tightening phase (phase II).

For the purpose of this study the maximum torque that is reached during insertion will be described as the insertional torque (IT) and the maximum torque before stripping occurs will be described as the stripping torque (ST).

3.1 Synthetic bone

The TP for an STS entered into a solid homogenous material (i.e. synthetic bone) demonstrates both phases of the insertion cycle clearly. The torque is seen to rise linearly as the screw is inserted, until the screw can no longer advance and the tightening

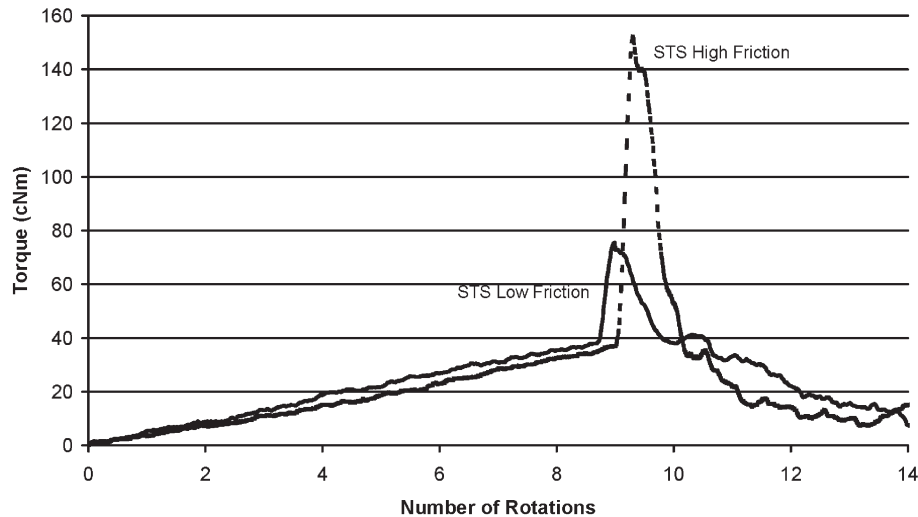


Fig. 4 TP for an STS in foam with and without friction

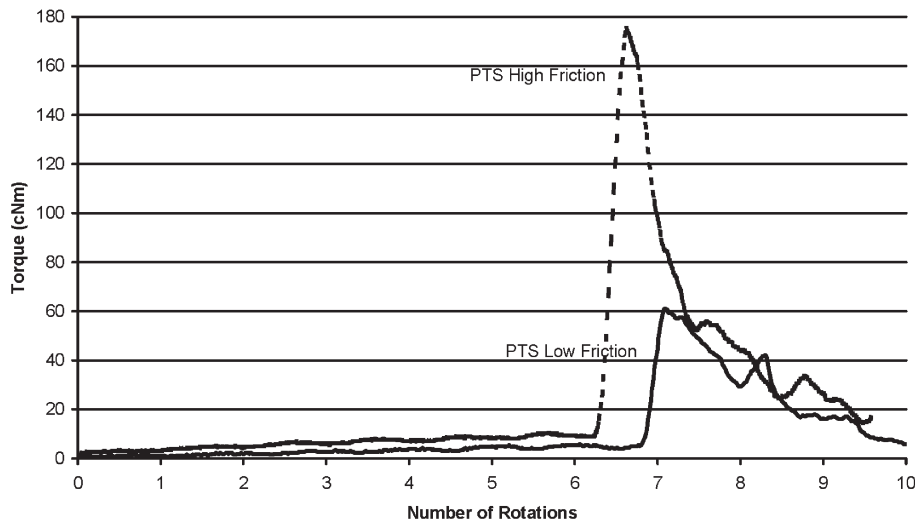


Fig. 5 TP for a PTS in foam with and without friction

phase begins. At this point the torque is seen to rise far more rapidly, until the ST is reached and the material fails (Fig. 4). The effect of friction between the screw head and the material surface can also be seen in the same graph. The solid curve is the TP with a bearing (low friction) and the dashed line is the TP with a plate (high friction). It should be noted that the number of rotations until tightening begins is greater than the eight full threads that entered. This is because the STS requires an unknown number of rotations before the thread starts to form fully.

