Nonsensus in the Treatment of Proximal Humerus Fractures? An Uncontrolled, Blinded, Comparative Behavioural Analysis Between Homo Chirurgicus Accidentus and Macaca Sylvanus

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Declarations

Contributor and guarantor information

Sam Razaeian has designed, conducted and written this analysis. Birgitt Wiese has performed the statistical analysis. Dafang Zhang, Nael Hawi and Christian Krettek have identified and contacted experts for the survey. Afif Harb has assisted the behavioural analysis and edited the manuscript. Sam Razaeian is responsible for the overall content as guarantor.

Funding

No funding has been obtained.

Conflict of Interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Transparency statement

The manuscript's guarantor affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

Ethics approval

This analysis was carried out in accordance with the Ethical standards of the 1964 Declaration of Helsinki as updated in 2004. No animal has been forced to participate or has been in any way misused, abused, or damaged. The behavioural analysis was carried out under supervision of a responsible park ranger on a voluntary basis by the Barbary macaques in their familiar enclosure under uncontrolled conditions.

The local ethical committee of Hannover Medical School has been requested to deliver an opinion on this behavioural analysis, but it did not assume responsibility for satirical analysis as this one (see supplemental material).

Patient consent

The manuscript includes images or information that may identify a patient. A signed consent has been obtained.

Public and Patient Involvement statement

Patients` clinical and radiographic records were used from an observational registry study (Hannover Humerus Registry – HHR, NCT 03060876) for the survey. The patients were not involved in the design, recruitment, and conduction of this analysis.

Availability of data and material

The manuscript has associated data in a data repository.

Transparency statement

The manuscript's guarantor affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

Research checklist

This study does not provide any research checklist as there is no relevant guideline for a behavioural analysis.

Dissemination declaration

Dissemination of the results is not applicable.

Acknowledgment

The authors would like to thank Mr. Silvio Dietzel as park ranger of Affenwald Straußberg (Sonderhausen, Thuringia, Germany) and supervisor of this analysis for his outstanding support enabling this study and for his non-commercial funding in form of Californian walnuts.

Abstract

Objectives

To investigate the interrater reliability of Barbary macaques compared with an expert group of surgeons regarding treatment choice and predicted outcome of proximal humerus fractures (PHFs).

Design

Uncontrolled, blinded, comparative behavioural analysis.

Setting

Transatlantic (Germany and United States).

Participants

Ten blinded experts in the field of orthopedic trauma surgery (Homo Chirurgicus Accidentus), with special focus on upper extremity surgery from Germany and the United States, and five Barbary macaques (Macaca Sylvanus) from a semi-free range enclosure.

Main outcome measures

Fleiss' kappa for assessing the reliability of agreement between raters.

Results

While Barbary macaques demonstrate inferior interrater reliability compared with experts regarding treatment choice (nonsurgical vs. surgical), they performed similarly compared with experts for the geriatric age group most frequently affected by PHFs, both in terms of treatment choice and choice of surgical procedure.

Agreement regarding predicted outcome was poor among the macaques and slight among the experts. However, all experts almost always predicted the outcome incorrectly and tended to underestimate it. While only 4 out of 90 (4.4%) experts predictions were correct, 13 out of 45 (28.9%) macaques predictions were correct.

Conclusions

Experts' interrater reliability regarding the management of PHFs is as poor as that of a group of Barbary macaques for the most frequently affected patient cohort over the age of 65 years, and only slightly better for patients under the age of 65 years. However, Barbary macaques tend to predict the clinical outcome of PHFs more accurately.

Therefore, Barbary macaques should be considered as a worthwhile, additional aid for therapeutic decision-making process, especially for geriatric patients with PHFs.

Trial registration

Not applicable.

Summary Boxes

Section 1: What is already known on this topic

- To date, there is no consensus on the optimal treatment of proximal humerus fractures.
- Increasing evidence suggests that nonoperative management may have similar functional outcomes compared with operative management with lower risks of complications and reoperation.
- Currently evidence-based guidelines are lacking to inform decision-making between different interventions, and expert consensus is considered to be poor.

