行政院國家科學委員會補助專題研究計畫成果報告

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※ **脊椎內固定器疲勞壽命之改善** ※
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計畫類別：■個別型計畫　　□整合型計畫
計畫編號：NSC 89－2213－E－002－136－
執行期間：八十八年八月一日至八十九年七月三十一日

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本成果報告包括以下應繳交之附件：
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執行單位：國立台灣大學醫學院骨科部

中　華　民　國　八十九 年　十　月　五　日

一、中文摘要

由於脊椎固定器所使用的

關鍵詞： 脊椎固定器、骨螺絲、疲勞壽命

Abstract

Keywords:

二、緣由與目的

Spinal fixation is currently a preferred surgical procedure for stabilization of the vertebral column in degenerative spinal disorders. Many innovative pedicle-fixation systems have been widely adopted for clinical applications in recent years.[29,30] Prior to clinical use, new devices need to be tested *in vitro*, either in isolation or in conjunction with artificial or cadaver-derived spinal specimens.[26] The results of these biomechanical tests provide the information about construct stiffness, fatigue resistance, and failure mechanisms for further improvement.[24]

Both titanium alloy (Ti-alloy) and 316L stainless-steel (316L-SS) spinal implants are quite commonly used for clinical applications. Ti-alloy is considered superior in terms of biocompatibility, enhanced corrosion resistance, and fewer resultant artifacts on CT scans and MRI images.[10,11,19,23] Acceptance of Ti-alloy spinal implants for clinical applications has been hampered, however, by the sensitivity of the material to surface condition (notch effect). Even with relatively superficial surface damage (eg. laser inscription), the fatigue strength of Ti-alloy is drastically reduced.[12] Hence, Scuderi et al.[28] have concluded that Ti-alloy is a poor choice for cervical-spine fixation systems due to increased notch sensitivity compared with 316L-SS. Further, Pienkowski et al.[26] have reported longer life for TSRH 316L-SS implants in a comparison with Ti-alloy. By contrast, Stambough et al.[32] have declared that prototypes manufactured from ISOLA Ti-alloy demonstrated improved resistance to fatigue compared to 316L-SS implants of identical size and design. To date, refinement of design and optimization of relevant factors to produce superior rigidity for Ti-alloy implants (over 316L-SS) still remains a challenge and has not been extensively studied.

The Formosa posterior spinal implant (FPI, Syntec Scientific Inc., Taiwan) was designed in this laboratory for the stabilization of the spine and correction of deformity. The FPI implant consists of three smooth rods of 6.0 mm in diameter, with polished surfaces, pairs of pedicle screws, and two connecting plates as cross linkages. The final assembly is depicted schematically in Fig. 1. The design of the connecting plates subjectively ensures the formation of a more rigid rectangular frame, thus increasing implant stiffness. Liu et al.[18] have reported that a 24% increase in pedicle-screw internal diameter resulted in an 104% increase in static strength. Therefore, two types of pedicle screw were incorporated in the design to investigate the effects of inner diameter of screw and notch sensitivity for Ti-alloy: a type A screw with uniform inner (3.7 mm) and outer (6.0 mm) diameters, and a tapering type B screw with inner and outer diameters equal at the screw hub (6.4 mm) in Fig. 2. These new implants were made from both 316L-SS and Ti-alloy (Carpenter Technology, Reading, PA), with identical dimensions.

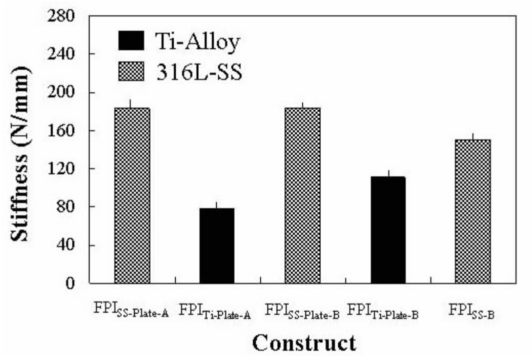
The purpose of this study was two-fold. Firstly, to test the mechanical performance of the FPI system by fixing prototypes to UHMWPE blocks as described in previous reports.[3,7,17] Secondly, to investigate the influence of materials, effect of screw design (at hub) and connecting-plates on construct stiffness and fatigue resistance.