With a surgical plate (high friction) the ST is approximately twice that when a bearing is used. It is interesting to note that the point from whence tightening begins (IT), to when ST is reached is the

same for the plate and bearing. Consequently the rate of increase in torque for the plate is approximately twice that of the bearing, as twice the value of ST is reached in the same number of rotations.

The TP for a PTS is similar to that of an STS, except that the torque increases at a far slower rate during the insertional phase. As expected, the effects of the plate and bearing are much the same (Fig. 5). It should be noted here that tightening has begun earlier than eight rotations, i.e. the number of threads inserted. This is because the screw requires a number of rotations to start the thread prior to the beginning of testing. As can be seen, the screw was entered for more rotations prior to the start of the high-friction test than for the low-friction test.

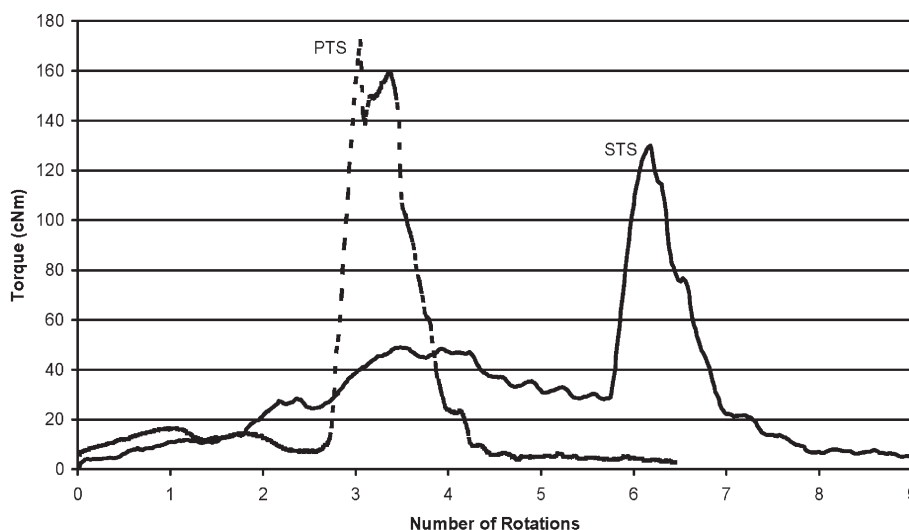


Fig. 6 TP for an STS and a PTS in a single cortical wall of bone

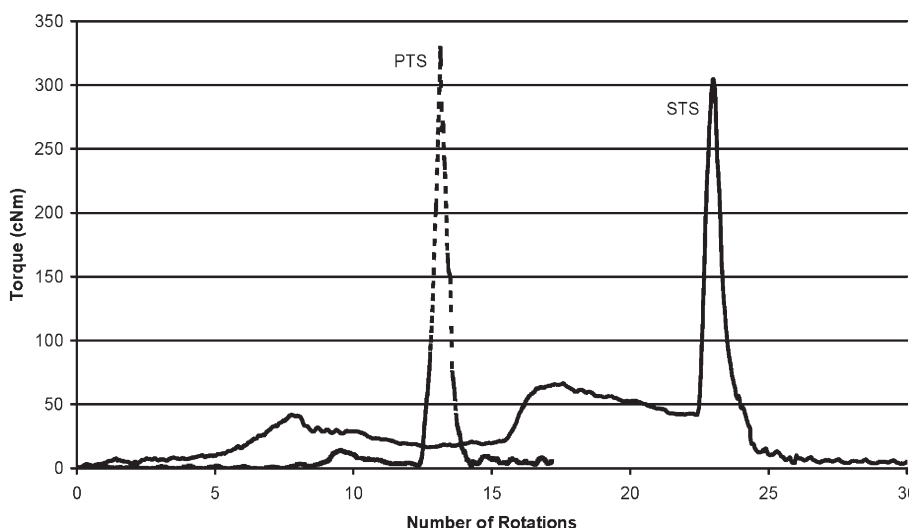


Fig. 7 TP for an STS and a PTS in a double cortical wall of bone

3.2 Sheep bone single wall

Figure 6 gives the TP for an STS and a PTS in a single cortical wall of sheep bone. The TP for a short STS inserted into a single wall of cortical bone demonstrated the same initial linear rise for the first four rotations, as seen in the foam. The torque, however, was seen to fall after the fourth rotation as the screw exited the cortical wall. Once again a rapid increase in torque was seen as the tightening phase began during the sixth rotation. This is also the case for the PTS although, as expected, the rise and fall during the insertional phase are far less pronounced. It should be noted that the insertional phase for the PTS required fewer rotations. This is because the screw was already entered for approximately three