Section 2: What this study adds

- Barbary macaques tend to predict the clinical outcome of PHFs more accurately than experts.
- Barbary macaques should be considered as a worthwhile, additional aid for therapeutic decision-making process, especially for geriatric patients with PHFs.

Introduction

Proximal humeral fractures (PHFs) are a common injury, representing approximately 6% of all adult fractures (1). Around 70% of these fractures occur in patients over the age of sixty years, with the greatest reported incidence among individuals eighty years of age or older. The incidence of PHFs has been increasing over the past few decades, due to an aging population and the associated increase in osteoporosis and low-energy falls from standing height. The incidence of PHFs is approximately 60 per 100,000 people in the United States, but in the age 65 years or older population, the incidence is four-fold higher at 253 per 100,000 people. In Finland, the incidence of PHFs had tripled between 1970 and 2002 to 105 per 100,000 people aged 60 or above (2-4). Therefore, the impact of PHF management will increasingly affect health care systems (5).

Although it is well known that the majority of PHFs (nearly 75 %) can be treated non-operatively with acceptable functional results, surgery became popular with advancements in the field of osteosynthetic implants such as locking nails, plates, and prosthetic shoulder joint replacements (4), with rates of surgically treated patients higher than 25 % in some institutions, leading to substantial variation worldwide in the management of this common injury (6).

In a review of a large sample of US Medicare data, the authors found a significant increase in the number of surgical procedures for PHFs without a corresponding increase in the incidence of PHFs for the period study, and moreover, with significant regional variation in the rates of surgery ranging from 0% to 68% (7). This heterogeneity of treatment is in the setting of a lack of scientific consensus on the optimal treatment of these fractures to date (4). Although the latest Cochrane review suggests evidence that nonoperative management may have similar functional outcomes to operative management with lower risks of complications and reoperation, there is yet insufficient evidence from current randomized controlled trials to inform decision-making between different non-surgical, surgical, or rehabilitation interventions for these fractures (8-10).

But there is still hope. Deep in the Thuringian basin of Germany, between the mottled sandstone hills of Windleite and the shell limestone formations of Hainleite, surrounded by the murmuring sound of Wernröder stream, the Barbary macaques (Macaca Sylvanus) live and still roam the vast beech forests of Germany in one of the biggest semi-free range enclosures in Europe. Besides humans, the only free-living primates in Europe, and besides geriatric patients with proximal humerus fractures, one of the most endangered species in the world (Figure 1).

As currently evidence-based guidelines are lacking and expert consensus is considered to be poor, this species could be promising for future decision-making processes due to its

impartiality and the ability to put itself into the same threatened position as patients with proximal humeral fractures.

The aim of this behavioural analysis is to investigate interrater reliability of Barbary macaques in comparison with an expert group of surgeons concerning choice of treatment as well as outcome prediction of proximal humerus fractures and to figure out whether this specie could serve as a more worthwhile and reliable aid for therapeutic decision-making .

Material and Methods

This behavioural analysis was carried out in accordance with the Ethical standards of the 1964 Declaration of Helsinki as updated in 2004. No animal has been forced to participate or has been in any way misused, abused, or damaged. However, some human beings may feel themselves so after reading this analysis.

Independent experts in the field of orthopedic trauma surgery with special focus on upper extremity surgery from Germany and the United States were identified and invited via email to participate in an anonymous web-based survey (SoSci Survey GmbH, Munich, Germany). The survey consisted of 9 case reports of acute proximal humerus fractures. All cases were randomly selected from a prospective, observational registry study (Hannover Humerus Registry – HHR, NCT03060876). Two independent study nurses evaluated all cases with a clinical and radiological follow-up of 12 months.

HHR is a prospective, CT-based single center registry study of a supraregional Level 1 trauma center, aiming to investigate the healing process of proximal humerus and humeral shaft fractures. All experts were informed about the intention of this analysis. They were blinded only to the actual treatment procedure and outcome. Besides details about memberships and professional working experience, the behaviour regarding the following questions with corresponding answer options was evaluated:

(1) Which treatment regime would you recommend?
Nonoperative or operative.

