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Thermoelastic stress analysis to validate tibial fixation technique in total ankle prostheses - a pilot study

Total diz protezlerinde tibial fiksasyon tekniğinin validasyonunda termoelastik gerilme analizi: Bir pilot çalışma

Andreas FİCKLSCHERER,[1] Bernd WEGENER,[1] Thomas NİETHAMMER,[1] Matthias F. PİETSCHMANN,[1] Peter E. MÜLLER,[1] Volkmar JANSSON,[1] Hans-Heinrich TROUİLLİER[2]

BACKGROUND

Recent literature has shown a persistently high rate of aseptic loosening of the tibial component in total ankle prostheses.

METHODS

We analyzed the interface between the tibial bone and tibial component with a thermoelastic stress analysis to demonstrate load transmission onto the distal tibia. In this regard, we used two established ankle prostheses, which were implanted in two human cadaveric and in two third-generation composite tibia bones (Sawbones®, Sweden). Subsequently, the bones were attached to a hydropulser and a sinusoidal load of 700 N was applied.

RESULTS

Both prostheses had an inhomogeneous load transmission onto the distal tibia. Instead of distributing load equally to the subarticular bone, forces were focused around the bolting stem, accumulating as stress maxima with forces up to 90 MPa. Furthermore, we were able to demonstrate load transmission into the metaphysis of the bone.

CONCLUSION

As demonstrated in this study, anchoring systems with stems used in all established total ankle prostheses lead to an inhomogeneous load transmission onto the distal tibia, and furthermore, to a distribution of load into the weaker metaphyseal bone. For these reasons, we favor a prosthetic design with minimal bone resection and without any stem or stem-like anchoring system, which facilitates a homogeneous load transmission onto the distal tibia. Thermoelastic stress analysis proved to be a fast and easy-to-perform method to visualize load transmission.

Key Words: Aseptic loosening; thermoelastic stress analysis; total ankle replacement.

AMAÇ

Güncel literatür total diz protezlerinde tibial komponentin aseptik gevşemesinin yüksek oranda oluştuğunu göstermektedir.

GEREÇ VE YÖNTEM

Distal tibiaya yük aktarımını göstermek amacıyla tibial kemikle, tibial komponentin arayüzünü bir termoelastik gerilme analiziyle inceledik. Bu amaçla, iki insan kadavrasına ve iki üçüncü kuşak kompozit tibia kemiklerine implante edilmiş iki diz protezini kullandık (Sawbones®, İsveç). Daha sonra kemikler bir hidropulsere monte edilip 700 N gücünde bir sinüzoidal yük uygulandı.

BULGULAR

Her iki protez de distal tibiaya homojen olmayan bir yük aktarımı gerçekleştirdi. Yükü eşit olarak subartiküler kemiğe dağıtmak yerine kuvvetler protezin stemine odaklanmış, 90 MPa'ya varan bir kümülatif maksimal gerilme kuvveti oluşmuştur. Ayrıca, kemik metafizi içine yük aktarımını göstermeyi başardık.

SONUÇ

Bu çalışmada gösterildiği gibi tüm total diz protezlerinde kullanılan stemlerle yapılan ankrajlar distal tibiaya homojen olmayan bir yük aktarımı ve yükün daha zayıf olan kemik metafizine dağılmasına yol açmaktadır. Bu nedenlerle minimal kemik rezeksiyonuyla birlikte tespit çubuğu veya benzeri malzemenin kullanılmadığı bir ankraj sistemini ve bu nedenle distal tibiaya homojen yük aktarımını tercih etmekteyiz.

Anahtar Sözcükler: Aseptik gevşeme; termoelastik gerilme analizi; total diz replasmanı.

[1]Department of Orthopaedic Surgery, University Hospital of Munich (LMU), Munich; [2]Franziskus Hospital, Bielefeld, Germany.

[1]Münih Üniversite Hastanesi, Ortopedi Cerrahisi Kliniği, Münih; [2]Franziskus Hastanesi, Bielefeld, Almanya.

