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# Stability of the TRACK-Distractor-Design

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## **Experimental and clinical findings**

#### Language: English

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#### Date/Event/Venue:

June 14th - 16th, 2001 3rd International Congress of Craniofacial and Maxillofacial Distraction Paris, Meridien Montparnasse

### Introduction

Vertical alveolar distraction performed by using a TRACK-family distractor has been proven to be a highly sufficient and effective tool for alveolar ridge augmentation. To avoid failures, however, resulting from insufficient stability and design of the device, biomechanical aspects also should be considered once a new surgical technique will be used more frequently.

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### Material and Methods

Therefore and synchronously to our first clinical trials TRACK-family distractors had been tested biomechanically by applying different forces to a distractor-bone-system under in-vivo-conditions testing the breaking load. The amounts of torque/ power generated by applying distraction, bending, pressure, twisting forces to a withstanding experimental model were measured in different series up to the breaking point

#### Laboratory Conditions



testing-material: nonmounted (frozen) human cadaver mandibles

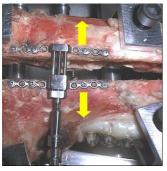


experimental conditions: torque- and forcemeasurement devices

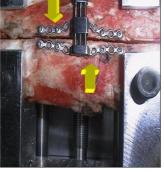


bone and distractor attached to the testing apparatus

### Experiment (Track 1.5-Old): Breaking Load



trial 1: distraction Track 1.5 1st generation, min. breaking load/ torque 35 Ncm



trial 2: pressure Track 1.5 1st generation, min. breaking load/ torque 100 N

### breaking load/torque



generation, min. breaking load/ torque 100-130 N

trial 3: bending Track 1.5 1st trial 4: torque Track 1.5 1st generation, min. breaking load/ torque 2.1-3.5 Nm

### Reactions (in-vitro)

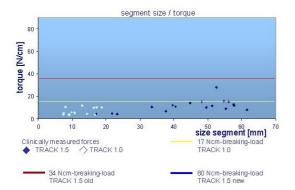


Deformation: Distractor Deformation: Plate Fracture: Plate Fracture: Guide Fracture: jointed shaft osseous burst 8% 319 3% MFS Uni Köln

distribution of reactions on testing Track 1.5 (1st generation), overview (proportional)

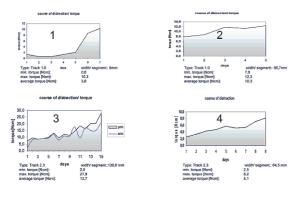
### **Clinical Measurements**

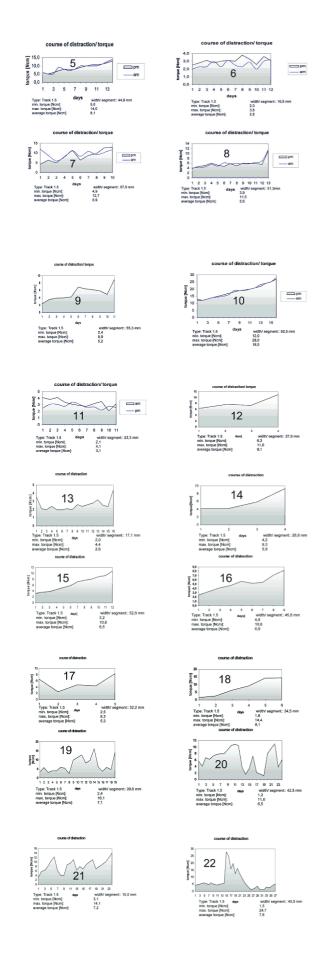
TRACK 1.0 and 1.5: torque max., clinical trial, n= 32



distributions of in-vivo torque measurements. TRACK 1.0 versus TRACK 1.5 with respect to in-vitro borderlines.