rotations before starting the test in order to prevent cross-threading. It is also interesting to note that the TP for the STS in bone (see Fig. 6) is very irregular when compared with foam (see Fig. 4). This is thought to be due to the anisotropic structure of cortical bone tissue.

3.3 Sheep bone double wall

As with the single wall the TP for an STS in a double wall demonstrated the same rise and fall each time that the screw passes through a wall. With the double wall, the TP was seen to rise and fall twice prior to the beginning of the tightening phase (Fig. 7).

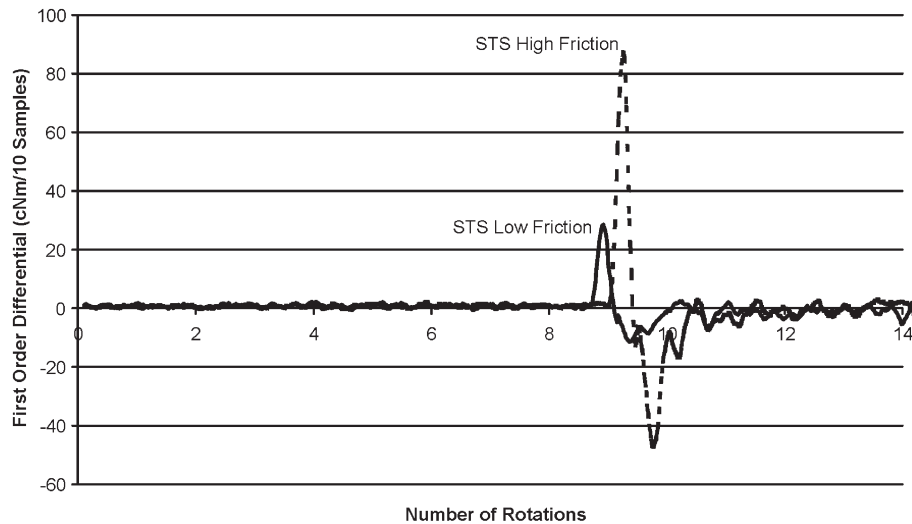


Fig. 8 First-order differential profile for an STS in foam with and without friction

No change in profile is apparent as the PTS leaves the first wall and only a small rise is seen as it passes through the second wall. The maximum torque (or ST) is far greater for both screws in a double wall than a single wall. The rate of increase in torque is also greater during the tightening phase.

3.4 Prevention of stripping during the insertional phase

It is vital to prevent over-tightening which may cause failure of the screw–bone interface due to stripping. In order to prevent over-tightening, it is necessary to detect the onset of tightening, i.e. the beginning of the tightening phase. The TP can be seen to rise rapidly at the beginning of the tightening phase and the rate of change in torque can be measured as the first-order differential (FOD). The FOD was calculated in this case by taking the average of the ten previous samples and dividing by the sampling time at every sample. This provided a smoother profile. The FOD of the TP for the STS in foam (see Fig. 4) is given in Fig. 8.