(2) Which procedure would you recommend, if you had to treat surgically?
Locking plate, cement-augmented locking plate, intramedullary nail, hemiarthroplasty, reverse shoulder arthroplasty, allograft-augmented locking plate, or something else.

(3) Which outcome (age- and sex adapted Constant Score (11)) would you expect one year after conservative treatment?
≤ 59, 60-69, 70-79, 80-89 or 90-100 of 100 points.

Similarly, the behaviour of Barbary macaques was evaluated regarding the same 9 cases and questions in one of the biggest semi-free range enclosures in Europe (Affenwald Straußberg, Sonderhausen, Thuringia, Germany). The web-based case presentations were printed as a 29.7 x 42 cm colored poster and positioned one after the other with the related questions using a customer stopper of a local ice cream vendor in the enclosure (Figure 2). With the aid of an internationally accepted and validated rating scale consisting of disposable, cellulose kidney dishes and laminated pictograms, the behaviour was observed (Figure 2). An equally dosed

mixture of Mediterranean sultanas and peanuts (Nutwork GmbH, Hamburg, Germany) and Californian walnuts (Märsch Importhandel GmbH, Ulm, Germany) functioned as environmental enrichment. The first grasp into a kidney dish was defined as selection and noted. Macaques that did not give complete responds to all cases and those with apparently severe conflict of interests were excluded from evaluation (Figure 3).

As this behavioural analysis was to be carried out on a voluntary basis by the macaques in their familiar enclosure under uncontrolled conditions, a calculation of number of complete responds was not possible in advance. Therefore, it was necessary to begin with the analysis of the macaques followed by analysis of the experts in order to arrive at approximately equally sized groups. For this reason, the web-based survey was closed to the experts after a comparable number of responds were obtained.

Statistical analysis

To assess the reliability of agreement between raters Fleiss' kappa was determined. The Landis and Koch benchmark scale was used to interpret the strength of agreement for Fleiss' kappa values as indicated in the following table (Table 1) (12). For the analyses, SPSS 25 (IBM, Armonk, New York) was used.

Species analyzed

Macaca Sylvanus (M. Sylvanus)

M. Sylvanus, also known as Barbary macaque or colloquially called magot, is the only surviving primate in Africa north of the Sahara desert, the only native species of primate to occur in Europe, and the only member of the genus Macaca that can be found outside Asia. While it has the ability to live in a variety of habitats, this species shows a preference for high-altitude cedar forests, and is also found in oak forests, coastal scrub, and overgrazed rocky slopes with vestigial vegetation. All the areas occupied by the macaque are under growing pressure from human activity, and habitat availability for M. sylvanus has decreased markedly in recent decades.

As such, they are listed as endangered by the IUCN (International Union for Conservation of Nature) Red List (13).

The Barbary macaque is gregarious, living in social groups of both sexes. Troops can have 10 to 100 individuals and are matriarchal, with their hierarchy determined by the lineage of the lead female.

Its diet is primarily composed of cedar and the oak, which make up over 50% of its total intake, but fruits, tree leaves, and nuts are also preferred (13).

Homo Chirurgicus Accidentus (H. Chirurgicus Accidentus)

Homo Chirurgicus Accidentus, also known as orthopedic trauma surgeon or colloquially called the ox (14), is a species of surgeon unique for its wide distribution in the world. While it has the ability to live in a variety of habitats, it is frequently encountered at bigger health care centres in urban regions.

Natural enemies are anesthetists, anesthesia nurses, anesthesia nurse assistants, and orthopedic trauma surgeons recommending non-operative treatments. Its sociocultural competences and mating behaviours are unknown due to its extreme work ethos. Both are currently subject of intensive research.

H. Chirurgicus Accidentus is nocturnal and therefore moody during most of the daytime, forming into groups of equally moody males, which are patriarchal with their hierarchy determined by direct lineage or personal favor of the lead male.

Its diet is primarily composed of bone fractures, damaged cartilage, infected soft tissues, and broken prosthetics, but profitable, elective outpatient surgeries are also preferred.