Detailed distribution curves on time/ torque excurse during in-vivo-measurements:





### Results

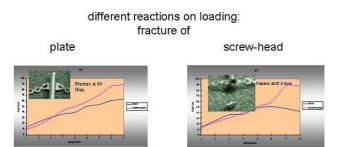
TRACK 1.5 distractors required significant higher torques (>80 Ncm) than TRACK 1.0 distractors (>20 Ncm) for a complete destruction. Bending experiments showed a positive effect and increased resistence of more than 60 N to withstand to applied forces when using a modified TRACK 1+ with an additional vertically orientated plate. A twist of the complete distractor in axial direction was not capable to break the system, whereas plate deformities were generally noted as early effects resulting from applied forces. Early onset of plate deformation as an effect of the flexible plate design subsequently had been interpreted positively as a safety factor prior to breakage.

#### **Patient Measurement**



torque measurement on a male patient (TRACK 1.0) using a crane torque star  $\ensuremath{\mathbb{R}}$ 

#### Track 1.5 (Zyl. Design)



different reactions of TRACK 1.5- 2nd -generationdistractors following in-vitro force application: plates and screw heads fractured at minimal 80 Ncm

#### **Experimental vs. Clinical**



breaking load Track 1.5 2nd -generation, Trial 1-5, up to 250% increased borderline forces

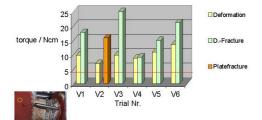
Torque measurements under clinical conditions were realized to compare experimental data with in-vivo findings. In 32 patients therefore torques had been measured once or twice a day during distraction period. Mean values of the TRACK 1.0 distractors associated with small alveolar segments did not exceed 8 Ncm, whereas TRACK 1.5 distractions required torques up to 28 Ncm according to size and width of the distracted segment. Compared with our experimental data the relevant power requirement for a twist of a patient's distractor is as low as 1/3 to 1/6 of its breaking load.



in-vitro-trial Track 1.0: disjointed screw head at 18 Ncm load

in-vivo observation: screw head disjointed as a sequel to counterclockwise (wrong!) activation of the distractor's spindle (reduced patient's compliance)

### **Distraction TRACK 1.0**



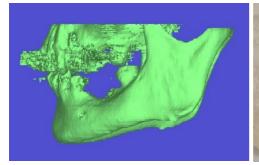
Track 1.0 trials: most important reaction on maximum loading: disjointed screw head!

### **Deviation of the osteotomized segment**



segment in certain situations displacement of the osteotomized segment due to insufficient stabilization of the distraction vector

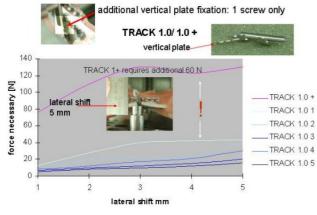
### Solution 1





CAD-model of an atrophic mandible, premolar A redesigned TRACK 1.0+ preoperatively region

attached to the CAD model for optimal vector control



lateral shift forces were increased to 80 N when the additional vector control plate aids in achieving a proper lingual angle



individual solution vs. customized solution

individual solution: increased stability of the customized solution: TRACK 1.0 distraction vector using conventional arch bars

reinforced by a new detachable vector control plate

### Conclusions

There is a negligible probability of a destruction of the TRACK system under clinical conditions as a consequence of the flexible plate design and related to the clinically applied forces. The device incorporates a high mechanical load capacity to withstand to applied forces. Experimental findings and clinical trials led to the conclusion that according to indication and appropriate size of the device biomechanical stability and proper function can be assured under normal circumstances.

### Abbreviations

TRACK = Tissue Regeneration by Alveolar Callusdistraction Koeln

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#### **Poster Faksimile:**

# STABILITY OF THE TRACK-DISTRACTOR-DESIGN EXPERIMENTAL AND CLINICAL FINDINGS Lazar F1; Uenal U1; Arens C1 Hidding J2; Zoeller J E1

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#### Introduction and Aims:

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### Results:

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