A Novel Prefabricated Final Fixed Solution for the Edentulous Mandible

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Introduction
– A novel full-arch solution with a prefabricated framework fixed on three implants (Trefoil™, Nobel Biocare AB, Gothenburg, Sweden) presents a patient-friendly treatment option for the mandible.
– Using a simplified clinical protocol and standardized drill guides makes the treatment a cost and time efficient fixed restoration. Guided surgery is invariably associated with minor implant misalignment.
– The prefabricated framework, anatomically designed to the natural arch comes fully assembled with three adaptive joints to adjust to horizontal, vertical and angular deviations from planned implant placement (Figure 1).

Vertical compensation
Horizontal compensation
Angular compensation

Figure 1: Compensation types provided by the adaptive mechanism of the prefabricated 3-implant framework.

Objective
The objectives of this investigation were to quantify the range of passive fit provided by the adaptive joints and evaluate the mechanical performance of the system.

Materials and methods
– The novel test system (Trefoil™) with an adaptive joint was tested against a comparison system, the Branemark Novum® [1] for mechanical performance (Figure 2).

– The worst case configuration was identified through mechanical and finite element analyses, and determined the passive fit range. The worst case system configuration consisted of lateral shift and angulation of positions of implant I and II to the their maximum passive fit (Figure 3).
– Three system configurations were tested: the ideal case test system, the worst case test system, and the ideal case comparison system, based on deviation of implant positions, with ideal being no deviation and worst being the maximum deviation within the passive fit range.
– Fatigue strength properties were characterized using the Median Fatigue Limit (MFL) according to the ASTM STP 731 standard.
– The load was applied to the posterior end of the cantilever to simulate maximum stress for the system (Figure 3). The results were compared using a two-sided two-samples t-test.

Conclusion
– The maximum independent range of passive fit provided by the adaptive joints was: angular error±4.0°, horizontal error±0.4mm, and vertical error ±0.5mm.
– The simulation indicated that the location with highest stress in the system was at the bar at implant I (location A, Figure 4).
– Failure location in experiments confirm the simulation (FEA) results (Figure 5).
– With regard to fatigue resistance, the test system showed no difference under the worst vs. ideal case conditions, but a significantly higher MFL value than the comparison system in ideal case conditions (Figure 6).

Results
– The maximum independent range of passive fit provided by the adaptive joints was: angular error±4.0°, horizontal error±0.4mm, and vertical error ±0.5mm.
– The compensation mechanism supports reliable and predictable resistance to mechanical fatigue within the full compensation range, superior to the comparison system.

Conclusions
– The adaptive joints of the novel prefabricated final fixed solution for the edentulous mandible provides angular, horizontal and vertical compensation for passive fit.
– The compensation mechanism supports reliable and predictable resistance to mechanical fatigue within the full compensation range, superior to the comparison system.
– These features offer the possibility of delivery of a final bridge with passive fit on the same day of surgery. A multi-center clinical study is ongoing (ClinicalTrials.gov NCT02940353).

References

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