The beginning of the tightening phase can clearly be seen in both cases from the spikes present. As described earlier, the maximum value of FOD is greater with friction since the tightening phase is completed in the same number of rotations. The FOD for the PTS was very similar, except that the spikes were slightly more distinguished because of the greater difference between the values of ST and IT. It is clear from this that the onset of tightening can be seen from the spikes in the FOD. This demonstrates that it is possible to prevent over-tightening by setting a threshold for the FOD. This

threshold would need to be high enough to allow completion of the insertional phase but low enough to halt the tightening phase before stripping occurs.

It is clear that the TP is far less regular in bone with STSs than PTSs. Therefore setting a FOD threshold to prevent over-tightening is more difficult for STSs. From the FOD in Fig. 9 it can be seen that in this case the threshold would need to be greater than 8 and less than 55.

The FOD for the STS in a double wall of bone demonstrates a more pronounced spike at the point of tightening with a value approximately double that of the single wall, as shown in Fig. 10. The points at which the screw exits both walls can also be seen clearly as much smaller peaks. In this case a suitable FOD threshold would have a value between 9 and 116.

The mean, maximum, and minimum values of the FOD for STSs for all ten tests in a double wall of bone can be seen in Table 1 and Fig. 11 for the insertional and tightening phases (i.e. phases I and II).

A safety factor could be derived for using an FOD to prevent over-tightening. This could be defined as the maximum value in the tightening phase divided by the maximum value in the insertional phase. If this ratio is calculated for all the ten tests and the mean values are used, then this gives an approximate value of $80/8 = 10$.

It is also possible to prevent over-tightening by setting a torque threshold. The maximum torque values for the STSs in a double wall of bone can be seen for all ten tests in Table 2 and Fig. 12. As with Fig. 11 the mean, maximum, and minimum values have also been given. In this case an approximate safety factor of $200/50 = 4$ is calculated.