Correspondence *(İletişim):* Andreas Ficklscherer, M.D. Department of Orthopaedic Surgery, University Hospital of Munich (LMU)-Campus Grosshadern, Marchioninistr 15, 81377 Munich, Germany. e-mail *(e-posta):* andreas.ficklscherer@med.uni-muenchen.de

Tibiotalar arthrodesis is the preferred method of treatment of posttraumatic, degenerative or inflammatory disease of the ankle when conservative treatment options have failed.[1,2] Prosthetic replacements of the ankle joint have so far eventually failed or have yielded unsatisfactory results.[3-5] This likely explains why arthroplasty at the upper ankle joint remains a questionable procedure, despite the fact that the first total ankle replacements (TARs) were performed in 1970, while the number of total hip and knee arthroplasties performed steadily increases.[6-8]

With implant loosening rates around 60-90% within the first 10 years, the number of failed systems was considerably higher than in knee or hip replacement.[9-11] Even if numbers dropped to 16-42% by changing the implantation technique from cemented to non-cemented, aseptic loosening is still the biggest challenge.[12-14] Newer implant designs therefore put more attention on rebuilding the natural anatomy.[15] Kinematic aspects have also been considered as well as ligament stability and mechanical alignment within the joint. The implant-to-bone interface has been unburdened by introducing two- and three-component implants, now allowing sliding and rotary motion. Anatomical studies, published in the 1980s and 1990s, demonstrated that only the subarticular bone has the strength needed to support the tibial component.[16-19] Still, most ankle prostheses feature anchoring systems, e.g. stems, to enhance stability. These components extend into the weaker metaphyseal bone with reduced trabecular architecture.[20]

Because it is the tibial component that is more often loosened aseptically,[12,21] the purpose of the present study was to investigate load transmission at the implant-to-bone interface. We chose a thermoelastic stress analysis model instead of using finite element methods, a computational model by approximation. Based on the so-called Kelvin effect, thermoelastic stress analysis is a well-established test procedure in industrial material testing, but relatively new in medicine.[22] The hypothesis was that the high failure rate of aseptic loosening is due to inappropriate load transmission onto the distal tibia, and that this can be displayed optically.

MATERIALS AND METHODS

We chose two established third-generation three-component ankle prostheses, which have been followed up by several authors and have an acceptable outcome compared to other ankle prostheses (STAR®, Waldemar Link, Germany and Salto®, Tornier, France).[12,21,23,24] Two human tibial bones (male, age 34) were obtained from the Institute of Legal Medicine of the Ludwig-Maximilian University of Munich within 24 hours after donor death. Soft tissue was removed preserving cortical bone. In addition, two third-generation composite tibia bones (Sawbones®, Sweden) were used. The prostheses were implanted by a skilled surgeon (HHT) in one session according to the manufacturer. X-ray scans were performed to assure proper implantation. Bones were then stored at -20°C until analysis and thawed to room temperature before testing.[25,26] For testing, bones were affixed in an aluminum drum with polymethylmethacrylate and mounted on the testing bench. To serve as a regular bearing, the talar components were affixed to the hydropulser plunger in a neutral position.

Based on the so-called Kelvin effect, thermoelastic stress analysis is a well- established test procedure in industrial material testing, but relatively new to human bone.[22] Load-dependent distension of a body causes changes in temperature. Metal, for example, grows warm under pressure load and cools down under tensile load. Performing a rapid change between pressure and tensile load, one can assume an adiabatic system (a system in which heat is neither applied nor discharged). Local change of temperature is then proportional to local change of tension and can be detected by the infrared camera system. In this study, we used a JADE MWIR infrared camera (CEDIP Infrared Systems, Germany) with an array resolution of 320 x 256 and a pixel pitch of 30 μm. The system measures infrared radiation with a wavelength of 3-5 μm, which is emitted by the specimen under cyclic loading. Generally, the infrared camera works just as a normal camera, but instead of a CCD-Chip or a negative film, the infrared camera features a resistance detector. This device transfers infrared radiation into heat and changes its resistance proportional to the heat applied. According to that change in resistance, the camera then displays load transmission in megapascal (MPa; 1 MPa = 1 N/mm^2).

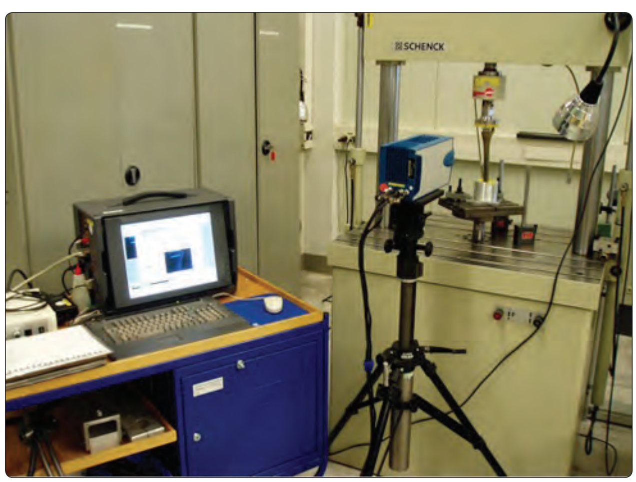

Fig. 1. The testing setup.