Results

Ten independent experts in the field of orthopedic trauma surgery with special focus on upper extremity surgery from Germany and the United States were available for the survey. The responder rate of the experts in the US were higher than in Germany (5/10 vs. 5/20). Only a group of 5 out of 22 macaques provided complete responds to all cases, probably due to fear of losing reputation. Reactions of nonresponders among the experts ranged from a diplomatic German “funny idea, but I am out, sry” to a warm-hearted American "it's wild what my alma mater and former colleagues are studying nowadays".

All experts from the US were members of the American Academy of Orthopaedic Surgeons (AAOS). One of them had more than 20 years, two had more than 15 and 10 years, and two had less than five years of professional experience as a senior physician. All experts from Germany were members of the German Association of Shoulder and Elbow surgery (DVSE), and except for one, all were also members of the European Society for the Surgery of the Shoulder and the Elbow (SECEC-ESSSE). One of them was additionall ay member of the American Shoulder and Elbow Surgeons (ASES). Two had more than 20 and 15 years, two had more than 10 years, and one had more than five years of professional experience as a senior physician. Memberships or professional qualifications of the macaques remained uncertain, but all of them were obviously fellowship-trained in picking one’s nose and delousing each other.

While among the experts, operative treatment was the more preferred treatment (56.7% of all selections), the macaques chose nonoperative treatment more frequently (55.6% of all selections). Overall interrater agreement regarding this choice was moderate among the experts and poor among the macaques, although there were marked differences between the two different nations. While agreement among the US experts was moderate with a slight preference for nonoperative treatment, agreement among German experts was only fair with a distinct preference for surgery (Tables 2 and 3).

In a subgroup analysis of the cases by patient age, the experts’ interrater agreement was as poor as the macaques’ for patients over the age of 65, and only slight for patients aged under 65. However, once again there were marked differences between the nations.

While the US experts achieved an unanimous agreement with respect to nonoperative treatment for patients over the age of 65, German experts’ reached only poor agreement with 4 out of 15 (26.7 %) selections tending to surgical treatment (Table 2).

In regards to the recommended surgical treatment procedure, the experts achieved only a slight agreement, while the macaques’ agreement was poor. However, once again the subgroup analysis revealed that the experts’ agreement was as poor as the macaques’ for patients over the age of 65, and only slight for patients aged under 65 (Table 4).

All 9 presented cases were actually treated nonoperatively with an excellent clinical outcome. The age- and sex-adapted Constant Score averaged 91 of 100 possible points after one year. Agreement regarding prediction of outcome was poor among the macaques and slight among the experts (Table 3). However, all experts almost always predicted the outcome incorrectly and tended to underestimate it. While only 4 out of 90 (4.4%) experts' predictions were correct, 13 out of 45 (28.9%) macaques' predictions were correct (Table 6).

Discussion

This is the first study investigating interrater reliability of Barbary macaques in comparison with an expert group concerning management and clinical outcome prediction of proximal humerus fractures. While Barbary macaques appear to have inferior interrater reliability compared to the experts regarding choice of treatment (nonsurgical vs. surgical), they performed similarly compared with experts for the geriatric age group most frequently affected by PHFs, both in terms of choices of treatment and choice of surgical treatment procedure.

These findings confirm Barbary macaques as a worthwhile and serious alternative, but also highlight the continuous controversy regarding the lack of any expert consensus on the optimal treatment of these fractures (4, 6, 15).

Surgical treatment of PHFs has been associated with complication rates as high as 49% and reoperation rates of 14%. Growing evidence from randomized controlled trials and meta-analyses showing similar outcomes between surgical and nonsurgical management of PHFs, which has called surgical treatment of PHFs for patients older than 65 years into question. (5, 6, 15, 16). In addition to prospective trials, pooled data of prior studies in a recent Cochrane review demonstrated no clinically important difference in functional outcomes and quality of life between surgical and nonsurgical treatment of proximal humerus fractures at one- to two-year follow-up (8, 12).