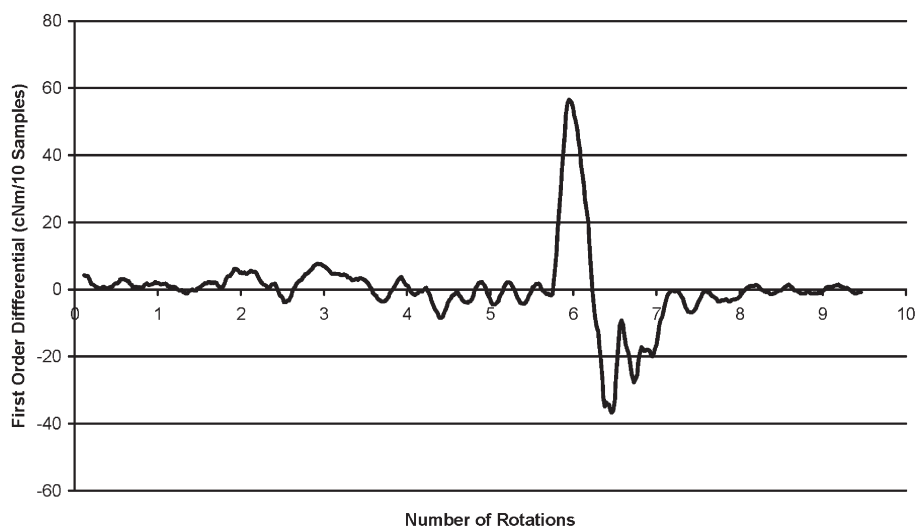


Fig. 9 First-order differential profile for an STS in a single cortical wall

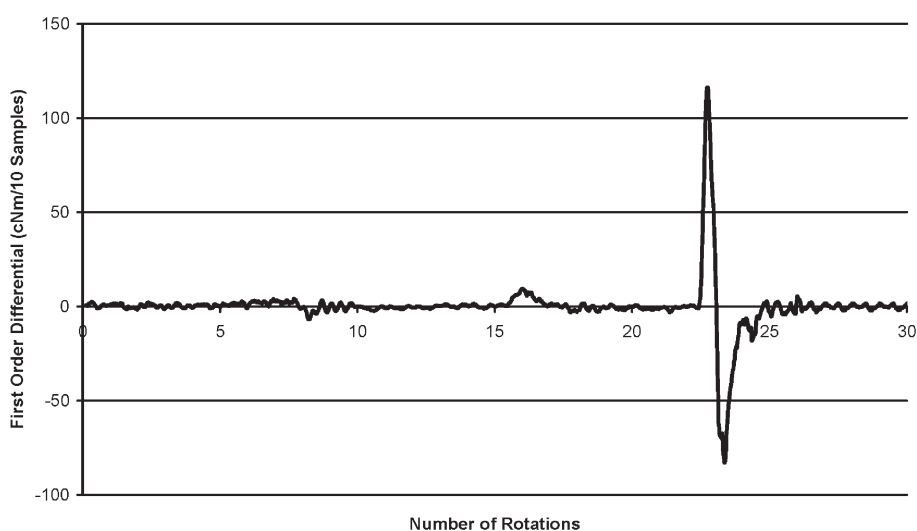


Fig. 10 First-order differential profile for an STS in a double cortical wall

Table 1 FOD levels, for phases I and II of screw insertion, for an STS in a double wall of bone

Test	FOD	
	Phase I	Phase II
1	9	116
2	9	96
3	7	62
4	8	106
5	8	70
6	8	75
7	6	67
8	8	73
9	9	63
10	9	95
Minimum	6	62
Mean	8	82
Maximum	9	116

This demonstrates clearly that setting a limit for the FOD is the safest method for preventing over-tightening, as the safety factor for FOD is over twice that of the torque safety factor.

3.5 Prevention of overrun during tapping

Figure 13 shows a typical drilling force and tapping torque profiles for a pilot hole in a double wall of bone. As expected, the TP for tapping was similar to the insertional phase for STS as both processes involve cutting a thread. A clear rise and fall in the TP can be seen when tapping through each cortical wall. This can best be seen by comparing tapping profiles with drilling profiles for the same hole, as

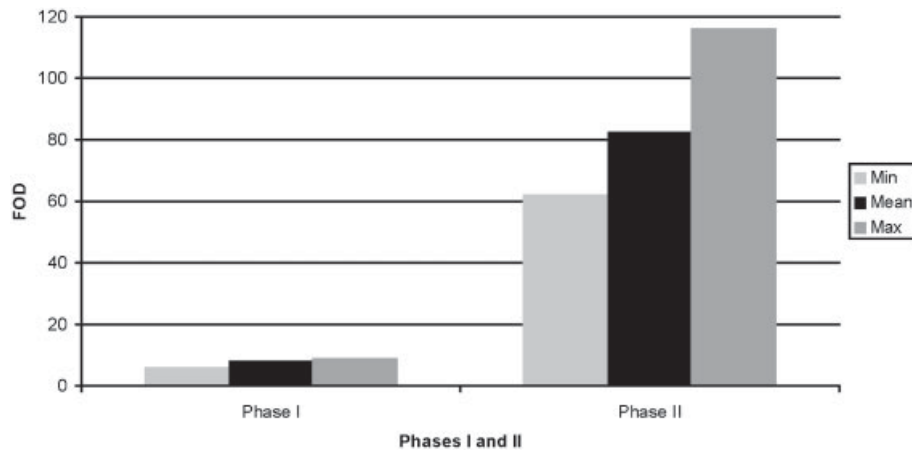


Fig. 11 Mean FOD levels, for phases I and II of screw insertion, for an STS in a double wall of bone

