A new test method to determine the biomechanical strength of the T2® Ankle Arthrodesis Nail

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Abstract

Based on a series of ground reaction force measurements, the bio-mechanical loads acting on the ankle region after arthrodesis were calculated. These loads were simulated in a new test configuration dedicated to testing the biomechanical strength of the new T2® Ankle Arthrodesis Nail (T2® AAN). The fatigue strength of the T2® AAN construct (nail plus locking screws) was found to be higher when compared directly to the Biomet® Ankle Arthrodesis construct.

1. Introduction and Purpose

Recently Stryker® added a new Ankle Arthrodesis Nail to the T2® family of IM Nails. During the development phase, a new mechanical test configuration based on in-vivo biomechanical loading was designed. This allowed the direct biomechanical comparison of the T2® AAN (Fig. 1a) to other commercially available ankle arthrodesis nail products (Biomet® Fig. 1b).

Fig. 1a T2® AAN

Fig. 1b Biomet® Ankle Nail

2. Measurement of ground reaction forces

2.1 Materials and methods

Ground reaction forces during a patients gait were measured by force measurement plates installed on the ground [1] (Fig. 2). The plates were equipped to measure forces in all 3 directions (i.e. Fx, Fy, and Fz).

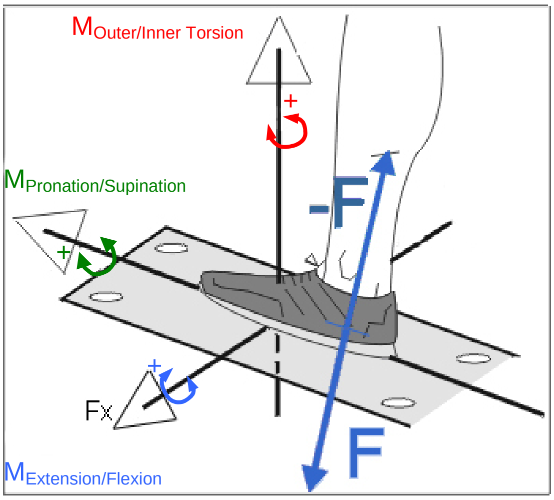

Fig. 2: Force measurement plate, left leg.

The measured forces in all three directions were recorded vs. gait cycle time (Fig 3).

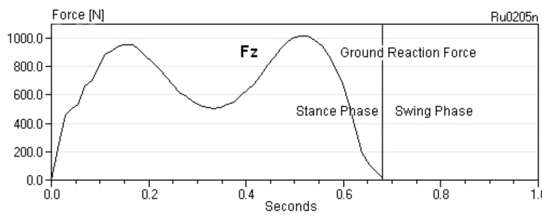

Fig. 3: Force diagram generated from ground reaction force measurement: Vertical force Fz is shown exemplarily [1].

In addition, pressure diagrams (Fig. 4) were generated for the whole gait cycle. With a known foot geometry, calculation of the resultant moments acting on the ankle joint throughout the patients gait was enabled.

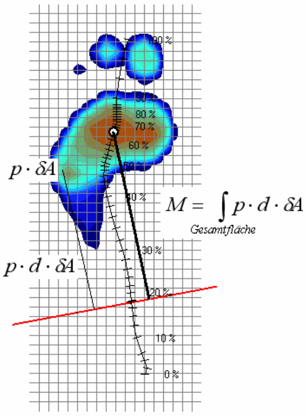

Fig. 4: Pressure diagram allows calculation of moments acting on ankle joint [1].

2.2 Results

Ground reaction forces

The loading situation in the ankle during patient gait is very complex and will only be described in a simplified manner.

Dynamic loading

The patient gait generates a dynamic loading pattern, resulting in forces and moments that are cyclicly changing with time. The load peaks on the foot occur during push-off within this dynamic load regime (Fig. 5).

Fig. 5: Patient gait. Push-off phase effecting maximum loads.

Forces

Vertical forces Fz acting on the foot during a patients gait are dominant and may be found as high as 1000N (125% of patient body weight, body weight 80kg). This is effected by patient weight and by gait acceleration forces. Forces in the other directions (i.e. Fx and Fy in Fig. 1) are negligible (Fig. 6).

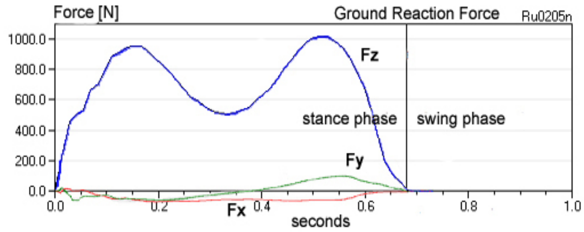

Fig. 6: Forces measured during patient gait, left leg [1].