(Color figure can be viewed in the online issue, which is available at www.tjtes.org).

To match the sinusoidal signal captured by the camera with a reference signal transmitted by the hydropulser, a correlator was used. In doing so, the measured signal was assigned by frequency, size and phase eliminating errors such as optical reflection or infrared radiation from another source.

To simulate ligament tension and to avoid luxation of the polyethylene sliding core in the status of complete unloading, a preload of 100 N was applied. After finishing all preparations, a sinusoidal oscillation frequency of 10 Hz was installed.[22] The peak load was limited to 700 N.

The camera was focused on the implant-to-bone interface. Scans were taken from ventral, lateral and dorsal views. According to the experimental setup, the images are upside down, and were flipped for better viewing. The testing setup can be seen in Fig. 1.

RESULTS

Figure 2a shows the STAR ankle prosthesis implanted in a human tibia from ventral view. The talar implant as well as the polyethylene gliding core can be seen at the bottom. The rugged and turbulent appearance of the surface can be attributed to the preparation (periosteum). Pressure load is shown as negative values. As can be seen, load transmission covers the whole distal tibia with irregular appearance and values from -20 N/mm^2 to - 100 N/mm^2 (=MPa; megapascal). Load transmission extends more into the metaphysis on the lateral side than medially.

Figures 2b and 2c (seen from ventral and medial views) show the same type of prosthesis implanted into a third-generation composite tibia. Because of the smooth bone surface load, there is a much better display of distribution. Still distribution patterns are similar. The load transmission is inhomogeneous with an accentuation around the medial stem. Values range from -27 N/mm^2 to -90 N/mm^2. In the medial view, load transmission is more ribbon-like. Values range between -27 N/mm^2 and -46 N/mm^2.

Figure 2d shows the Salto ankle prosthesis implanted in a human tibia from ventral view. Again,