Nonetheless, surgical treatment of this injury has been increasingly utilized over the past two decades (5). Ironically, it was the relevant age group of patients over the age of 65 years where interrater agreement across the two species was equally poor. The marked differences between the two nations should be considered in the context of reported national treatment trend developments in the literature. According to an analysis of the National Inpatient Sample (NIS) database, the percentage of surgically treated PHFs increased by 6% between 2004 and 2012 in the US, but nonetheless nonoperative treatment remained the most common treatment modality in 59% of patients (17). Conversely, according to a recent trend analysis of German Federal Statistical Office data, surgical procedures increased by 39 % with about 68.9 % of all procedures being performed in elderly patients between 2007 and 2016 in Germany. Locking plate fixation was the most commonly used procedure within all age groups, although it has already been identified as an independent risk factor for inpatient adverse events and mortality in patients older than 65 years compared to nonoperative inpatient treatment (9, 18). This is even more concerning from a health economical view, as previous epidemiologic and cost analyses demonstrated fractures of the shoulder to be a substantial contributor to the rising treatment costs for upper limb fractures (5).

There are some limitations to our study that should be considered. Although it is a promising observation that the macaques have chosen nonoperative treatment more frequently than the experts, their agreement regarding optimal treatment was consistently poor. However, a systematic confounding behaviour was unfortunately observed during the whole study. Some senior primates with apparently severe conflict of interests biased responders during their selections (Figure 3 and 4). The authors believe that this fact may have adversely affected their results, and that their agreement and their outcome prediction ability would be much better without this disruptive factor. Self-reported conflicts of interest are also common in orthopedic trauma surgeons, and it is known that they are able to influence reported outcomes (19). The conspicuous finding that all experts almost always underestimated and predicted the outcome of nonoperatively treated PHFs incorrectly suggests interference among the alleged independent experts. However, it remains unclear whether, to what extent, and how the experts examined here were affected, as the self-disclosure referred to only details about scientific memberships and professional working experience.

In addition, in retrospect the mixture of Mediterranean sultanas, peanuts, and Californian walnuts as environmental enrichment was an unfavorable choice by the authors. Unfortunately, significant differences in popularity of these treats could be observed in an above-mentioned order. This led in parts to dependent selections, when the kidney dishes were not refilled equally immediately.

This form of selection bias must be seen as a major methodological weakness. The authors recommend Californian walnuts as a single treats for future behavioural analysis.

Conclusion

Experts' interrater reliability regarding the management of PHFs is as poor as that of a group of Barbary macaques for the most frequently affected patient cohort over the age of 65 years, and only slightly better for patients aged under 65 years. However, Barbary macaques tend to predict the clinical outcome of PHFs more accurately.

Therefore, Barbary macaques should be considered as a worthwhile, additional aid for therapeutic decision-making process, especially for geriatric patients with PHFs.

Tables

Fleiss` Kappa	Interpretation
< 0	Poor agreement
0.01 – 0.20	Slight agreement
0.21 – 0.40	Fair agreement
0.41 – 0.60	Moderate agreement
0.61 – 0.80	Substantial agreement
0.81 – 1.00	Almost perfect agreement

Table 1: Benchmark scale according to Landis and Koch for interpretation of strength of agreement for Fleiss' kappa values.

Species	All PHFs	≤ 65 years	> 65 years
All experts	0.45	0.18	-0.09
US	0.6	0.23	1
Germany	0.27	0.04	-0.19
Barbary macaques	-0.17	-0.22	-0.07

Table 2: Interrater reliability of the analyzed species in the form of Fleiss` kappa regarding recommended treatment (nonoperative vs. operative).

Species	All PHFs	≤ 65 years	> 65 years
All experts	0.57	0.78	0.13
US	0.49	0.73	0
Germany	0.64	0.83	0.27
Barbary macaques	0.44	0.43	0.47

Table 3: Conditional probability for recommending operative treatment.

Species	All PHFs	≤ 65 years	> 65 years
All experts	0.09	0.11	0
US	0.15	0.19	-0.03
Germany	0.02	0.08	-0.13
Barbary macaques	-0.1	-0.16	-0.12

Table 4: Interrater reliability of the analyzed species in the form of Fleiss` kappa regarding recommended surgical procedure.