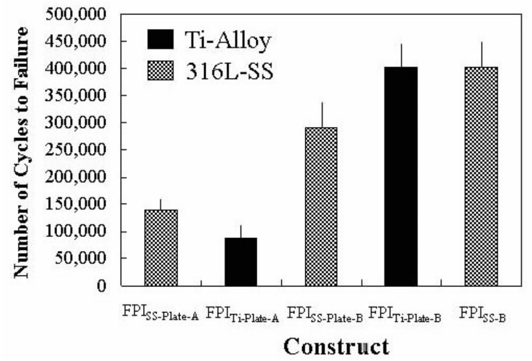
三、結果

Failure Mechanisms: All prototypes incorporating screw A ($FPI_{SS\text{-}Plate\text{-}A}$ and $FPI_{Ti\text{-}Plate\text{-}A}$) consistently failed at the cephalic screw hub (Table 1). By contrast, all $FPI_{SS\text{-}Plate\text{-}B}$, $FPI_{Ti\text{-}Plate\text{-}B}$, and $FPI_{SS\text{-}B}$ prototypes failed due to rod fracture/bending at the cephalic rod/plate junctions (Table 1). The cracks initiated at the tensile side of the cephalic-screw hub and longitudinal rod, propagating perpendicular to the direction of the greatest tensile stress. Typical fatigue striations were observed at the fracture surface and no sign of permanent rod and screw deformation was observed.

Multicycle Stiffness: The derived statistics for multicycle stiffness and fatigue life of the five FPI implant groups are detailed in Table 2. The mean multicycle stiffness for the FPI implants are revealed in Fig. 3. On average, the stiffness of the 316L-SS prototypes, $FPI_{SS\text{-}Plate\text{-}A}$ and $FPI_{SS\text{-}Plate\text{-}B}$, were respectively 77.5% ($p<0.001$) and 64.9% ($p<0.001$) greater than for the Ti-alloy prototypes, $FPI_{Ti\text{-}Plate\text{-}A}$ and $FPI_{Ti\text{-}Plate\text{-}B}$. The use of connecting plates for $FPI_{SS\text{-}Plate\text{-}B}$ variants raised the stiffness for $FPI_{SS\text{-}B}$ variants by about 22.2% ($p<0.001$). With the lower inner diameter, the $FPI_{SS\text{-}Plate\text{-}A}$ and $FPI_{Ti\text{-}Plate\text{-}A}$ systems demonstrated lower bending stiffness of 138.8 and 78.2 N/mm, respectively f- ference of 41.4% and 29.55% when compared to the $FPI_{SS\text{-}Plate\text{-}B}$ and $FPI_{Ti\text{-}Plate\text{-}B}$ systems, respectively.

Fatigue Life: The $FPI_{SS\text{-}Plate\text{-}B}$ and $FPI_{Ti\text{-}Plate\text{-}B}$ prototypes achieved means of 290,000 and 400,000 cycles fatigue life, respectively, however standard deviations were as high as 14.5% and 13.1% of the mean (Table 2 and Fig. 4). The $FPI_{SS\text{-}Plate\text{-}A}$ and $FPI_{Ti\text{-}Plate\text{-}A}$ prototypes achieved means of 140,000 and 87,000 cycles fatigue life, with comparatively high standard deviations of 18.7% and 28.3%, respectively. The fatigue life for $FPI_{Ti\text{-}Plate\text{-}B}$ was significantly greater ($p<0.05$) than that for $FPI_{SS\text{-}Plate\text{-}B}$, but the result for $FPI_{Ti\text{-}Plate\text{-}A}$ and $FPI_{SS\text{-}Plate\text{-}A}$ was reversed ($p<0.05$). On average, the increases in fatigue life for $FPI_{SS\text{-}Plate\text{-}B}$ and $FPI_{Ti\text{-}Plate\text{-}B}$ were 107.4% and 364.2% greater than $FPI_{SS\text{-}Plate\text{-}A}$ and $FPI_{Ti\text{-}Plate\text{-}A}$, respectively. The removal of the connecting plate in the $FPI_{SS\text{-}B}$ variants avoided the stress concentrated on the rod/plate junctions and increased the fatigue life by 38.2% compared to the $FPI_{SS\text{-}Plate\text{-}B}$ analogs ($p<0.001$).