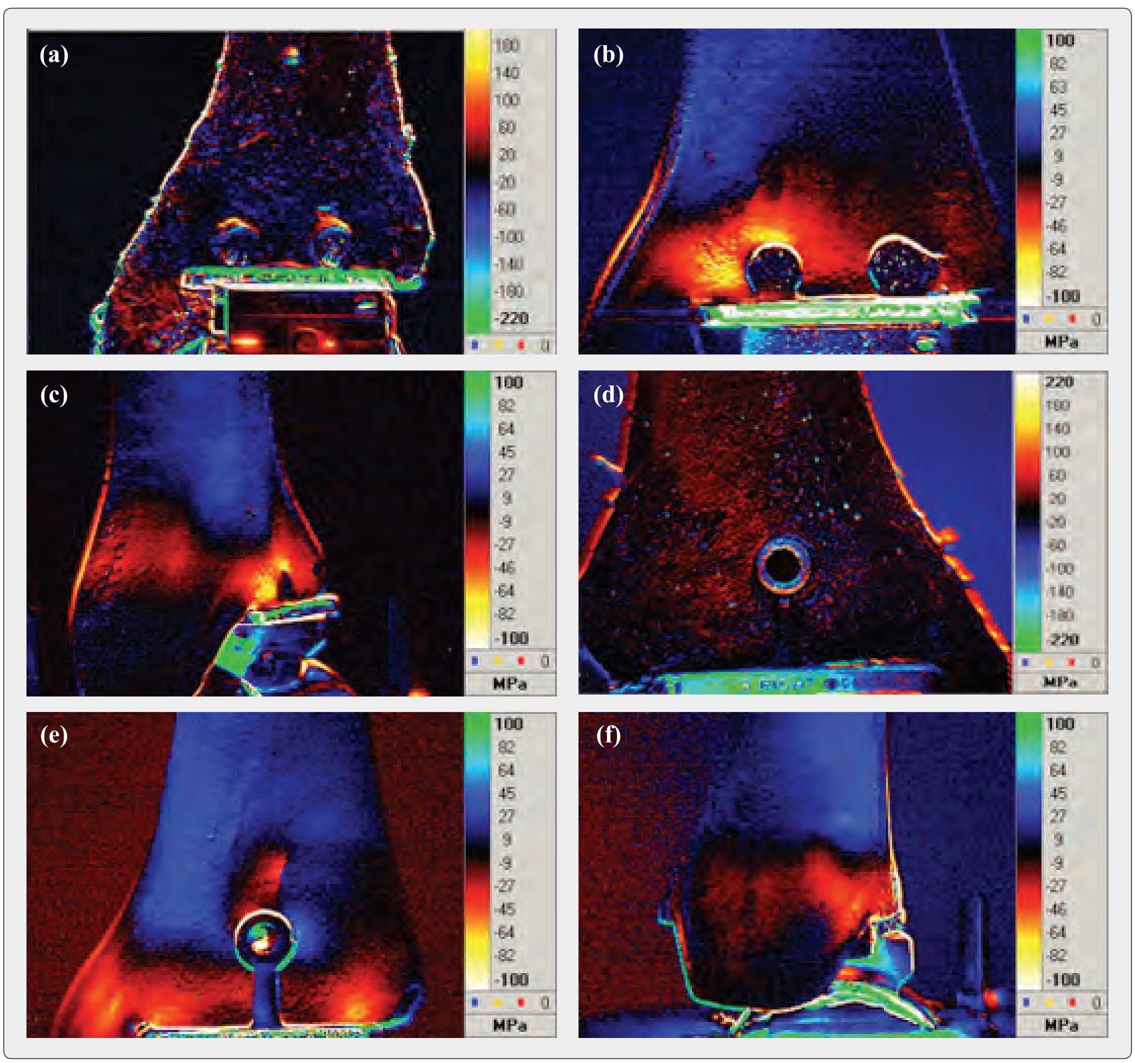

Fig. 2. See text for detailed information. *(Color figures can be viewed in the online issue, which is available at www.tjtes.org).*

because of the remaining periosteum, the surface appears disturbed. Load transmission is distributed homogeneously along the base-plate with pressure loads ranging from -60 N/mm^2 to -20 N/mm^2. Around the anchoring stem, pressure load ranges from -60 N/mm^2 to -100 N/mm^2.

Figures 2e and 2f represent the Salto prosthesis implanted into composite tibias from ventral and medial views. On the ventral side, a more homogenous band of load distribution is seen, with values between -25 N/mm^2 and -45 N/mm^2, putting slightly more stress on the malleolus medialis.

DISCUSSION

Despite the multitude of designs and the many changes that have been made in the approach of TAR, aseptic loosening of the tibial component remains a drawback to match the successes with arthrodesis or hip and knee arthroplasty.[9-11] Even though anatomic and kinematic aspects have been implemented in newer prosthetic designs, all prostheses[15] come with an anchoring system reaching from the joint space into the metaphysis (in our study 8 mm with STAR and 15 mm with Salto). Although the prosthetic design has been an issue for many years, this method of anchoring has been hardly questioned. Our hypothesis was that the relatively high failure rate of aseptic loosening in current total ankle prostheses is due to an inappropriate load transmission onto the distal tibia and that this can be displayed optically. We therefore investigated the tibial anchoring system in two established total ankle prostheses and introduced thermoelastic stress analysis as a method to visualize stress load at the implant-to-bone interface.

As published in several anatomical studies describing the distal tibia, bone density and bone stability diminish within the very first 10 mm due to architectural reasons concerning the cancellous bone.[16-20,27,28] Therefore, bone resection should be minimized to the extent possible and structural conditions should be considered.[20,27] In contrast to the above, the subchondral bone plate is routinely removed or at least depleted during surgery when performing TAR.

In this study, we found that due to the anchoring system, stress load is transferred into weaker, metaphyseal bone, and accumulates there to stress maxima. These stress maxima, with values up to 100 MPa, stand in total contrast to what Kimizuka et al.[29] described as a normal load-bearing pattern. He measured a maximum peak pressure at 13 MPa with 1500 N load in eight human ankle joints (average 9.9 MPa at 1500 N). Moreover, we compared the load transmission we visualized with thermoelastic stress analysis with X-ray scans published in literature. Our hypothesis was confirmed by Bonnin et al.[21] and Anderson et al.,[12] who described an accumulation of radiolucency-lines and aseptic loosening, respectively, where we found stress maxima.

As demonstrated in this study with two established TAR prostheses, load transmission accumulates with high maxima around the anchoring systems (stems), and because of the stem length, these maxima are directed into the weaker metaphyseal bone. This effect was more prominent in the Salto than in the STAR prosthesis.

For these reasons, we favor a prosthetic design with minimal bone resection and without any stem or stem-like anchoring system, which facilitates a homogeneous load transmission onto the distal tibia.

In contrast to finite element analysis, thermoelastic stress analysis is fast, easy-to-perform and well-established in industrial material testing. With this relatively new method, we were able to demonstrate visually stress load in human bones. In our opinion, this non-invasive method can be helpful in optimizing the design of next-generation total ankle prostheses.

The limitations of our study include the relatively small number of specimens and the evaluation of only two prosthetic models. Furthermore, thermoelastic stress analysis is limited to the bone surface and therefore only displays changes in heat on the very surface.

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