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INTRODUCTION

Osseointegrated extra-oral implants have been used effectively as the anchoring points for facial prostheses. The success of the extra-oral implants is dependant upon the continuing health of the bone-implant interface, and although the success rate of extra-oral implants is high there are still recorded failures in all the bones of the face. One of the factors that is believed to influence the health of the bone-implant interface is the type and magnitude of loads applied to the implant and consequently the strains induced in the supporting bone. The mechanostat theory by Frost [1] attempts to relate the response of bone to various levels of strain. In this theory, the minimum effective strain for bone remodeling (the normal turnover of bone) is between 100µε and 300µε.

In order to determine the strains generated in the bone, first the magnitude and type of loads applied to extra-oral implants must be established. For a prosthesis supported by multiple implants there are two main types of loads that are generated. There is a static preload that is created by connecting a non-passive superstructure to the implants. The second is the dynamic functional load that is caused by attaching or removing the prosthesis. The purpose of this study was to quantify the type and magnitudes of loads, both *in vitro* and *in vivo*, that are applied to extra-oral implants supporting an auricular prosthesis.

METHODS AND RESULTS

Both the *in vitro* misfit preloads and the *in vivo* misfit preloads and functional loads were measured using strain gauges attached to abutments as described by Miller [2]. In addition, an estimate of the strains created in the bone due to the measured loads was made based on the results from a study by Del Valle [3].

In Vitro Study

For the *in vitro* study ten, two-implant superstructures with the same geometry were constructed by five separate centers: Craniofacial Ossoeintegration Maxillofacial Prosthetic Rehabilitation Unit (COMPRU) in Edmonton Alberta, Canada; Morriston Hospital in Swansea, Wales; Queen Elizabeth Hospital in Birmingham, England; Insitiut Fur Epithesen in Siegen, Germany, and Sahlgrens Hospital in Gotenborg, Sweden. The amount of vertical misfit of each superstructure was measured using a Griffen and George cathetometer. For this study, a superstructure was considered non-passive if there was greater than a 150µm vertical gap between the superstructure and the abutment when the opposite side of the superstructure was connected—this is based on the one-screw test described by Jemt [4]. The preloads, for each of the tightening sequences, were then measured using the instrumented abutments.

The measured vertical gaps for the ten superstructures ranged from $10\pm10\mu$ m to $210\pm10\mu$ m. Of the ten superstructures tested each center had constructed one passive superstructure and one non-passive superstructure based on the 150µm criterion. However, there was no correlation between the measured misfits and resulting misfit preloads which ranged from -78±11N to 177±13N and -6.4±0.7N·cm to 27.1±0.9N·cm. In fact, some of the superstructures that were considered passive had higher misfit preloads then the non-passive superstructures. This was most probably due to the fact that the vertical gap measurement does not quantify the total misfit of the superstructure—there could also be horizontal or rotational misfits. The estimated strains that would have been created in the bone due to the measured misfit loads are shown in Figure 1. As can be seen, the majority of the strains were within the range for normal bone remodeling.



Figure 1: The Estimated Strains in the Bone Due to the Measured *In Vitro* Misfit Preloads

In Vivo Study

Four patients with auricular prostheses, which had been in place for four to nine years, participated in the *in vivo* study done at COMPRU. For each patient, the preloads caused by attaching the patients superstructure and the functional loads caused by installing and removing the auricular prosthesis were measured using the instrumented abutments.

The *in vivo* study showed similar results to the *in vitro* study. Although all of the frameworks were considered to be clinically passive the misfit loads ranged from $-72\pm32N$ to $129\pm70N$ and $-7.0\pm2.6N$ cm to $18.3\pm1.2N$ cm. In addition to the misfit preloads, the functional loading was measured during prosthesis removal and installation. The functional loads were quite small in comparison to the misfit loads. The prosthesis removal loads ranged from $-14\pm11N$ to $30\pm11N$ and from $3.4\pm0.7N$ cm to $20.5\pm0.7N$ cm. The prosthetic replacement loads ranged from $-51\pm11N$ to $26\pm14N$ and $2.8\pm0.7N$ cm to $37.3\pm1.2N$ cm. The estimated strain induced in the bone due to the misfit preloads and the dynamic functional loads is shown in Figure 2. As with the *in vitro* results, the misfit preloads resulted in strains that were basically between $-200\mu\epsilon$ and $200\mu\epsilon$. When the functional loads were added to the misfit preloads, the resulting strains were still essentially in the range for normal bone remodeling.



Figure 2: The Estimated Strains in Bone Due to the *In Vivo* Misfit Preloads and Functional Loads

CONCLUSIONS

The results from the *in vitro* study indicated that passive superstructures were not dependant on the construction method used by the individual centers that participated in this study. The resulting strains that would have been induced in the bone by these misfit loads were within the range for normal bone remodeling.

The results of the *in vivo* study suggest that the preloads that exist are relatively small, and are comparable to the measured *in vitro* misfit loads. However, all of the patients that were involved in the study had their prostheses for some time (four to nine years), and it is possible that some of the original misfit could have been compensated by small changes in the supporting bone surrounding the implants. The measured functional loads were smaller than the misfit preloads, and the overall estimated total strain in the bone due to the combined misfit and functional loads was still within acceptable limits.

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