四、討論

The purpose of the spinal implant is to provide better conditions for bony fusion. At the very least, the implant is expected to remain intact until fusion is achieved. Otherwise, if any part of the implant breaks or comes loose after surgery, the stability of the fusing segments will be lost and/or the deformity may recur, marking the failure of the surgical intervention. Although optimal implant design has yet to be established, evolution of the design of the individual components and selection of the most appropriate spinal-implant materials are mandated as part of that process of refinement, and should be investigated thoroughly. In this study, we adopted a new design to compare the mechanical performance of two metals, two screw shapes and the effect of connecting plates.

Failure Mechanisms: As for previous reports,[14,25,31-33] failure mechanisms for our spinal-implant prototypes were bending/fracture of pedicle screw and longitudinal rod, with failures consistently occurring at the cephalic, rather than caudal end. This may be because the plastic block on the cephalic side had a greater range of actuation than the block on the caudal side. The type A screw reveals a fairly uniform thread depth throughout the threaded portion, with a relatively small inner diameter close to the hub compared with the type B screw. Consequently, $FPI_{SS\text{-}Plate\text{-}A}$ and $FPI_{Ti\text{-}Plate\text{-}A}$ screws typically broke/fractured at the hub, indicating that the load was concentrated on the weaker part of the screw. For $FPI_{SS\text{-}Plate\text{-}B}$ and $FPI_{Ti\text{-}Plate\text{-}B}$ variants, the hub site was much stronger due to the greater inner diameter. The cephalic fracture/bending of $FPI_{SS\text{-}Plate\text{-}B}$ and $FPI_{Ti\text{-}Plate\text{-}B}$ variants was as a result of the use of connection plates, with fracture sites shifting from the screw hubs to rod/plate junctions in response to the concentration of induced stress in this area.[32,33]

Multicycle Stiffness: Implant stiffness was measured to verify the ability of the implant to stabilize the spinal segments and enhance spinal fusion *in vivo*[16,20]. Clinically, the implant stiffness varies with the number of load cycles as a result of intraspecimen slippage and microcracks in the implant material. In this study, the multicycle stiffness at the steady-state phase was selected for its clinical values and it might not need implants for single load-to-failure test.

The construct stiffness of the stressed structure was influenced by two factors – structure design and material properties. For the type B screw, inner and outer screw diameters at the hub are equal resulting in 1.4- and 1.3-times greater multicycle stiffness compared to implants using type A screws, for both titanium alloy and stainless steel, respectively. As for previously published data,[25,32] the bending stiffness of 316L-SS systems was definitely greater ($p<0.001$) than for the dimensionally identical Ti-alloy counterparts (Fig. 3). This is attributable to the fact that the elastic modulus for 316L-SS is 1.84 times greater than for Ti-alloy.[13] Johnston et al.[16] have suggested that increased implant stiffness enhances the incorporation of fusion mass of the short segments. Thus 316L-SS implants may be biomechanically superior to the Ti-alloy analogs for short-term immobilization during the post-operative period, However, some studies have revealed that the reduction in stiffness may be preferable in order to redistribute some of the stress to the instrumented segments and the stress-shielding effect may be minimized and implant life prolonged, eventually promoting spinal fusion.[5,20,34] In an evaluation of long-bone fracture, Uhthoff et al.[35] conducted a study using the femoras from 36 beagle dogs, recommending titanium alloy as a promising material for bone plate with superior bone-remodeling characteristics (at the osteotomy level) compared with 316L-SS. Given this complex interaction, the increased stiffness of the 316L-SS implant may have no clinical advantage in practice.

