

学位論文の要旨

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学位論文名 Effect of Bone Density on the Drill-Hole Diameter Made by a Cannulated Drill Bit in Cancellous Bone
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論文内容の要旨

INTRODUCTION

Bone drilling is an essential technique in orthopedic surgery for skeletal disorders. When osteosynthesis is desired, a pilot hole is made prior to a screw's insertion into the bone. Since bone is a fragile material, the use of a drill bit made of a hard material such as metal is likely to cause damage to the wall of the drill hole. Such hole-wall damage contributes to subsequent screw loosening. Investigations of this damage have focused on the use of solid drills, although a cannulated drill has been more commonly used for medical purposes, such as for drilling a pilot hole for a cannulated cancellous screw (CCS). CCSs are used for a variety of applications, but one of the main uses is screw-only osteosynthesis at the metaphysis and epiphysis. We have searched for but found no published study concerning the hole-wall damage that occurs with a cannulated drill. Although cannulated drills are controlled by guide pins, it is still possible to damage the hole wall, depending on the bone quality. For example, surgeons have often observed that in patients with osteoporosis, sufficient screw fixation strength cannot be obtained when bone fragments at metaphysis and epiphysis are fixed with a CCS, making treatment difficult. The aim of this study was to clarify the relationship in cancellous bone between bone density and drill-hole diameters made by cannulated drills. We hypothesized that the drill-hole diameters in cancellous bone would be enlarged in osteoporotic bone compared to healthy bone, even with the use of hollow drills.

MATERIALS AND METHODS

Drill Bits

Two types of surgical cannulated drill bits that have different tip shapes were prepared. The drill bits with a triple (Type "T") flute (Teijin Medical Technologies, Osaka, Japan) and the drill bits with a quadruple (Type "Q") flute (Meira Co., Aichi, Japan). Type T1 bits with 3.5 mm

and Type T2 bits with 4.4 mm diameters. Type Q1 bits with 3.5 mm and type Q2 bits with 4.2 mm diameters.

Simulated Bone

Polyurethane foam blocks (Sawbones, Vashon Island, WA, USA) with a density of 5, 10, 15, or 20 pounds per cubic foot (pcf) were used as simulated bone. Composite blocks minimize inter-specimen variability and meet the American Society for Testing and Materials (ASTM) standard #F1839-08.

Drilling Procedure

Drilling was performed manually in simulated bones with four densities: 5, 10, 15, and 20 pcf. Matching guide pins were manually inserted into small holes (40 holes/block and 160 holes in total) uniformly located in each of the bone blocks simulating one of the four bone densities. The drilling was then performed along the guide pin with the use of a rotary tool with a constant rotational speed of 1,900 rpm

Measurement of Drill-Hole Diameters

The diameter of each hole was measured using a coordinate-measuring machine (model UPMC850; Carl Zeiss Co., Oberkochen, Germany). Five measurement points were selected at 2, 5, 10, 15, and 20 mm from the simulated bone surface, and measurements were performed once for each hole.

Measurement of Screw Pull-out Strength

Screw pull-out strengths were measured for the drill holes made by the Type T1 and Q1 drill bits (n=10 drill holes for each bit). The same cannulated cancellous screw made from titanium alloy was used in all cases. The pull-out strength was measured by a mechanical loading machine (model 5565; Instron, Canton, MA, USA). The maximum load achieved without the screw coming loose was defined as the pull-out strength.

Statistical analysis

The data were analyzed with the JMP 16 program (SAS Institute, Cary, NC, USA). A simple regression analysis was applied to examine the relationships between the drill-hole diameters and the density of the simulated bone. Mann-Whitney's U-test was used to compare the drill-hole diameters and screw pull-out strength between the different-type (T1 vs. Q1) drill bits with same diameter in each density of simulated bone. Probability (p)-values <0.05 were considered significant in all statistical analyses.

RESULTS AND DISCUSSION

In all cases, the diameter of the drill hole was larger than that of the drill bit. The diameters of the holes drilled using the Type T drill bits expanded by 1.3%–12.3% relative to the bit diameter. The diameters of the holes drilled using the Type Q drill were expanded by 1.1%–4.7%, which

was less than for the Type T drill bits. These enlargement ratios tended to be greater in the low-density simulated bone (5 or 10 pcf) and showed large differences between the drill types. In contrast, in the high-density simulated bone (15 or 20 pcf), the enlargement ratios were quite low and showed little difference between the drill types.

For all four drill bits, the drill-hole diameter was negatively correlated with the density of the simulated bone. The regression coefficient indicated the ease of hole enlargement, with the T1 drill bit having the largest value at -0.028 , followed by the T2 drill bit at -0.016 , the Q1 drill bit at -0.009 , and the Q2 drill bit having the smallest value at -0.008 .