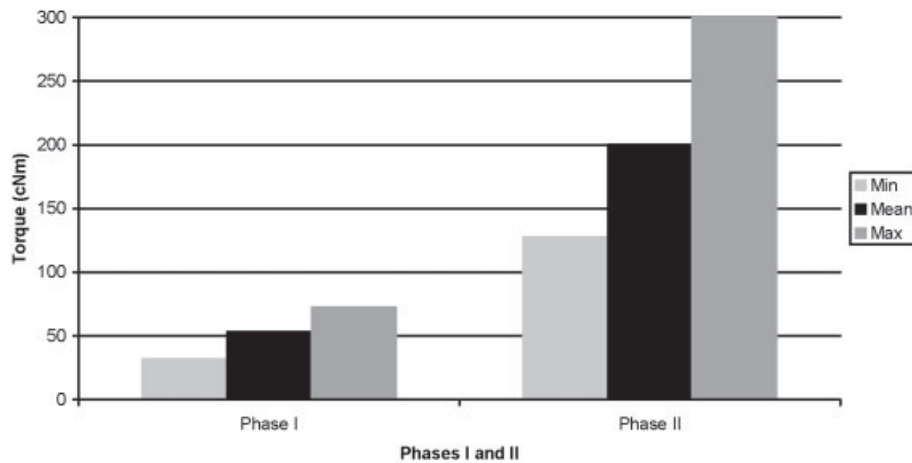


Fig. 12 Mean torque levels, for phases I and II of screw insertion, for an STS in a double wall of bone

demonstrated by Fig. 13. The pilot hole was drilled using a mechatronic drill that recorded a force profile. The depth of drilling has been converted to

Table 2 Torque levels, for phases I and II of screw insertion, for an STS in a double wall of bone

Test	Torque (cNm)	
	Phase I	Phase II
1	65	304
2	62	224
3	32	129
4	73	248
5	40	159
6	40	184
7	40	169
8	57	193
9	60	204
10	66	220
Minimum	32	129
Mean	54	204
Maximum	73	304

number of tap rotations in order to compare the tapping and drilling profiles.

The drilling force profile is seen to rise and fall rapidly as the drill passes through each wall. The TP for tapping also rises and falls in a similar fashion as it passes through each wall. If this characteristic were always repeatable, then a control algorithm may be implemented to detect the exit from a wall and prevent overrun. In some cases, however, a third rise and fall, as shown in Fig. 13, was seen in the TP prior to entering the second wall. The cause of this is uncertain, but it may be due to malalignment of the tap as it enters the second wall. A control algorithm would be unable to distinguish this from exiting the second wall and thus would halt the process prematurely. It is clear, however, that under these testing conditions the depth of tapping is directly proportional to the number of rotations. This means that, if the thickness of the bone is known, then