The effects of cross-linkage on stiffness performance for posterior spinal implants has been measured by various researchers.[8,9,33] These studies have revealed that cross-linkage did not significantly increase the stiffness of posterior implants for compression/flexion motion. In the present study, the increase in stiffness of $FPI_{SS\text{-}Plate\text{-}B}$ implants was 22.2% compared to the $FPI_{SS\text{-}B}$ variant ($p<0.001$). This discrepancy and the favorable results produced by adding cross-links may be attributable to the more rigid frame formed by the FPI connecting plates.

Fatigue Life: The fatigue life of the stressed structure was also determined by structure and material. McKinley et al.[22] and Yerby et al.[36] have determined that the greatest bending moment occurs at the screw hub. Hence, by minimizing the notch effect and enlarging the inner diameter, prototypes incorporating screw B demonstrated an fatigue life from 2.1 (316 L-SS) to 4.6 (Ti alloy) times higher than screw-A implants (Fig. 4). The endurance limit of Ti-alloy is about 1.68 times that of 316L-SS.[13] Therefore, the superiority of Ti-alloy for the $FPI_{Ti\text{-}Plate\text{-}B}$ variant in terms of fatigue limits emerged when the notch effect at the screw hub was minimized, producing a 38.5% increase in fatigue life compared to the 316L-SS counterparts. For Ti-alloy variants incorporating lower-diameter type A screws, however, fatigue life was reduced by 38.1 % in comparison with 316L-SS variants (Fig. 4), demonstrating that notch effect is much more critical for the Ti-alloy.

Also, the connecting plates used for the $FPI_{SS\text{-}Plate\text{-}B}$ prototypes shifted the stress concentration from the screw hub to the rod/plate junctions, reducing the fatigue life by 27.6% compared to FPI_{SS-B}, which was without supplemental cross-links (p<0.001).

Interestingly, the increase in inner hub diameter from screw A to screw B resulted in significantly greater increases for fatigue life than for stiffness. For stainless steel, prototypes incorporating screw B were 31.8% stiffer than screw-A equivalents, while for titanium alloy the screw-B variant was 41.9% more rigid. However, the same increase in fatigue life for the previous type of stainless steel was 107.4%, while for the titanium alloy, screw-B implants demonstrated 364.2% longer fatigue life than screw-A analogs. This demonstrates that the structural change had a more pronounced influence on fatigue life than on stiffness, especially in the case of titanium alloy and should be considered during the design process for new implants.

In addition to structure design and material properties, the biomechanical performance of the spinal construct was additionally influenced by loading and boundary conditions. Normal physiological loading on the L3-L4 disc may involve compressive forces of about 200% body weight (≈1700 N for a 70-kg man)[21]. Also, Rohlmann et al.[27] and Stambough et al.[32] have demonstrated that the loading rate and small changes in relative position of the implants have the marked influences on fatigue cracking site and the distribution of the loads across the implants. In the worst-case scenario, without adequate load sharing through anterior bone- or device-related support, the testing load (60 N ~ 600 N) in this study was below the aforementioned physiological loads and only the frequency (5 Hz) was within the critical range. Hence, results for fracture site and fatigue life may not be directly applicable to other testing conditions. Also, this study was not able to establish the optimal trade-off between pull-out strength and pedicle-screw fatigue strength because no variations for screw-thread shape were systematically tested.

Johnston et al.[15] have used bovine implants to investigate the contour effect for fatigue life of 316L-SS Luque rods. Correlating the measured strain at the rod apex with the degree of deformity, it was determined that relatively low axial loads produced enough tensile stress to induce implant fatigue. With the surface damage that inevitably results from surgical contouring by bent bars, the vulnerability of the contoured Ti-alloy rod implants to fatigue failure may be greater than for the 316L-SS analogs. Very little is known, however, about the effect of rod contouring on fatigue resistance of Ti-alloy implant. Hence, we suggest that future studies, involving the corpectomy model and utilizing contoured Ti-alloy rod, are conducted to explore the effects of surgical contouring on component strength.

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