Moments

Vertical forces are not that critical for ankle arthrodesis nail fatigue strength. However, the moments generated by these forces are the most critical loads since they effect bending stresses in the nail and the locking screws.

Extension moments

The resultant moments acting at the peak of ankle dorsiflexion are approximate 140Nm for an 80kg patient (Fig. 7).

Pronation moments

Pronation moments are 3 to 5 times lower [1, 2] than dorsal extension moments and approximate 30 to 50Nm (Fig. 7).

Torsional moments

Torsional moments are lower by more than an order of magnitude when compared to the dorsiflexion moments. They typically reach up to 5Nm.

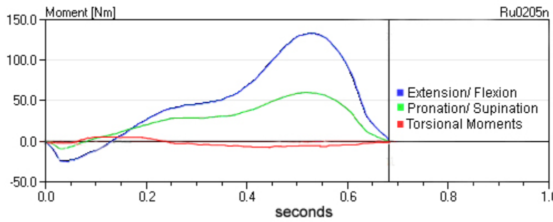

Fig. 7: Extension / flexion moments, pronation / supination moments and torsional moments calculated during patient gait.

In summary, the loads seen across the ankle during a patients gait are dynamic with the dorsiflexion and the pronation moments occurring in a ratio of approximately 5:1. Torsional moments can be neglected. However, it has to be considered that these calculations neglected the complex influence of muscles and tendons which may influence the results.

3. Ankle nail construct tests

3.1 Materials and methods

Test set up

Using the results from the ground reaction force measurements, a dynamic test was designed using the configuration as shown in Figures 8 and 9 [3].

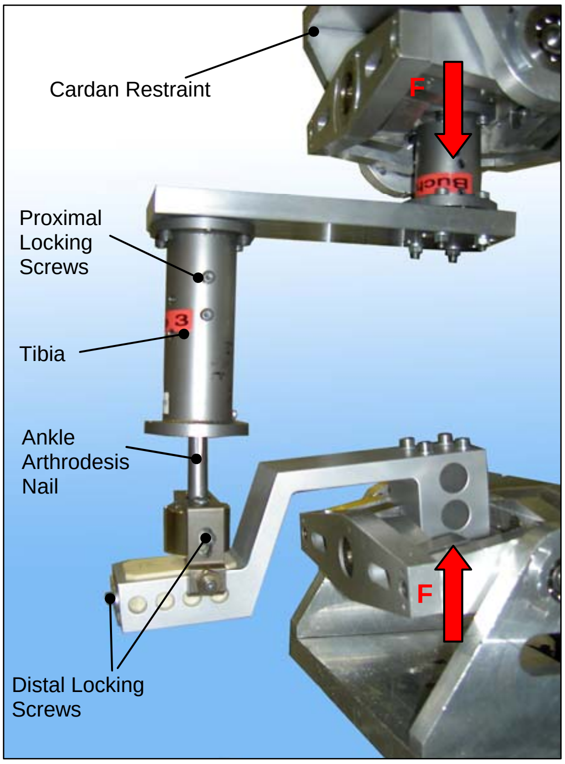

Fig. 8: Test configuration for nail construct.

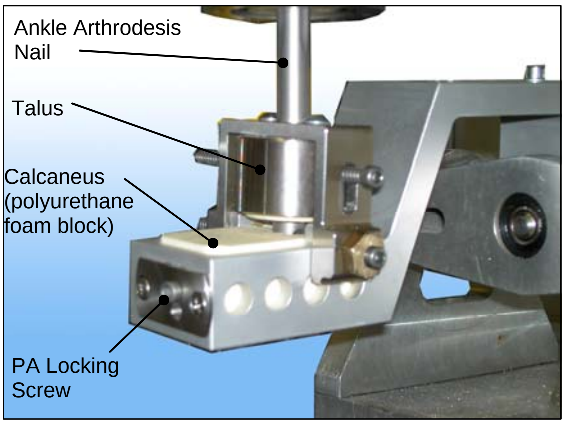

Fig. 9: Test configuration: calcaneus and talus model details.

The ratio of dorsiflexion moments to pronation moments was chosen to be 5:1. Vertical forces were applied in addition to these moments. Torsional loads were neglected. To simulate patient gait, a dynamic pulsating load with a frequency of 3 Hz was used. The load was applied according to a so-called "staircase method" whereby the load magnitude was increased every 83,000 cycles until the end of the test (Fig. 10).

Test end was defined as a gross failure of either the nail or the locking screws. Each nail construct was tested three times.