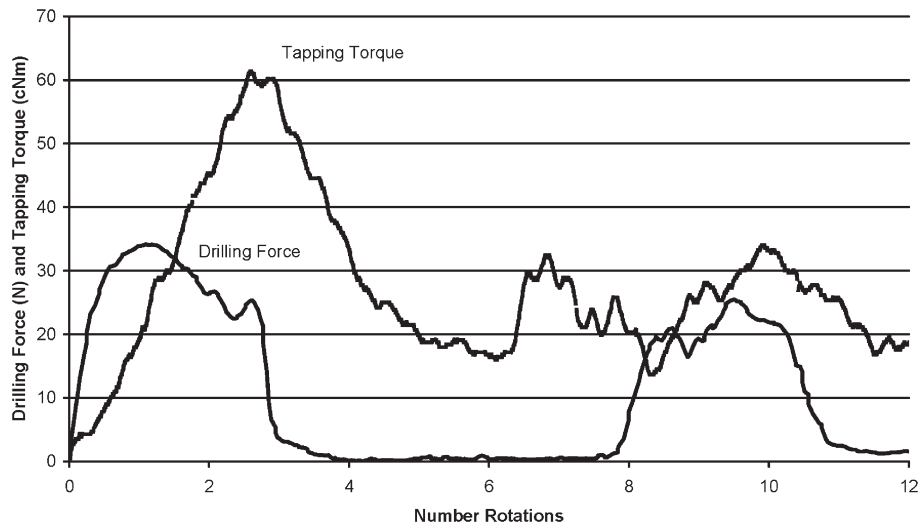


Fig. 13 Drilling and tapping profiles in a double wall of bone

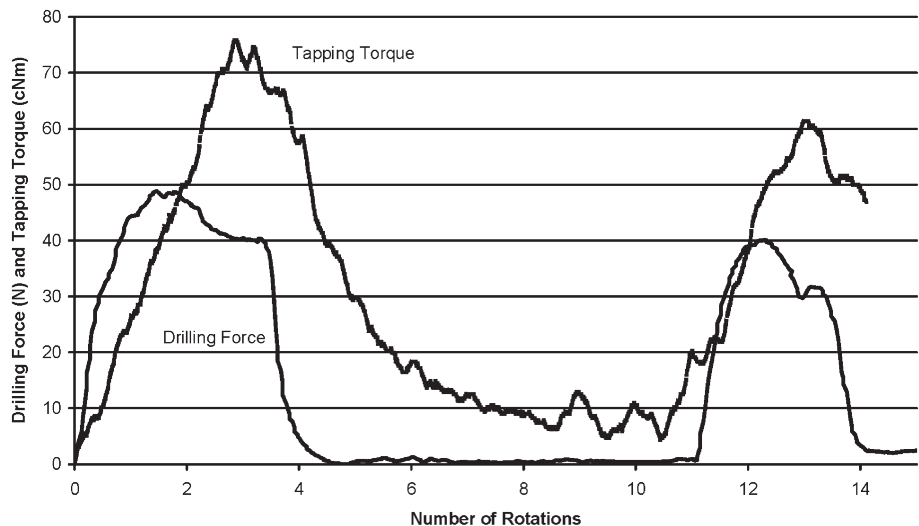


Fig. 14 Drilling and tapping profiles in a double wall of bone

limiting the number of rotations can prevent overrun of the tap.

3.6 Automated tapping and screw insertion

As indicated above, a simple control algorithm could prevent overrun and over-tightening during pre-tapping and screw insertion if the thickness of the bone is known. Such an algorithm was tested by attaching a plate to a bone. A plate requiring six screws was attached to separate bones using PTSs and STSs. The pilot holes were drilled using the mechatronic drill previously described, which provided information about bone thickness. This was used to limit the number of rotations during tapping and prevent overrun. Figure 14 shows (typical)

tapping and drilling profiles for one of the holes. As can be seen tapping was halted just as the tap exited the second wall. This proved successful for all six holes.

Over-tightening was prevented during screw insertion for both PTSs and STSs by setting a threshold for the FOD. A value of 20 was chosen as the threshold, which from previous data gives a safety factor of approximately 4. All screws were successfully inserted without premature shutdown or over-tightening. The TPs for all the six STSs can be seen in Fig. 15. The mean torque reached before shutdown for all six tests was 70 cNm, which is 35 per cent of ST. If the previous ten tests (used in section 3.4) had been halted automatically, using the same FOD threshold value of 20, then the average torque for all