There were differences in the drill-hole diameters between the Type T1 and Type Q1 drill bits, even though they had same diameter. The drill-hole diameter made with the Type T1 drill bit was larger than that made with the Type Q1 bit, with the diameter difference being 0.267 mm at 5 pcf, 0.204 mm at 10 pcf, 0.027 mm at 15 pcf, and 0.006 mm at 20 pcf. There were significant differences between drill types, with the exception being the 20-pcf simulated bone. In the osteoporosis model, differences in the drill-hole diameters between the drill bits were clearly observed. In the healthy bone model, we observed the same tendency for drill-hole diameter differences, but the differences were smaller, and the only significant difference was observed for the 15-pcf bone.

The pull-out strength was lower in the Type T1 cases which had larger hole diameters compared to the Type Q1 cases, with the exception of the 20-pcf bone. The pull-out strength with Type Q1 was 2.31 times higher in 5 pcf, 1.21 times higher in 10 pcf, and 1.03 times higher in 15 pcf than that of Type T1. At 20 pcf, the pull-out strength for the drill holes made with the Type T1 bit was higher than that of the drill holes made with the Type Q1 bit.

CONCLUSION

At least in the case of cannulated drill bits of 3.5, 4.2 or 4.4 mm diameter, the drill-hole diameters for osteoporotic cancellous bone tend to be larger than those for healthy cancellous bone. Additionally, four-flute drills may achieve smaller hole diameter enlargement compared to three-flute drills. Our findings underscore that drill-hole diameter should be considered for the prevention of implant loosening in osteoporotic bone, and further developments in both implants and related tools such as drill bits are expected.

論文審査及び最終試験又は学力の確認の結果の要旨

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論文審査の結果の要旨

整形外科領域における骨折に対する骨接合術において、骨スクリューを挿入するための骨ドリリングは必須の手技であって、正確な手術のために予めガイドピンを骨折部に挿入し中空ドリルで骨スクリューのための骨孔を作製する。しかし、骨粗鬆症骨は骨梁構造の脆弱さゆえに健常骨の2~6倍の骨スクリューの弛みが生じるといわれているものの、日常臨床では健常骨の骨折と同じ中空ドリルを用いて骨ドリリングをしており、中空ドリルによる骨孔が健常骨に比して骨粗鬆症骨では拡大するか否かについては不明であった。そこで、申請者は標準化されたポリウレタン製模擬骨を用いて、2種類の中空ドリル(T type : 3 flute, ϕ 3.5 mm, 4.4 mm; Q type : 4 flute, ϕ 3.5 mm, 4.2 mm)、1900回転/分の回転速度で、深さ25 mmの骨孔160個を作製し、中空ドリル径と骨密度や引き抜き強度との関係を統計学的に解析した。結果、T typeでは健常骨では1.3~2.1%、骨粗鬆症骨で5.2~12.3%の骨孔拡大を示した一方、Q typeではそれぞれ1.1~2.1%および3.9~4.7%の骨孔拡大を示した。両群とも骨粗鬆症骨では骨孔は拡大し、 ϕ 3.5 mmの中空ドリル同士ではT typeの骨粗鬆症骨における骨孔拡大は有意に大きかった。また、骨孔径と骨密度は線形回帰し骨密度が低下するとともに骨孔径は拡大した。一方、引き抜き強度は骨粗鬆症骨ではQ typeが有意に高かった。以上より、骨孔径は骨粗鬆症骨では同じ中空ドリルを用いても拡大すること、また中空ドリル形状によって骨孔拡大率が異なることが明らかになった。本研究は、臨床における骨接合術の課題を明らかにするとともに、骨孔拡大率を低減させ、臨床成績の向上に資する新規中空ドリルの開発に寄与する研究であると考えられ、医学博士の学位授与に値すると判断した。

最終試験又は学力の確認の結果の要旨

整形外科臨床での骨接合における海綿骨へのスクリュー固定を行う際には、骨質に関わらず同一の骨ドリルが使用されていることに関するトランスレーショナルリサーチであり、独創性が高い。とくに超高齢社会の本邦では骨粗鬆症患者は多く、既存の手術手技を改善する重要な知見を示した。研究の発展性と、関連知識も豊富であり学位授与に値すると判断した。(主査 管野 貴浩)

骨折手術ではスクリュー固定に先立ってドリルで穿孔するが、その骨孔径が拡大するとスクリューのゆるみの原因となる。申請者は骨孔径と骨密度の間には負の相関があること、骨粗鬆症では健常な海綿骨と比較して骨孔が拡大すること、ドリル形状が4本溝のものが3本溝のものより骨孔拡大が小さいことを明らかにした。手術器具の改良に繋がる重要な知見であり、関連知識も豊富であるため学位にふさわしいと判断した。(副査 馬庭 壯吉)

スクリュー固定は骨接合に必須の医療技術である。本研究は未だ基礎的検討が不十分な骨粗鬆症症例におけるスクリュー固定時のガイド孔の影響を詳細に検討し、骨粗鬆症状態でもドリル形状により骨孔拡大が低減可能であることを示した。この成果はこの領域の臨床応用の発展に寄与する貴重な研究報告である。発表・質疑応答に際し豊富な学識を備えており、博士に資する者としての学位授与を推薦する。(副査 山本 昌弘)

(備考) 要旨は、それぞれ400字程度とする。