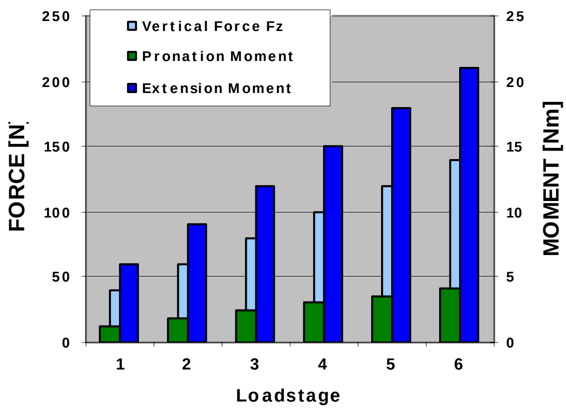

Fig. 10: Load-increase staircase method [3].

Test samples

Description	REF No.	Dimensions
T2® Ankle Arthrodesis Nail	1818-1120	Ø 11x200mm, left
T2® Locking Screw Fully Threaded	1896-5080	Ø 5x80mm
Biomet® Ankle Nail, straight	345145	Ø 11x180mm
Biomet® Ti-Screw Buttress Thread	33-345442	Ø 5x80mm

The nail constructs were implemented in accordance with the manufacturers Operative Technique Guides as closely as possible.

A static locking situation (see Fig. 1a, 1b), without applying inter-fragmentary compression, was designed to simulate a mechanical worst case scenario.

The construct was then challenged by major bending moments with minor support provided by the simulated tibio-talar-calcaneal bone construct.

3.2 Results of construct tests

The results from the construct test are shown in Fig. 11.

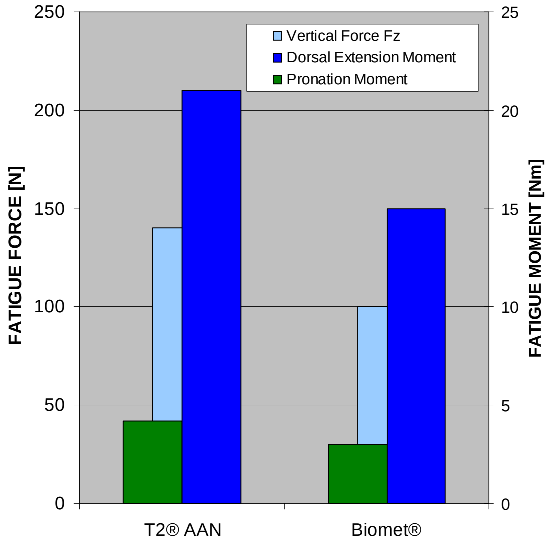

Figure 11: Construct fatigue strength [3].

Failure mode for both systems was fatigue fracture of the most distal locking screw (Fig. 12) placed in the calcaneus in the PA direction. Failure occurred at the antero-superior exit of the PA locking screw from nail hole.

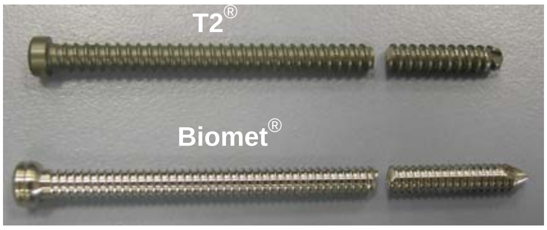

Fig. 12: Failure of PA locking screw.

4. PA locking screw tests

Further dynamic tests with isolated PA locking screws for both the T2® AAN and the Biomet® Ankle Arthrodesis Nail were performed to validate the results obtained within the construct tests.

4.1 Materials and methods

Test set up

The standardized test configuration was originally designed to simulate a supra-condylar locking situation. This is regarded as a worst case scenario for locking screws due to the large distance between the outer screw supports. However, the basic mechanical loading pattern is also applicable to locking screws used in ankle arthrodesis. A dynamic pulsating load was applied to determine the locking screws fatigue strength. 6 samples each were tested for statistical safety (T2® AAN, Biomet®).

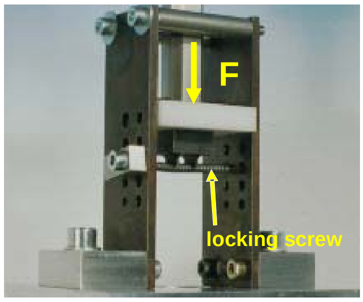

Fig. 13: Test configuration for locking screw fatigue test [4, 5, 7].

Locking Screw Test Samples

Description	REF No.	Diameter
T2® Locking Screw Fully Threaded [5]	1896-5080	Ø5mm
Biomet® Ti-Screw Buttress Thread [4]	33-345442	Ø5mm

4.2 Results of locking screw tests

The results from the dynamic locking screw tests (Fig. 14) confirmed those found in the construct test. Again, the T2 screws showed highest fatigue strength.