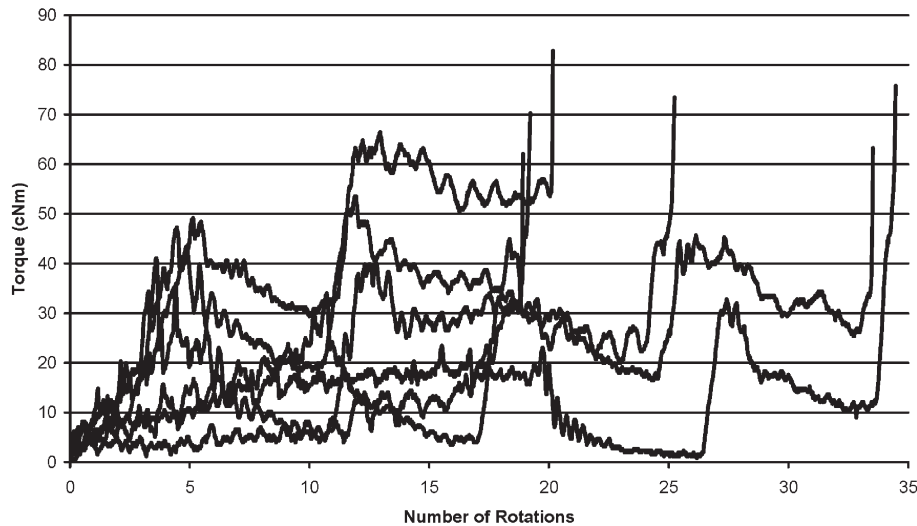


Fig. 15 TPs for six STSs inserted automatically into sheep bone

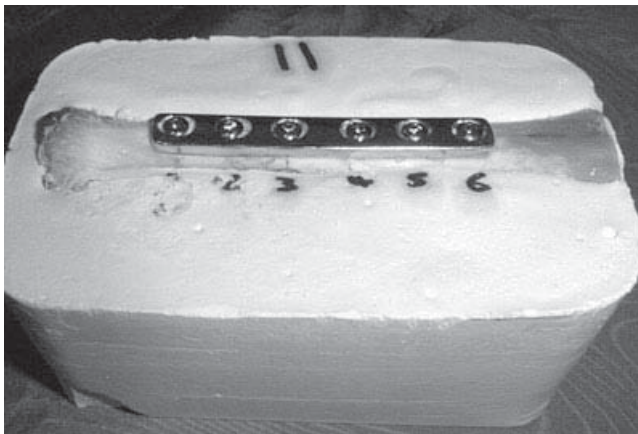


Fig. 16 Plate automatically attached to bone

ten tests would have been 68 cN m, i.e. 34 per cent of the mean ST of 200 cN m. This is much lower than the value of 65 per cent, recommended by other researchers, which demonstrates the safety of the system.

A photograph showing the plate attached to the bone can be seen in Fig. 16.

4 CONCLUSIONS

An automated screw placement system for use in surgery has been proposed for preventing over-tightening of PTSs and STSs. Currently, prevention of over-tightening is dependent upon when the surgeon detects the onset of tightening, both visually and from the feel of the rapid increase in torque. If detection is too late, then over-tightening or stripping can occur. This study is concerned with using a

mechatronic screwdriver to control the tapping depth and to prevent the over-tightening of screws, with the aim of improving surgical procedures. The effects of various parameters upon the torque profile during tapping and screw insertion have been investigated in synthetic bone and sheep tibia.

It has been shown that monitoring the number of rotations can be used to control the depth of tapping. If the width of the bone is known, then overrun can be prevented during tapping. The width of the bone can easily be determined following the drilling of the pilot holes, either manually or automatically using a mechatronic drill, which can easily provide the bone thickness while producing the pilot hole. It has also been shown that over-tightening can be prevented in two ways: first, by setting a torque limit to prevent stripping and, second, by setting a limit on the rate of change in the torque to detect the onset of tightening. However, the latter method, using the rate of change in the torque, is safer and more reliable for completing the insertional phase and detecting the start of the tightening phase. As can be seen from Figs 15 and 16, this system was demonstrated to work in real time for the insertion of six STSs in sheep bone. However, there would be additional challenges associated with the application of the proposed system within a clinical environment, e.g. the variability of friction in the screw–bone system due to the presence of various fluids. Therefore, additional experimental tests would be necessary to evaluate the system in a simulated clinical environment in the first instance, followed by clinical trials, to establish and evaluate fully the performance of the system.

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