Species	All PHFs	≤ 65 years	> 65 years
All experts	0.13	0.04	-0.04
US	0.14	0.01	-0.02
Germany	0.14	-0.02	-0.04
Barbary macaques	-0.01	-0.08	-0.02

Table 5: Interrater reliability of the analyzed species in the form of Fleiss` kappa regarding outcome prediction of nonoperative treatment.

	Experts		Barbary macaques	
	amount	percentage	amount	percentage
Case 1	0	0 %	0	0 %
Case 2	0	0 %	0	0 %
Case 3	0	0 %	3	60 %
Case 4	0	0 %	1	20 %
Case 5	0	0 %	1	20 %
Case 6	0	0 %	0	0 %
Case 7	0	0 %	2	40 %
Case 8	0	0 %	3	60 %
Case 9	4	40 %	3	60 %

Table 6: Absolute and relative distribution of correctly predicted outcomes by the two species.

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Figure 1: Conservation status of PHFs and Barbary macaques according to the IUCN (13). The figure above shows a minimally displaced proximal humerus fracture according to the most commonly used Neer classification (20). The 70-year-old woman was treated with an intramedullary nail at a German Level 1 trauma center in 2019, probably due to its biomechanical superiority over extramedullary implants (21). After only three months, conversion to reverse shoulder arthroplasty was performed, probably due to its biomechanical superiority over intramedullary nails.

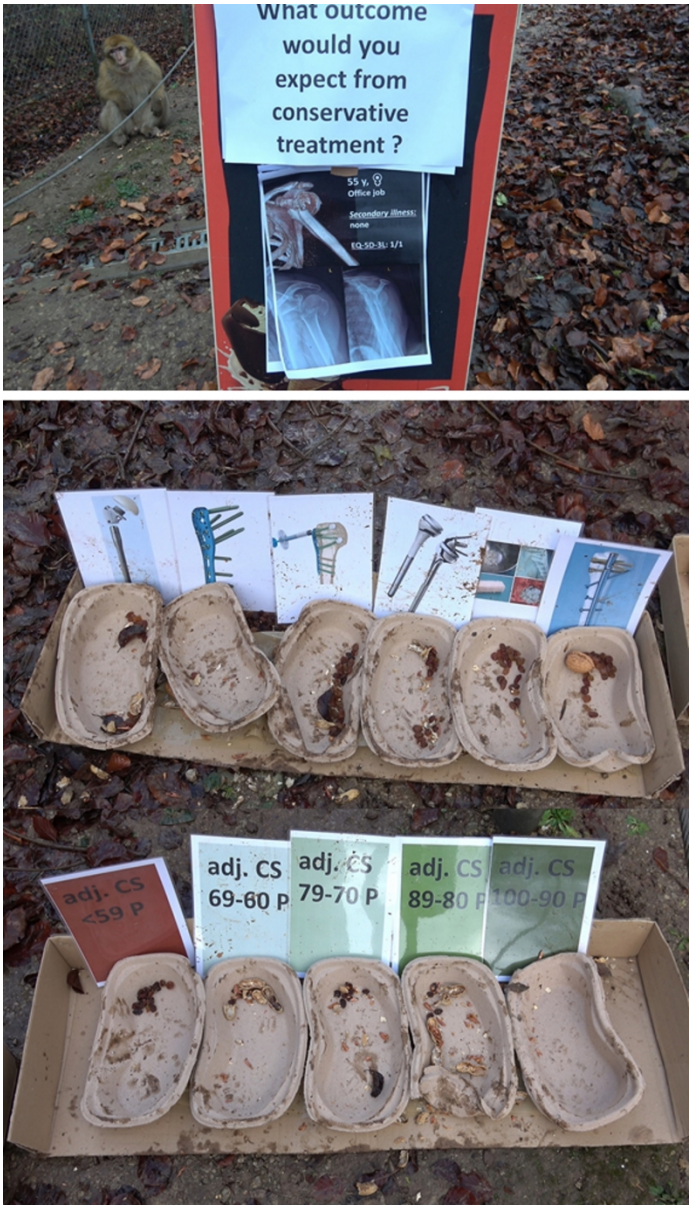

Figure 2: Case report presented on a customer stopper of a local ice cream vendor in the enclosure and condition of the validated rating scales after the analysis.