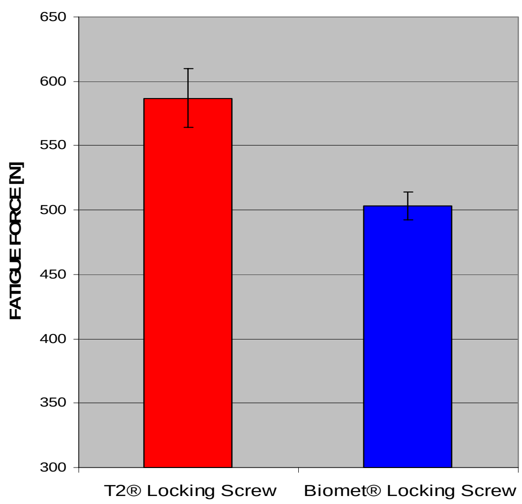

Fig. 14: PA locking screw test results [4, 5].

5. Discussion

During the development phase of the T2 AAN a new test configuration was created based on an analysis of the in vivo loading situation. As with all biomechanical in vitro test models, this new configuration has limitations, i.e.:

- the complex in vivo loading pattern is simplified. Muscle forces as well as the joint capsule support are neglected,
- the biological environment with regard to bone resorption and healing process is neglected.

However, the test configuration allows for standardized comparative testing of different ankle arthrodesis nailing systems with reproducible results. The validity of the test was supported by finite element analysis carried out on T2 AAN constructs. Here the highest mechanical stress under load was also located at the distal PA locking hole and screw (Fig. 15).

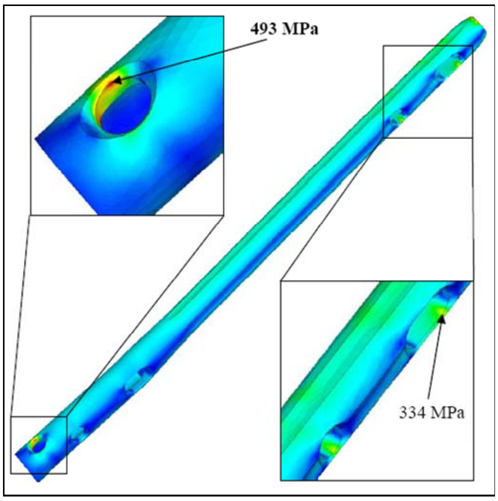

Fig. 15: FEA analysis [6].

6. Conclusion and Outlook

The goal to establish a new method for comparative biomechanical testing of ankle nail constructs was accomplished. Within this test campaign the T2® AAN proved to have a superior fatigue strength when compared to the Biomet® system [3, 4, 5]. Further investigations on ankle nails biomechanical behaviour will be published in due course.

7. References

[1] Mitternacht, J. “Sprunggelenk-Arthrodesennagel-Empfehlung für die biomechanische Produkttestung”. Gang- und Bewegungsanalyselabor der Klinik für Orthopädie und Sportorthopädie der TU München. December 31st, 2004.

[2] Mitternacht, J; v.Oldenburg, G. Phone conversation on “Sprunggelenk-Arthrodesennagel-Empfehlung für die biomechanische Produkttestung”. Gang- und Bewegungsanalyselabor der Klinik für Orthopädie und Sportorthopädie der TU München. February 23rd, 2005.

[3] Kaschner, H. “Test Report 010905HK1: T2® Ankle: Dyn. Belastungstest von Sprunggelenks-Arthrodesennägeln/ Mitbewerbervergleich“. Stryker Osteosynthesis, Kiel, Germany. December 12th, 2005.

[4] Kaschner, H. “Test Report 130905HK1: Biomet® Vollgewindeschraube ø5mm: MFL im Vergleich zur T2® Schraube ø5mm“. Stryker Osteosynthesis, Kiel, Germany. September 19th, 2005.

[5] Gomez, M. “Test Report 160600MG1: Titan Locking Screw ø 5.0 mm (Ti6Al4V): Dynamic strength of blasted, lapped and anodized type II 5.0mm screws made from Ti6Al4V”. Stryker Osteosynthesis, Kiel, Germany. July 7th, 2000.

[6] Gerber, C. “Test Report 130505CG1: T2® Ankle Arthrodesis Nail: Strength Calculation (FEA) of 10mm T2® Ankle Arthrodesis Nail”. Stryker Osteosynthesis, Kiel, Germany. June 1st, 2005.

[7] ASTM International. “F 1264-01: Standard Specification and Test Methods for Intramedullary Fixation Devices”. Annual Book of ASTM Standards 2002, Section 13: Medical Devices and Services. West Conshohocken, USA. 2002.