Figure 3: A senior macaque with apparently severe conflict of interests is biasing one of its inferior subjects.

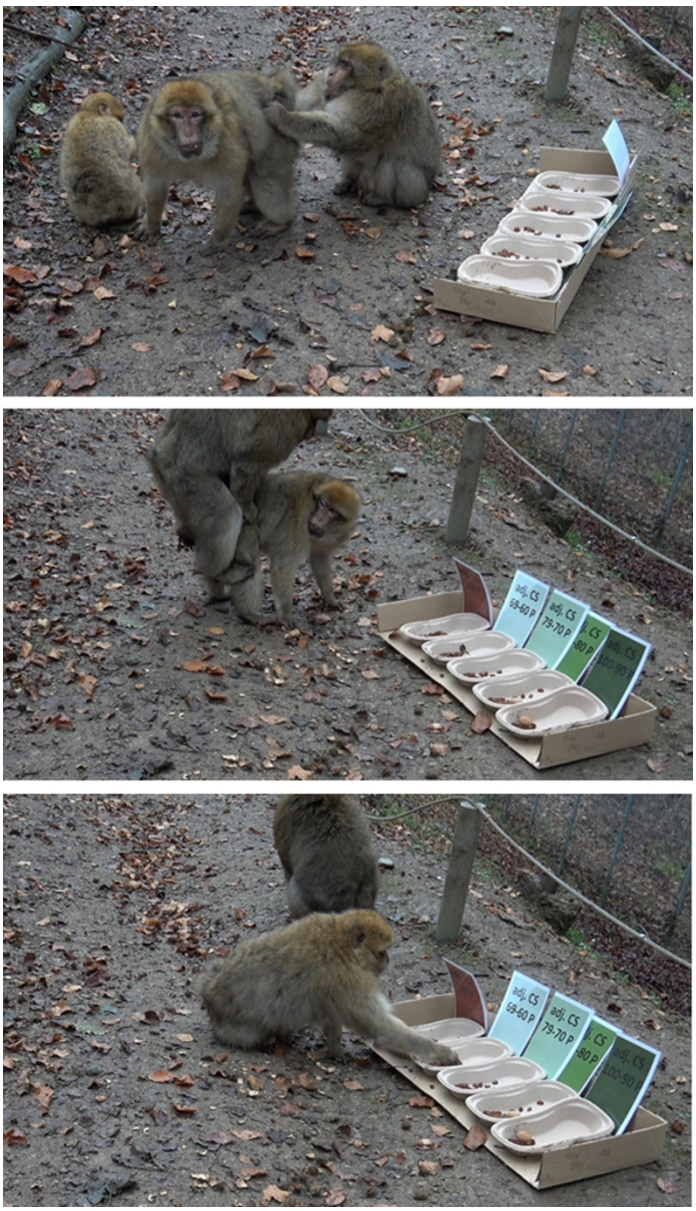

Figure 4: A biased macaque is adversely affected and therefore predicts a poorer outcome.

146x254mm (300 x 300 DPI)

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OE 6230 – im Hause

22.01.2020/MLa

Ihr Antrag Interrater-Reliabilität in der Behandlung proximaler Humerusfrakturen – eine Beobachtungsstudie an Mensch und Primat vom 01.06.2019 (Posteingang 07.01.2020)

Sehr geehrter Herr Razaeian,

die Ethikkommission erkennt keinen wissenschaftlichen Erkenntniszuwachs durch das Vorhaben und sieht darin keine Forschung.

Die Ethikkommission sieht sich nicht als zuständig für Vorhaben an, die keine Forschungsvorhaben darstellen.

Mit besten Grüßen

Prof. Dr. Stefan Engeli
Vorsitzender der Ethikkommission
(nach Diktat verreist)

PD Dr. Urs-Vito Albrecht
Stellvertreter

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